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01 SA (4/20/07) – Notice of Inspection – notifies lab that failure to permit inspection results in revocation of certificate

SA Letterhead

NOTICE OF INSPECTION

You are hereby notified that this representative of the [STATE AGENCY NAME] and the federal Centers for Medicare & Medicaid Services (CMS) is present to perform an inspection of your laboratory and its records.

This representative has been granted the authority to inspect your laboratory and its records under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578. Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable CLIA regulations in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Compliance with these regulations is a condition of certification for the CLIA program.

Failure to permit this inspection may result in the suspension or revocation of your laboratory's CLIA certificate and the cancellation of your laboratory's participation in the Medicaid and Medicare reimbursement programs, pursuant to 42 C.F.R. § 493.49(c) and 42 C.F.R. § 493.1773(g).

This document serves as official notice that CMS will take enforcement action against your laboratory if this representative is refused entry or not permitted to inspect your laboratory to determine continued compliance with all CLIA requirements, or if your laboratory refuses to cooperate with the survey process.

Inspection Refused By: _____ Date: _____

Name of Laboratory: _____ CLIA #: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Contact telephone number: _____

02 SA (4/20/07) – Failure to cooperate with survey – refer to CMS for sanction action

IMPORTANT NOTICE – PLEASE READ CAREFULLY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: FAILURE TO ALLOW INSPECTION

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The [STATE AGENCY NAME] attempted to conduct [CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint] survey of your laboratory during normal hours of operation on [SURVEY DATES]. However, the surveyors were not able to complete the survey due to the laboratory's failure to cooperate with the survey process. [GIVE DETAILS OF HOW LAB FAILED TO COOPERATE.] On [DATE], the surveyors advised your laboratory that failure to cooperate in the survey process constitutes failure to permit inspection, and your laboratory would be subject to CLIA sanctions.

As a result of the laboratory's failure to allow survey, your laboratory is out of compliance with the CLIA Condition of inspection:

42 C.F.R. § 493.1771 Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.

A form CMS-2567, Statement of Deficiencies, documenting your laboratory's non-compliance is enclosed.

Laboratories that do not meet a CLIA Condition may not be certified to perform testing under the CLIA program. Based on your laboratory's failure to allow inspection, the [STATE

AGENCY NAME] is recommending to the **[NAME OF RO]** Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. These include alternative sanctions (Civil Money Penalty of \$3,000 per day of noncompliance per 42 C.F.R. § 493.1834) and principal sanctions (suspension and revocation of your laboratory's CLIA certificate and cancellation of you laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

By this letter we are forwarding your file to the CMS Regional Office to initiate sanction actions. The CMS Regional Office will be notifying you in writing regarding its determination to impose sanction actions against your laboratory's CLIA certificate.

If you have questions regarding this letter, please contact me at **[PHONE #]**.

Sincerely,

[SURVEYOR NAME], [TITLE]
[STATE AGENCY NAME]

Enclosure: CMS-2567, Statement of Deficiencies

cc: CMS Regional Office

03 SA (4/20/07) – Failure to cooperate with scheduling of survey – last chance appointment

IMPORTANT NOTICE – PLEASE READ CAREFULLY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: FAILURE TO ALLOW INSPECTION – FINAL ATTEMPT TO SCHEDULE SURVEY

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The [STATE AGENCY NAME] has attempted to conduct [CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint] survey of your laboratory to determine compliance with CLIA requirements. Your laboratory was contacted on [GIVE HISTORY OF ATTEMPT(S), I.E., DATES OF CONTACT AND RECORD OF WHAT TRANSPIRED] to schedule the survey. However, your laboratory has continued to be uncooperative in scheduling the survey.

By this letter, we are notifying you that we have scheduled the following date and time to survey your laboratory: [10 DAYS FROM THE DATE OF LETTER OR THEREAFTER, DEPENDING ON SURVEYOR SCHEDULE] at [TIME].

Failure to be present at the laboratory at the appointed time to allow access will constitute failure to permit inspection and your laboratory will be subject to CLIA sanctions. The [STATE AGENCY NAME] will recommend to the [NAME OF RO] Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. These will include alternative sanctions (Civil Money Penalty of \$3,000 per day of noncompliance per 42 C.F.R. § 493.1834) and principal sanctions (suspension and revocation of your laboratory's CLIA certificate and cancellation of you laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

Please be advised that pursuant to 42 C.F.R. § 493.1001.1301, failure to allow immediate access for inspection is basis for the Office of Inspector General (OIG) to exclude your laboratory from participation in all Federal and State health care programs.

If you have questions regarding this letter, please feel free to contact me at [**PHONE #**].

Sincerely,

[**SURVEYOR NAME**], [**TITLE**]
[**STATE AGENCY NAME**]

04 SA (4/20/07) – Failure to cooperate with scheduling of survey – refer to CMS for sanction action

IMPORTANT NOTICE – PLEASE READ CAREFULLY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: FAILURE TO ALLOW INSPECTION – REFERRAL TO CMS FOR SANCTION ACTION

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The [STATE AGENCY NAME] has attempted to conduct [CHOOSE SURVEY TYPE: an initial, a routine recertification, or a complaint] survey of your laboratory to determine compliance with CLIA requirements. Your laboratory was contacted on [GIVE HISTORY OF ATTEMPT(S), I.E., DATES OF CONTACT AND RECORD OF WHAT TRANSPIRED] to schedule the survey. However, your laboratory has continued to be uncooperative in scheduling the survey.

As a result of your laboratory's failure to allow survey, your laboratory is out of compliance with the CLIA Condition of inspection:

42 C.F.R. § 493.1771 Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.

A form CMS-2567, Statement of Deficiencies documenting your laboratory's non-compliance is enclosed.

Laboratories that do not meet a CLIA Condition may not be certified to perform testing under the CLIA program. Based on your laboratory's failure to allow inspection, the [STATE

AGENCY NAME] our is recommending to the [**NAME OF RO**] Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. These include alternative sanctions (Civil Money Penalty of \$3,000 per day of noncompliance per 42 C.F.R. § 493.1834) and principal sanctions (suspension and revocation of your laboratory's CLIA certificate and cancellation of you laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

By this letter we are forwarding your file to the CMS Regional Office to initiate sanction actions. The CMS Regional Office will be notifying you in writing regarding its determination to impose sanction actions against your laboratory's CLIA certificate.

You are reminded that pursuant to 42 C.F.R. § 493.1001.1301, failure to allow immediate access for inspection is basis for the Office of Inspector General (OIG) to exclude your laboratory from participation in all Federal and State health care programs.

If you have questions regarding this letter, please contact me at [**PHONE #**].

Sincerely,

[SURVEYOR NAME], [TITLE]
[STATE AGENCY NAME]

Enclosure: CMS-2567, Statement of Deficiencies

cc: CMS Regional Office

05 SA (4/20/07) – Terminate CLIA certificate – new lab not ready for survey or lab ceased testing prior to recertification

IMPORTANT NOTICE – PLEASE READ CAREFULLY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: TERMINATION OF CLIA CERTIFICATE

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

[FOR INITIAL LAB NOT READY FOR SURVEY, USE FOLLOWING 3 PARAGRAPHS:

Your laboratory applied for and was issued a CLIA number effective [APPLICATION DATE ON 116 SCREEN 3.1]. The [STATE AGENCY NAME] has attempted to conduct an initial survey of your laboratory to determine compliance with CLIA requirements. Your laboratory was contacted on [GIVE HISTORY OF ATTEMPT(S), I.E., DATES OF CONTACT AND RECORD OF WHAT TRANSPIRED] to schedule the survey. However, your laboratory has indicated that it is not ready for survey.

By this letter, we are notifying you that we are terminating your laboratory's CLIA certificate effective with the date of application. When your laboratory is fully operational, you may contact our office again to reapply for CLIA certification and schedule the mandatory compliance survey at that time after applicable fees have been paid.

You are also advised that until your laboratory is appropriately certified by CLIA, you are not authorized to conduct any patient testing, including waived testing and provider performed microscopy procedures, or to bill Medicare or Medicaid for any such testing. Any facility that

performs patient testing without proper CLIA certification shall be subject to imprisonment, or fines, or both. See 42 U.S.C. 263(a)(1).]

[FOR RECERTS – IF LAB HAS CEASED TESTING, USE THE FOLLOWING PARAGRAPH:

In attempting to schedule a recertification survey to determine compliance with CLIA requirements, we were informed that your laboratory has ceased testing effective [DATE]. Based on this information, we are terminating your laboratory's CLIA certificate effective [DATE], the date testing ceased. If your laboratory wishes to resume testing in the future, you may contact our office to reinstate your CLIA certificate or reapply for CLIA certification, as appropriate.]

If you have questions regarding this letter, please feel free to contact me at [PHONE #].

Sincerely,
[SURVEYOR NAME], [TITLE]
[STATE AGENCY NAME]

06 SA (4/20/07) – No deficiencies found

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA #[CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: CERTIFICATION OF COMPLIANCE

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The [STATE AGENCY] conducted [CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint] survey of your laboratory on [SURVEY DATE]. The results of the survey showed that all CLIA Condition-level requirements were met during the time of the onsite survey. We are recommending to CMS that your laboratory be [CHOOSE ONE: certified, recertified] in the CLIA program.

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every instance of non-compliance that may have occurred in the laboratory. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

If you have questions regarding this letter, please contact me at [PHONE #].

Sincerely,

[SURVEYOR NAME], [TITLE]

[STATE AGENCY NAME]

Enclosure: CMS-2567

IMPORTANT NOTICE – ACTION NECESSARY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA #[CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: STANDARD-LEVEL DEFICIENCIES

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The [STATE AGENCY NAME] (State agency) conducted [CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint] survey of your laboratory that was completed on [SURVEY DATE]. [ADD THE FOLLOWING SENTENCE WHEN APPROPRIATE: Please note that this routine survey was expedited because your laboratory's CLIA certificate has expired or is about to expire.] Enclosed is form CMS-2567, Statement of Deficiencies, listing the deficiencies found during the survey. The deficiency statement references the CLIA regulations at 42 C.F.R. § 493.

You are required to respond within 10 days of receipt of this notice. Please indicate your corrective actions on the right side of the form CMS-2567 in the column labeled "Provider Plan of Correction", keying your responses to the deficiencies on the left. Additionally, indicate your anticipated completion dates in the column labeled "Completion Date."

Please return the completed form CMS-2567, dated and signed by the director, within 10 days of receipt of this notice.

Regulations at 42 C.F.R. § 493.1816 state that if a laboratory has deficiencies that are not at the Condition level, the laboratory must submit a plan of correction that is acceptable to CMS (Centers for Medicare & Medicaid Services) in content and time frames. Further, regulations at

42 C.F.R. § 493.1816 require all deficiencies to be corrected within 12 months after the last day of the survey. Please note that depending on the nature and seriousness of the deficiency, the acceptable time frame for correction may be less than 12 months.

If your laboratory does not respond timely to this request, or if your laboratory submits a Plan of Correction that is not acceptable in content and time frames, or if your laboratory does not demonstrate compliance with all CLIA requirements by the specified completion date, we will recommend to CMS imposition of principal sanctions, i.e., suspension, limitation and/or revocation of your laboratory's CLIA certificate and concurrent cancellation of your laboratory's approval for Medicare payments per 42 C.F.R. § 493.1816.

Your laboratory will also be required to provide acceptable evidence of correction for the cited deficiencies. For your information, acceptable evidence of correction must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- 3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/surveys may be conducted by the [STATE AGENCY NAME] at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have questions regarding this letter, please contact me at [PHONE #].

Sincerely,

[SURVEYOR NAME], [TITLE]
[STATE AGENCY NAME]

Enclosure: CMS-2567, Statement of Deficiencies

08 SA (4/20/07) – Standards only – POC acceptable

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director
[OWNER NAME], Owner(s)
[LAB NAME]
[ADDRESS]
[CITY], [STATE] [ZIP]

CLIA #[CLIA NUMBER]
[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: PLAN OF CORRECTION AND EVIDENCE OF CORRECTION ACCEPTABLE

Dear Director/Owner(s):

By letter dated [LETTER DATE], we notified you that based on the onsite survey completed on [SURVEY DATE], your facility was not in compliance with standard-level CLIA requirements. In our letter we requested that you submit an acceptable plan of correction and acceptance evidence of correction. We received your response on [SUBMISSION DATE], and have determined that your plan of correction and evidence of correction are acceptable.

We encourage your laboratory to maintain compliance with all CLIA requirements. It is the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

If it is discovered that your plan of correction was not implemented or that compliance was not maintained, the [STATE AGENCY NAME] will refer the case to the Regional Office of the Centers for Medicare & Medicaid Services (CMS) for appropriate action, and recommend that sanctions be taken against your laboratory's CLIA certificate.

If you have questions regarding this letter, please contact me at [PHONE #].

Sincerely,

[SURVEYOR NAME], [TITLE]
[STATE AGENCY NAME]

09 SA (4/20/07) – Standards only – POC not received or unacceptable – second request for acceptable POC

IMPORTANT NOTICE – ACTION NECESSARY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA #[CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: PLAN OF CORRECTION [CHOOSE AS APPROPRIATE: NOT RECEIVED OR UNACCEPTABLE]

Dear Director/Owner(s):

[BEGIN WITH THE FOLLOWING 2 PARAGRAPHS IF POC NOT RECEIVED:

You were notified by our letter dated [DATE OF POC REQUEST LETTER] of deficiencies found at the [SURVEY DATE] survey of your laboratory. We requested you submit an acceptable plan of correction and evidence of correction for the deficiencies cited within ten days of receipt of our notification letter. To date we have received no response from your laboratory.

You are reminded that if you do not submit an acceptable plan of correction and acceptable evidence of correction, or if you submit a plan of correction that is determined to be unacceptable, the [STATE AGENCY NAME] will recommend to the [RO NAME] Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. As you were previously advised, these may include principal sanctions of suspension, limitation and/or revocation of your laboratory's CLIA certificate and cancellation of you laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814.

[BEGIN WITH THE FOLLOWING 2 PARAGRAPHS IF POC UNACCEPTABLE:

You were notified by our letter dated [DATE OF POC REQUEST LETTER] of deficiencies found at the [SURVEY DATE] survey of your laboratory. We requested you submit a plan of correction for the deficiencies cited within ten days of receipt of our notification letter. You were advised that the plan of correction must be acceptable in content and time frames.

We received your plan of correction on [DATE]. We have reviewed your submission and find that it is unacceptable for the following reasons:

EXPLAIN WHY POC IS UNACCEPTABLE]

[FOR BOTH SITUATIONS, USE THE FOLLOWING LANGUAGE FOR SECOND REQUEST FOR ACCEPTABLE POC:

We are providing another opportunity for you to submit an acceptable plan of correction for the cited deficiencies. You must respond **WITHIN 10 DAYS OF RECEIPT** of this notice and provide a plan of correction that is acceptable in content and time frames.

You are reminded that your laboratory will also be required to provide acceptable evidence of correction for the cited deficiencies by the specified completion date in your plan of correction once it has been determined to be acceptable. We remind you that acceptable evidence of correction must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- 3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.]

[END WITH THE FOLLOWING PARAGRAPH IF POC NOT RECEIVED:

If we do not hear from you, or if we do not receive from you an acceptable plan of correction with acceptable evidence of correction **WITHIN 10 DAYS** from receipt of this notice, we will forward your case to the CMS Regional Office with recommendations for sanction action against your laboratory's CLIA certificate. Once your case has been referred, the CMS Regional Office has the final authority for any sanction actions to be imposed and will inform you of its determination and the appeals procedures.]

[END WITH THE FOLLOWING PARAGRAPH IF POC UNACCEPTABLE:

Please note that if your laboratory does not provide a plan of correction that is acceptable in content and time frames, or if your laboratory does not demonstrate compliance with all CLIA requirements by the specified completion dates in your plan of correction, we will refer your case to the Centers for Medicare & Medicaid Services (CMS) with recommendations that sanctions be imposed against your laboratory's CLIA certificate.]

If you have questions regarding this letter, please contact me at **[PHONE #]**.

Sincerely,

[SURVEYOR NAME], [TITLE]
[STATE AGENCY NAME]

IMPORTANT NOTICE – ACTION NECESSARY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA #[CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: CONDITION-LEVEL DEFICIENCIES

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The [STATE AGENCY NAME] (State agency) conducted [CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint] survey of your laboratory that was completed on [SURVEY DATE]. [ADD THE FOLLOWING SENTENCE WHEN APPROPRIATE: Please note that this routine survey was expedited because your laboratory's CLIA certificate has expired or is about to expire.] As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. Specifically, the following Conditions were not met: [DELETE CONDITIONS THAT DO NOT APPLY.]

- D2000 - 42 C.F.R. § 493.801 Condition: Enrollment and testing of [proficiency testing] samples;
- D2016 - 42 C.F.R. § 493.803 Condition: Successful participation [proficiency testing]
- D3000 - 42 C.F.R. § 493.1101 Condition: Facility Administration
- D5002 - 42 C.F.R. § 493.1201 Condition: Bacteriology ;
- D5004 - 42 C.F.R. § 493.1202 Condition: Mycobacteriology;
- D5006 - 42 C.F.R. § 493.1203 Condition: Mycology;
- D5008 - 42 C.F.R. § 493.1204 Condition: Parasitology;
- D5010 - 42 C.F.R. § 493.1205 Condition: Virology;
- D5012 - 42 C.F.R. § 493.1207 Condition: Syphilis serology;

- D5014 - 42 C.F.R. § 493.1208 Condition: General immunology;
- D5016 - 42 C.F.R. § 493.1210 Condition: Routine chemistry;
- D5018 - 42 C.F.R. § 493.1211 Condition: Urinalysis;
- D5020 - 42 C.F.R. § 493.1212 Condition: Endocrinology;
- D5022 - 42 C.F.R. § 493.1213 Condition: Toxicology;
- D5024 - 42 C.F.R. § 493.1215 Condition: Hematology;
- D5026 - 42 C.F.R. § 493.1217 Condition: Immunohematology;
- D5028 - 42 C.F.R. § 493.1219 Condition: Histopathology;
- D5030 - 42 C.F.R. § 493.1220 Condition: Oral pathology;
- D5032 - 42 C.F.R. § 493.1221 Condition: Cytology;
- D5034 - 42 C.F.R. § 493.1225 Condition: Clinical cytogenetics;
- D5040 - 42 C.F.R. § 493.1226 Condition: Radiobioassay;
- D5042 - 42 C.F.R. § 493.1227 Condition: Histocompatibility;
- D5200 - 42 C.F.R. § 493.1230 Condition: General laboratory systems;
- D5300 - 42 C.F.R. § 493.1240 Condition: Preanalytic systems;
- D5400 - 42 C.F.R. § 493.1250 Condition: Analytic systems;
- D5800 - 42 C.F.R. § 493.1290 Condition: Postanalytic systems;
- D5980 - 42 C.F.R. § 493.1355 Condition: Laboratories performing PPM procedures;
laboratory director;
- D5990 - 42 C.F.R. § 493.1355 Condition: Laboratories performing PPM procedures;
testing personnel;
- D6000 - 42 C.F.R. § 493.1403 Condition: Laboratories performing moderate complexity
testing; laboratory director;
- D6033 - 42 C.F.R. § 493.1409 Condition: Laboratories performing moderate complexity
testing; technical consultant;
- D6056 - 42 C.F.R. § 493.1415 Condition: Laboratories performing moderate complexity
testing; clinical consultant;
- D6063 - 42 C.F.R. § 493.1421 Condition: Laboratories performing moderate complexity
testing; testing personnel;
- D6076 - 42 C.F.R. § 493.1441 Condition: Laboratories performing high complexity testing;
laboratory director;
- D6108 - 42 C.F.R. § 493.1447 Condition: Laboratories performing high complexity testing;
technical supervisor;
- D6134 - 42 C.F.R. § 493.1453 Condition: Laboratories performing high complexity testing;
clinical consultant;
- D6141 - 42 C.F.R. § 493.1459 Condition: Laboratories performing high complexity testing;
general supervisor;
- D6153 - 42 C.F.R. § 493.1467 Condition: Laboratories performing high complexity testing;
cytology general supervisor
- D6162 - 42 C.F.R. § 493.1481 Condition: Laboratories performing high complexity testing;
cytotechnologist;
- D6168 - 42 C.F.R. § 493.1487 Condition: Laboratories performing high complexity testing;
testing personnel;
- D8100 - 42 C.F.R. § 493.1771 Condition: Inspection requirements applicable to all CLIA-
certified and CLIA-exempt laboratories.

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program. You must take steps to bring any unmet Conditions into compliance immediately.

You are directed to submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited. Please document your allegation of compliance using the enclosed CMS-2567, Statement of Deficiencies, in the columns labeled “Provider Plan of Correction” and “Completion Date” located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed CMS-2567 documented with a credible allegation of compliance to our office WITHIN 10 DAYS FROM RECEIPT of this notice. You must also submit documented evidence that verifies that the corrections were made. We may conduct a follow-up onsite survey in approximately 30-45 days to verify the corrections if we find your allegation of compliance to be credible and the submitted evidence to be acceptable. If your laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey. (Your allegation of compliance will be included in the public record of the inspection.)

A credible allegation of compliance is a statement or documentation that is:

- 1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
- 2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
- 3) Indicates resolution of the problems.

For your information, acceptable evidence of correction must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- 3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be still out of compliance with any CLIA Condition-level requirements at the time of the follow-up visit, [STATE AGENCY NAME] will recommend to the [NAME OF RO] Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. These may include alternative sanctions (Civil Money Penalty of up to \$3,000 per day of noncompliance per 42 C.F.R. § 493.1834, Directed Plan of Correction per 42 C.F.R. § 493.1832, State Onsite Monitoring per 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of your laboratory's

CLIA certificate and cancellation of you laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assurance measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/surveys may be conducted by the State agency at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have questions regarding this letter, please contact me at **[PHONE #]**.

Sincerely,

[SURVEYOR NAME], [TITLE]
[STATE AGENCY NAME]

Enclosure: CMS-2567, Statement of Deficiencies

11 SA (4/20/07) – Condition(s) out – AOC credible

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: ALLEGATION OF COMPLIANCE CREDIBLE AND EVIDENCE OF CORRECTION ACCEPTABLE

Dear Director/Owner(s):

By letter dated [LETTER DATE], we notified you that based on the onsite survey completed on [SURVEY DATE], your facility was not in compliance with Condition-level CLIA requirements. In our letter we requested that you submit a credible allegation of compliance and acceptance evidence of correction. We received your response on [SUBMISSION DATE], and have determined that your allegation of compliance is credible and evidence of correction is acceptable.

We encourage your laboratory to maintain compliance with all CLIA requirements. It is the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

If it is discovered that the alleged corrective action was not implemented or that compliance was not maintained, the [STATE AGENCY NAME] will refer the case to the Regional Office of the Centers for Medicare & Medicaid Services (CMS) for appropriate action, and recommend that sanctions be taken against your laboratory's CLIA certificate.

If you have questions regarding this letter, please contact me at [PHONE #].

Sincerely,

[SURVEYOR NAME], [TITLE]
[STATE AGENCY NAME]

12 SA (4/20/07) – CONDITIONS OUT – AOC CREDIBLE – COMPLIANCE WITH CONDITIONS VERIFIED AT F/U survey, standards remain

IMPORTANT NOTICE – ACTION NECESSARY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director
[OWNER NAME], Owner(s)
[LAB NAME]
[ADDRESS]
[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]
[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: CONDITIONS CORRECTED, STANDARDS REMAIN

Dear Director/Owner(s):

A survey of your laboratory was completed on [INITIAL SURVEY DATE] which found your laboratory to be out of compliance with Condition-level CLIA requirements. A follow-up survey of your laboratory was conducted on [FOLLOW UP SURVEY DATE], following a submission of a credible allegation of compliance and evidence of correction for the [INITIAL SURVEY DATE] survey of your laboratory.

It was determined at the follow-up survey that all Conditions were met, but standard-level deficiencies still remain. [ADD IF APPROPRIATE: These include deficiencies still uncorrected from the [SURVEY DATE OF ORIGINAL SURVEY] survey as well as others identified during the revisit survey.] Enclosed is form CMS-2567, Statement of Deficiencies, listing the remaining deficiencies.

You are required to respond WITHIN 10 DAYS OF RECEIPT of this notice. Please indicate your corrective actions on the right side of the form CMS-2567 in the column labeled "Provider Plan of Correction", keying your responses to the deficiencies on the left. Additionally, indicate your anticipated completion dates in the column labeled "Completion Date."

Please return the completed form CMS-2567, dated and signed by the director, within 10 days of receipt of this notice.

Regulations at 42 C.F.R. § 493.1816 state that if a laboratory has deficiencies that are not at the Condition level, the laboratory must submit a plan of correction that is acceptable to CMS (Centers for Medicare & Medicaid Services) in content and time frames. Further, regulations at 42 C.F.R. § 493.1816 require all deficiencies be corrected within 12 months after the last day of

the survey. Please note that depending on the nature and seriousness of the deficiency, the acceptable time frame for correction may be less than 12 months.

If your laboratory does not respond timely to this request, or if your laboratory submits a Plan of Correction that is not acceptable in content and time frames, or if your laboratory does not demonstrate compliance with all CLIA requirements by the specified completion date, we will recommend to CMS imposition of principal sanctions, i.e., suspension, limitation and/or revocation of your laboratory's CLIA certificate and concurrent cancellation of you laboratory's approval for Medicare payments per 42 C.F.R. § 493.1816.

Your laboratory will also be required to provide acceptable evidence of correction for the cited deficiencies. You are reminded that acceptable evidence of correction must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- 3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If you have questions regarding this letter, please contact me at [**PHONE #**].

Sincerely,

[**SURVEYOR NAME**], [**TITLE**]
[**STATE AGENCY NAME**]

Enclosure: CMS-2567, Statement of Deficiencies

13 SA (4/20/07) – **Conditions out** – AOC not credible, language for 1) no repeat deficiencies or 2) repeat deficiencies

IMPORTANT NOTICE – ACTION NECESSARY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: ALLEGATION OF COMPLIANCE NOT CREDIBLE, EVIDENCE OF CORRECTION UNACCEPTABLE

Dear Director/Owner(s):

You were notified by our letter dated [DATE OF AOC REQUEST LETTER] of deficiencies found at the [SURVEY DATE] survey of your laboratory. We requested you submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited within ten days of receipt of our notification letter. You were advised that a credible allegation of compliance is a statement or documentation that is:

- 1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
- 2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
- 3) Indicates resolution of the problems.

You were also advised that acceptable evidence of correction must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

- 3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

We received your response on [DATE]. We have reviewed your submission and find that it does not constitute a credible allegation of compliance and acceptable evidence of correction for the following reasons):

[EXPLAIN WHY AOC/EVIDENCE OF CORRECTION UNACCEPTABLE]

[OPTION 1 – USE THE FOLLOWING 3 PARAGRAPHS IF NO REPEAT DEFICIENCIES:

You are reminded that if you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be still out of compliance with any CLIA Condition-level requirements at the time of the follow-up visit, the [STATE AGENCY NAME] will recommend to the [RO NAME] Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. As you were previously advised, these may include alternative sanctions (Civil Money Penalty of up to \$3,000 per day of noncompliance per 42 C.F.R. § 493.1834, Directed Plan of Correction per 42 C.F.R. § 493.1832, State Onsite Monitoring per 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of your laboratory's CLIA certificate and cancellation of you laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

We are providing you another opportunity to submit a credible allegation of compliance and acceptable evidence of correction for the cited deficiencies. You must respond WITHIN 10 DAYS from receipt of this notice. **[IF REPEAT CONDITIONS OUT BASED ON SAME DEFICIENCIES AND THE LAB HAS FAILED TO MAINTAIN COMPLIANCE, SA MAY CHOOSE TO REFER CASE IMMEDIATELY TO RO FOR SANCTION. SEE OPTION 2 BELOW.]**

If we do not hear from you, or if we do not receive from you a credible allegation of compliance and acceptable evidence of correction WITHIN 10 DAYS from receipt of this notice, we will forward your case to the CMS Regional Office with recommendations for sanction action against your laboratory's CLIA certificate. Once your case has been referred, the CMS Regional Office has the final authority for any sanction actions to be imposed and will inform you of its determination and the appeals procedures.]

[OPTION 2 – USE THE FOLLOWING 3 PARAGRAPHS IF REPEAT DEFICIENCIES AND SA DETERMINES IT APPROPRIATE BASED ON AOC REVIEW TO REFER CASE IMMEDIATELY TO RO FOR SANCTION:

We note that deficiencies cited at the [DATE OF SURVEY] survey of your laboratory are repeat deficiencies from previous surveys. **[GIVE DETAILS OF FINDINGS FROM PRIOR SURVEYS.]** You were notified in our letter dated [DATE OF AOC REQUEST LETTER]

that failure to come into Condition-level compliance would result in a referral to the Centers for Medicare & Medicaid Services (CMS) for sanction action against your laboratory's CLIA certificate.

Since your facility has not taken the necessary action to correct the deficiencies cited at the current survey, and based on your laboratory's history of non-compliance and failure to sustain compliance with CLIA Condition-level requirements, we are recommending to the CMS Regional Office that the following principal and/or alternative sanctions be imposed:

Civil Money Penalty of \$3,000 per day for each day of non-compliance;
State On-site Monitoring; Directed Plan of Correction;
Suspension, Limitation and/or Revocation of your CLIA certificate;
Cancellation of all Medicare/Medicaid Payments.

The CMS Regional Office has the final authority for any sanction actions to be imposed and will inform you of its determination and the appeals procedures.]

If you have questions regarding this letter, please contact me at [PHONE #].

Sincerely,

[SURVEYOR NAME], [TITLE]
[STATE AGENCY NAME]

[FOR OPTION 2, CC RO:
cc: CMS Regional Office]

14 SA (4/20/07) – **Conditions out** – no AOC submitted, language for 1) no repeat deficiencies or 2) repeat deficiencies

IMPORTANT NOTICE – ACTION NECESSARY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: ALLEGATION OF COMPLIANCE NOT RECEIVED

Dear Director/Owner(s):

You were notified by our letter dated [DATE OF AOC REQUEST LETTER] of deficiencies found at the [SURVEY DATE] survey of your laboratory. We requested that you submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited within ten days of receipt of our notification letter. To date we have received no response from your laboratory.

[OPTION 1 – USE THE FOLLOWING 3 PARAGRAPHS IF NO REPEAT DEFICIENCIES:

You are reminded that if you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be still out of compliance with any CLIA Condition-level requirements at the time of the follow-up visit, the [STATE AGENCY NAME] will recommend to the [RO NAME] Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. As you were previously advised, these may include alternative sanctions (Civil Money Penalty of up to \$3,000 per day of noncompliance or per violation per 42 C.F.R. § 493.1834, Directed Plan of Correction per 42 C.F.R. § 493.1832, State Onsite Monitoring per 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of your laboratory's CLIA certificate and cancellation of you laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

We are giving you another opportunity to submit a credible allegation of compliance and acceptable evidence of correction for the cited deficiencies. You must respond WITHIN 10 DAYS from receipt of this notice. **[IF REPEAT CONDITIONS OUT AND THE LAB HAS**

FAILED TO MAINTAIN COMPLIANCE, SA MAY CHOOSE TO REFER CASE IMMEDIATELY TO RO FOR SANCTION. SEE OPTION 2 BELOW.]

If we do not hear from you, or if we do not receive from you a credible allegation of compliance and acceptable evidence of correction WITHIN 10 DAYS from receipt of this notice, we will forward your case to the CMS Regional Office with recommendations for sanction action against your laboratory's CLIA certificate. Once your case has been referred, the CMS Regional Office has the final authority for any sanction actions to be imposed and will inform you of its determination and the appeals procedures.]

[OPTION 2 – USE THE FOLLOWING 3 PARAGRAPHS IF REPEAT DEFICIENCIES AND SA DETERMINES IT APPROPRIATE BASED ON AOC REVIEW TO REFER CASE IMMEDIATELY TO RO FOR SANCTION:

We note that deficiencies cited at the **[DATE OF SURVEY]** survey of your laboratory are repeat deficiencies from previous surveys. **[GIVE DETAILS OF FINDINGS FROM PRIOR SURVEYS.]** You were notified in our letter dated **[DATE OF AOC REQUEST LETTER]** that failure to come into Condition-level compliance would result in a referral to the Centers for Medicare & Medicaid Services (CMS) for sanction action against your laboratory's CLIA certificate.

Since your facility has not taken the necessary action to correct the deficiencies cited at the current survey, and based on your laboratory's history of non-compliance and failure to sustain compliance with CLIA Condition-level requirements, we are recommending to the CMS Regional Office that the following principal and/or alternative sanctions be imposed:

Civil Money Penalty of \$3,000 per day for each day of non-compliance;
State On-site Monitoring; Directed Plan of Correction;
Suspension, Limitation and/or Revocation of your CLIA certificate;
Cancellation of all Medicare/Medicaid Payments.

The CMS Regional Office has the final authority for any sanction actions to be imposed and will inform you of its determination and the appeals procedures.]

If you have questions regarding this letter, please contact me at **[PHONE #]**.

Sincerely,

[SURVEYOR NAME], [TITLE]
[STATE AGENCY NAME]

[FOR OPTION 2, CC RO
cc: CMS Regional Office]

15 SA (4/20/07) – Conditions out – AOC credible, Conditions still out at FU survey

IMPORTANT NOTICE – ACTION NECESSARY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: CONDITIONS STILL OUT

Dear Director/Owner(s):

A survey of your laboratory was conducted on [INITIAL SURVEY DATE]. You were notified by letter dated [NOTICE DATE] of the deficiencies found and that you must be in Condition-level compliance to be certified in the CLIA program.

A revisit survey of your laboratory was conducted on [FOLLOW UP SURVEY DATE], following a submission of a credible allegation of compliance and evidence that indicated correction of the deficiencies cited at the [INITIAL SURVEY DATE] survey of your laboratory. The follow-up survey resulted in the finding that your laboratory is still out of compliance with the following Condition-level requirement(s):

[LIST CONDITIONS.]

Standard-level deficiencies cited at the [ORIGINAL SURVEY DATE] survey also remain uncorrected. **[DELETE FOLLOWING SENTENCE IF NOT APPLICABLE: Additional standard-level deficiencies were also found at the follow-up survey.]** Enclosed is form CMS-2567, Statement of Deficiencies, detailing all deficiencies found at the time of the follow-up survey.

You were notified in our letter dated [NOTICE DATE] that failure to come into Condition-level compliance would result in a referral to the Centers for Medicare & Medicaid Services (CMS) for sanction action against your laboratory's CLIA certificate. Since your facility has not taken the necessary corrective action to come into Condition-level compliance with all CLIA requirements, we are recommending to the CMS Regional Office that the following principal and/or alternative sanctions be imposed:

Civil Money Penalty of \$3,000 per day for each day of non-compliance; State On-site Monitoring; Directed Plan of Correction; Suspension, Limitation and/or Revocation of your CLIA certificate; Cancellation of all Medicare/Medicaid Payments.

If your laboratory has evidence of correction for the deficiencies, you should submit this evidence no later than 10 days from the date of this notice. You are reminded that acceptable evidence of correction must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- 3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur; and
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If we do not hear from you, or if we do not receive from you acceptable evidence of compliance with all CLIA Condition-level requirements **WITHIN 10 DAYS FROM RECEIPT OF THIS NOTICE**, we will forward your case to the CMS Regional Office to initiate the recommended sanction actions. Once your case has been referred, the CMS Regional Office has the final authority for any sanction actions to be imposed and will inform you of its determination and the appeals procedures.

If you have questions regarding this letter, please contact me at [**PHONE #**].

Sincerely,

[**SURVEYOR NAME**], [**TITLE**]
[**STATE AGENCY NAME**]

Enclosure: CMS-2567, Statement of Deficiencies

16 SA (4/20/07) – Conditions out at FU survey – compliance not achieved after warning letter, refer to CMS for sanctions

IMPORTANT NOTICE – PLEASE READ CAREFULLY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director
[OWNER NAME], Owner(s)
[LAB NAME]
[ADDRESS]
[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]
[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: REFERRAL TO CMS FOR SANCTION ACTION

Dear Dr. [DIRECTOR NAME]:

You were notified by letter dated [NOTICE DATE] that Condition-level deficiencies remained at the follow-up survey of your laboratory conducted on [FOLLOW UP SURVEY DATE]. You were notified in the same letter that our office would refer your case to the Regional Office OF THE Centers for Medicare & Medicaid Services (CMS) with recommendations for sanction actions. You were given 10 days in which to submit evidence verifying that all Condition-level deficiencies had been corrected. The 10-day time frame has passed, and we have not received such evidence of correction.

Accordingly, by this letter we are forwarding your file to the CMS Regional Office to initiate sanction actions. The CMS Regional Office will be notifying you in writing regarding its determination to impose sanction actions against your laboratory's CLIA certificate.

If you have questions regarding this letter, please contact me at [PHONE #].

Sincerely,

[SURVEYOR NAME], [TITLE]
[STATE AGENCY NAME]

cc: CMS Regional Office

17 SA (4/20/07) – Immediate Jeopardy – AOC request letter

IMPORTANT NOTICE – ACTION NECESSARY

VIA FACSIMILE TO XXX XXX-XXXX AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA #[CLIA NUMBER]

[OPTIONAL] State I.D. # [STATE ID NUMBER]

RE: CONDITIONS OUT - IMMEDIATE JEOPARDY

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The [STATE AGENCY NAME] (State agency) conducted [CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint] survey of your laboratory that was completed on [SURVEY DATE]. As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. In addition, it was determined that the deficient practices of your laboratory pose immediate jeopardy to patient health and safety. (Immediate jeopardy is defined by the CLIA regulations as a situation in which immediate corrective action is necessary because the laboratory's non-compliance with one or more Condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public.) Specifically, the following Conditions were not met: [DELETE CONDITIONS THAT DO NOT APPLY.]

D2000 - 42 C.F.R. § 493.801 Condition: Enrollment and testing of [proficiency testing] samples;

D2016 - 42 C.F.R. § 493.803 Condition: Successful participation [proficiency testing]

D3000 - 42 C.F.R. § 493.1101 Condition: Facility Administration

D5002 - 42 C.F.R. § 493.1201 Condition: Bacteriology ;

D5004 - 42 C.F.R. § 493.1202 Condition: Mycobacteriology;
D5006 - 42 C.F.R. § 493.1203 Condition: Mycology;
D5008 - 42 C.F.R. § 493.1204 Condition: Parasitology;
D5010 - 42 C.F.R. § 493.1205 Condition: Virology;
D5012 - 42 C.F.R. § 493.1207 Condition: Syphilis serology;
D5014 - 42 C.F.R. § 493.1208 Condition: General immunology;
D5016 - 42 C.F.R. § 493.1210 Condition: Routine chemistry;
D5018 - 42 C.F.R. § 493.1211 Condition: Urinalysis;
D5020 - 42 C.F.R. § 493.1212 Condition: Endocrinology;
D5022 - 42 C.F.R. § 493.1213 Condition: Toxicology;
D5024 - 42 C.F.R. § 493.1215 Condition: Hematology;
D5026 - 42 C.F.R. § 493.1217 Condition: Immunohematology;
D5028 - 42 C.F.R. § 493.1219 Condition: Histopathology;
D5030 - 42 C.F.R. § 493.1220 Condition: Oral pathology;
D5032 - 42 C.F.R. § 493.1221 Condition: Cytology;
D5034 - 42 C.F.R. § 493.1225 Condition: Clinical cytogenetics;
D5040 - 42 C.F.R. § 493.1226 Condition: Radiobioassay;
D5042 - 42 C.F.R. § 493.1227 Condition: Histocompatibility;
D5200 - 42 C.F.R. § 493.1230 Condition: General laboratory systems;
D5300 - 42 C.F.R. § 493.1240 Condition: Preanalytic systems;
D5400 - 42 C.F.R. § 493.1250 Condition: Analytic systems;
D5800 - 42 C.F.R. § 493.1290 Condition: Postanalytic systems;
D5980 - 42 C.F.R. § 493.1355 Condition: Laboratories performing PPM procedures;
laboratory director;
D5990 - 42 C.F.R. § 493.1355 Condition: Laboratories performing PPM procedures;
testing personnel;
D6000 - 42 C.F.R. § 493.1403 Condition: Laboratories performing moderate complexity
testing; laboratory director;
D6033 - 42 C.F.R. § 493.1409 Condition: Laboratories performing moderate complexity
testing; technical consultant;
D6056 - 42 C.F.R. § 493.1415 Condition: Laboratories performing moderate complexity
testing; clinical consultant;
D6063 - 42 C.F.R. § 493.1421 Condition: Laboratories performing moderate complexity
testing; testing personnel;
D6076 - 42 C.F.R. § 493.1441 Condition: Laboratories performing high complexity testing;
laboratory director;
D6108 - 42 C.F.R. § 493.1447 Condition: Laboratories performing high complexity testing;
technical supervisor;
D6134 - 42 C.F.R. § 493.1453 Condition: Laboratories performing high complexity testing;
clinical consultant;
D6141 - 42 C.F.R. § 493.1459 Condition: Laboratories performing high complexity testing;
general supervisor;
D6153 - 42 C.F.R. § 493.1467 Condition: Laboratories performing high complexity testing;
cytology general supervisor
D6162 - 42 C.F.R. § 493.1481 Condition: Laboratories performing high complexity testing;
cytotechnologist;
D6168 - 42 C.F.R. § 493.1487 Condition: Laboratories performing high complexity testing;
testing personnel;

D8100 - 42 C.F.R. § 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

Because of the seriousness of these deficiencies, your laboratory no longer meets the requirements to perform testing under CLIA. Based on the finding of immediate jeopardy, this office has contacted the Centers for Medicare & Medicaid Services (CMS), and has recommended a determination of non-compliance and the following sanctions be imposed and/or enforcement actions be taken if your laboratory does not remove jeopardy and come into Condition-level compliance:

Principal sanction of suspension and revocation of your laboratory's CLIA certificate 42 C.F.R. § 493.1806 and 493.1812);

Cancellation of all Medicare and Medicaid payments (42 C.F.R. § 493.1807 and § 493.1808);

and civil money penalties of \$10,000 per day of violation (42 C.F.R. § 493.1806 and § 493.1834).

When a laboratory's deficiencies pose immediate jeopardy, CMS requires the laboratory to take immediate action to remove the jeopardy and come into Condition-level compliance. Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program.

Please be advised that sanctions and/or enforcement actions can be rescinded only when compliance is verified. Please also be advised that due to the potential significant hazard to the public health and safety posed by the deficiencies identified, sanctions may become effective 23 calendar days from the survey date.

You have 10 CALENDAR DAYS from the date of this notice to provide this office, with a copy to CMS (at the address shown at the end of this notice), with a credible allegation of compliance and acceptable evidence documenting that the immediate jeopardy has been removed and that action has been taken to correct all of the Condition-level deficiencies in question.

You are directed to document your allegation of compliance using the enclosed CMS-2567, Statement of Deficiencies, in the columns labeled "Provider Plan of Correction" and "Completion Date" located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed CMS-2567 documented with a credible allegation of compliance to our office WITHIN 10 CALENDAR DAYS from the date of this notice. You must also submit documented evidence that verifies that the corrections were made.

For your information, a credible allegation of compliance is a statement or documentation that is:

- 1) Made by a representative of a laboratory with a history of having maintained a

commitment to compliance and taking corrective action when required;

- 2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
- 3) Indicates resolution of the problems.

In addition, acceptable evidence of correction must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- 3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If you submit by [**DATE OF LETTER PLUS 10 DAYS**] a credible allegation of compliance and acceptable evidence that your laboratory has removed jeopardy and come into Condition-level compliance, and we are able to verify compliance with all CLIA requirements through a follow-up survey, sanctions will not be imposed. If your laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey. (Your allegation of compliance will be included in the public record of the inspection.)

If jeopardy is not removed and your laboratory does not come into Condition-level compliance, we will refer your case to CMS for sanction action. CMS will make the final determination and will advise you in writing of the sanction(s) to be imposed and/or enforcement action(s) that will be taken. CMS will also notify you of your appeal rights at that time.

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assurance measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/surveys may be conducted by the State agency at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have questions regarding this letter, please contact me at [**PHONE #**].

Sincerely,

[SURVEYOR NAME], [TITLE]
[STATE AGENCY NAME]

Enclosure: CMS-2567, Statement of Deficiencies

cc: CMS Regional Office

18 SA (4/20/07) – PT desk review finds 1st unsuccessful – request AOC

IMPORTANT NOTICE – ACTION NECESSARY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: CONDITIONS OUT – FIRST UNSUCCESSFUL PT PERFORMANCE

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

Subpart H of 42 C.F.R. § 493 requires each laboratory certified to test specimens under the CLIA regulations to successfully participate in an approved proficiency testing (PT) program. The [STATE AGENCY NAME] reviewed PT results submitted to CLIA by your PT provider and found unsatisfactory performance in the events listed below:

<u>PT Provider</u>	<u>Testing Event</u>	<u>Analyte/specialty/subspecialty</u>	<u>Score</u>
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[LIST UNSATISFACTORY EVENTS.]

The CLIA regulations at 42 C.F.R. § 493.2 defines unsuccessful PT performance as failure to attain the minimum satisfactory score for an analyte, test, subspecialty or specialty for two consecutive or two out of three consecutive testing events. Based on the PT failures listed above, your facility is not in compliance with the Conditions of successful participation in PT and Laboratory Director. Enclosed is Form CMS-2567, Statement of Deficiencies, documenting your laboratory's failure to meet these requirements: **[DELETE ANY DIRECTOR CONDITION THAT DOES NOT APPLY.]**

D2016 - 42 C.F.R. § 493.803 Condition: Successful participation [proficiency testing]

D6000 - 42 C.F.R. § 493.1403	Condition: Laboratories performing moderate complexity testing; laboratory director;
D6076 - 42 C.F.R. § 493.1441	Condition: Laboratories performing high complexity testing; laboratory director;

Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program. You must take steps to bring any unmet Conditions into compliance immediately.

You are directed to submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited. Please document your allegation of compliance using the enclosed CMS-2567, Statement of Deficiencies, in the columns labeled “Provider Plan of Correction” and “Completion Date” located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed CMS-2567 documented with a credible allegation of compliance to our office WITHIN 10 DAYS FROM RECEIPT of this notice. You must also submit documented evidence that verifies that the corrections were made. Your allegation of compliance will be subject to disclosure to the public upon request.

A credible allegation of compliance is a statement or documentation that is:

- 1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
- 2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
- 3) Indicates resolution of the problems.

For your information, acceptable evidence of correction must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- 3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

CLIA regulations at 42 C.F.R. § 493.1838 allow a laboratory at the first occurrence of unsuccessful PT performance to undertake training of its personnel, or obtain necessary technical assistance, or both, if appropriate to the circumstances. If your laboratory determines that training/technical assistance is the appropriate corrective action, evidence must be submitted to document that the training and/or technical assistance have been undertaken and were effective in correcting the problems that caused the unsuccessful PT performance. In particular, the evidence must include documentation that your laboratory has taken action to correct actual or

potential patient outcome during the period of PT failure. See the requirements for acceptable evidence of correction above.

If you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be out of compliance with the CLIA Condition of successful participation in PT at the time of the next on-site survey, the **[STATE AGENCY NAME]** will recommend to the **[RO NAME]** Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. These may include alternative sanctions (Civil Money Penalty of up to \$3,000 per day of noncompliance or per violation per 42 C.F.R. § 493.1834, Directed Plan of Correction per 42 C.F.R. § 493.1832, State Onsite Monitoring per 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of your laboratory's CLIA certificate and cancellation of you laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

If you have questions regarding this letter, please contact me at **[PHONE #]**.

Sincerely,

[NAME, TITLE]

[STATE AGENCY NAME]

Enclosure: CMS-2567, Statement of Deficiencies

19 SA (4/20/07) – PT desk review 1st unsuccessful – AOC credible

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: ALLEGATION OF COMPLIANCE CREDIBLE AND EVIDENCE OF CORRECTION
ACCEPTABLE

Dear Director/Owner(s):

By letter dated [DATE OF LETTER], the [STATE AGENCY NAME] notified you that your laboratory was not in compliance with the Conditions of successful participation in proficiency testing (PT) and Laboratory Director based on unsatisfactory performance in PT for [NAME OF ANALYET/SPECIALTY/SUBSPECIALTY] for the testing events [LIST PT EVENTS]. In the letter, we requested that you submit a credible allegation of compliance and acceptance evidence of correction. We received your response on [SUBMISSION DATE], and have determined that your allegation of compliance is credible and evidence of correction is acceptable.

We caution your laboratory to maintain compliance with all CLIA requirements for proficiency testing. If it is discovered that your allegation of compliance was not implemented or that compliance was not maintained, the [STATE AGENCY NAME] will refer the case to the Regional Office of the Centers for Medicare & Medicaid Services (CMS) for appropriate action, and recommend that sanctions be taken against your laboratory's CLIA certificate.

Any future proficiency testing failure that results in a subsequent occurrence of unsuccessful participation in proficiency testing will be basis for such referral to the CMS Regional Office to initiate sanction actions against your laboratory's CLIA certificate. These sanctions may include alternative sanctions of a Directed Plan of Correction, Civil Money Penalty and suspension of the laboratory's approval to receive Medicare payments as well as principal sanctions of suspension, limitation or revocation of your laboratory's CLIA certificate and cancellation of the laboratory's approval to receive Medicare payments.

If you have questions regarding this letter, please contact me at [**PHONE #**].

Sincerely,

[**SURVEYOR NAME**], [**TITLE**]
[**STATE AGENCY NAME**]

20 SA (4/20/07) – SA PT desk review 1st unsuccessful – AOC not credible, second chance to submit credible AOC

IMPORTANT NOTICE – ACTION NECESSARY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: ALLEGATION OF COMPLIANCE NOT CREDIBLE/EVIDENCE OF CORRECTION UNACCEPTABLE

Dear Director/Owner(s):

You were notified by our letter dated [DATE OF AOC REQUEST LETTER] of your laboratory's failure to meet the CLIA requirements for successful participation in PT and Laboratory Director. We requested you submit a credible allegation of compliance and acceptable evidence of correction within ten days of receipt of our notification letter and Form CMS-2567, Statement of Deficiencies. You were advised that a credible allegation of compliance is a statement or documentation that is:

- 1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
- 2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
- 3) Indicates resolution of the problems.

You were also advised that acceptable evidence of correction must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

- 3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

We received your response on [DATE]. We have reviewed your submission and find that your laboratory remains out of compliance with the CLIA Conditions of successful PT participation and Laboratory Director. The submission does not constitute a credible allegation of compliance and acceptable evidence of correction for the following reasons:

[EXPLAIN WHY AOC/EVIDENCE OF CORRECTION UNACCEPTABLE. FOR EXAMPLE: Your laboratory did not submit evidence that it has corrected actual or potential patient outcome during the period of PT failure.]

You are reminded that if you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be out of compliance with the requirement for successful participation in PT at the time of the next on-site survey, the [STATE AGENCY NAME] will recommend to the [RO NAME] Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. As you were previously advised, these may include alternative sanctions (Civil Money Penalty of up to \$3,000 per day of non-compliance or per violation per 42 C.F.R. § 493.1834, Directed Plan of Correction per 42 C.F.R. § 493.1832, State Onsite Monitoring per 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of your laboratory's CLIA certificate and cancellation of you laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

We are giving you another opportunity to submit a credible allegation of compliance and acceptable evidence of correction for the cited deficiencies. You must respond WITHIN 10 DAYS from receipt of this notice.

If we do not hear from you, or if we do not receive from you a credible allegation of compliance and acceptable evidence of correction WITHIN 10 DAYS from receipt of this notice, we will forward your case to the CMS Regional Office with recommendations for sanction action against your laboratory's CLIA certificate. Once your case has been referred, the CMS Regional Office has the final authority for any sanction actions to be imposed and will inform you of its determination and the appeals procedures.

If you have questions regarding this letter, please contact me at [PHONE #].

Sincerely,

[NAME, TITLE]
[STATE AGENCY NAME]

21 SA – PT desk review 1st unsuccessful – no AOC or AOC not credible, refer to CMS RO for sanction action

IMPORTANT NOTICE – PLEASE READ CAREFULLY

VIA FACSIMILE TO XXX XXX-XXXX AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]

[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: REFERRAL TO CMS FOR SANCTION ACTION

Dear Dr. [DIRECTOR NAME]:

[USE THE FOLLOWING PARAGRAPH IF NO AOC SUBMITTED:

On [DATE] a letter was sent to you from the [STATE AGENCY NAME] requesting that you reply on Form CMS-2567, Statement of Deficiencies, in the “Provider Plan of Correction” column with a credible allegation of compliance for unsuccessful proficiency testing and submit evidence of corrective actions. Subsequent to that letter, the [STATE AGENCY NAME] sent another notice via certified mail again requesting that your laboratory provide a credible allegation of compliance and evidence of corrective actions for the unsuccessful proficiency testing by no later than ten (10) calendar days after receipt. You were advised in the letters that failure to come into compliance would result in our office referring your case to the Centers for Medicare & Medicaid Services (CMS) with recommendations for sanction action. As of this date, this office has not received any response from your laboratory to address your failure to meet the CLIA Condition of successful participation in proficiency testing.]

[USE THE FOLLOWING PARAGRAPH IF AOC CONTINUES TO BE NOT CREDIBLE:

You were notified by letter dated [NOTICE DATE] that your laboratory’s allegation of compliance was not credible and evidence of correction was not acceptable, and that your laboratory remains out of compliance with the CLIA Conditions of successful participation in proficiency testing and Laboratory Director. You were reminded in the same letter that failure to come into compliance would result in our office referring your case to the Regional Office of the Centers for Medicare & Medicaid Services (CMS) with recommendations for sanction action. You were given another opportunity to submit a credible allegation of compliance and acceptable evidence of correction within 10 days. The 10-day time frame has passed, and we have

not received such evidence of correction. [**OR:** We received a second submission from your laboratory and again found it to be unacceptable for the following reasons: **GIVE REASONS.**]

Accordingly, we are forwarding your file to the CMS Regional Office to initiate sanction actions. The CMS Regional Office will be notifying you in writing regarding its determination to impose sanctions against your laboratory's CLIA certificate and will inform you of your laboratory's appeal rights.

If you have questions regarding this letter, please contact me at [**PHONE #**].

Sincerely,

[**NAME, TITLE**]
[**STATE AGENCY NAME**]

cc: CMS Regional Office

22 SA (4/20/07) – PT – survey finds 1st unsuccessful – AOC request, language for 1) unsuccessful participation in PT only; and 2) other Condition(s) out in addition to unsuccessful participation in PT

IMPORTANT NOTICE – ACTION NECESSARY

VIA FACSIMILE TO [XXX XXX-XXXX] AND FIRST CLASS MAIL. (CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director
[OWNER NAME], Owner(s)
[LAB NAME]
[ADDRESS]
[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]
[OPTIONAL: State I.D. # [STATE ID NUMBER]

RE: CONDITIONS OUT – UNSUCCESSFUL PARTICIPATION IN PROFICIENCY TESTING

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

[OPTION 1 – 1ST UNSUCCESSFUL ONLY ISSUE CAUSING CONDITIONS OUT:

The [STATE AGENCY NAME] conducted [CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint] survey of your laboratory that was completed on [SURVEY DATE]. [ADD THE FOLLOWING SENTENCE WHEN APPROPRIATE: Please note that this routine survey was expedited because your laboratory's CLIA certificate has expired or is about to expire.] As a result of the survey, it was determined that there was unsatisfactory performance in proficiency testing (PT) for the events listed below:

<u>PT Provider</u>	<u>Testing Event</u>	<u>Analyte/specialty/subspecialty</u>	<u>Score</u>
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[LIST UNSATISFACTORY EVENTS]

The CLIA regulations at 493.2 defines unsuccessful PT performance as failure to attain the minimum satisfactory score for an analyte, test, subspecialty or specialty for two consecutive or

two out of three consecutive testing events. Based on the PT failures listed above, your facility is not in compliance with the Conditions of successful participation in PT and Laboratory Director: **[DELETE CONDITIONS THAT DO NOT APPLY.]**

- D2016 - 42 C.F.R. § 493.803 Condition: Successful participation [proficiency testing]
- D6000 - 42 C.F.R. § 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
- D6076 - 42 C.F.R. § 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.]

[OPTION 2 – OTHER CONDITIONS OUT IN ADDITION TO 1ST UNSUCCESSFUL:

The **[STATE AGENCY NAME]** conducted **[CHOOSE SURVEY TYPE:** an initial, a routine recertification, a complaint] survey of your laboratory that was completed on **[SURVEY DATE]**. **[ADD THE FOLLOWING SENTENCE WHEN APPROPRIATE:** Please note that this routine survey was expedited because your laboratory's CLIA certificate has expired or is about to expire.] As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program, including the Condition of successful participation in proficiency testing (PT). Specifically, the following Conditions were not met: **[DELETE CONDITIONS THAT DO NOT APPLY.]**

- D2000 - 42 C.F.R. § 493.801 Condition: Enrollment and testing of [proficiency testing] samples;
- D2016 - 42 C.F.R. § 493.803 Condition: Successful participation [proficiency testing]
- D3000 - 42 C.F.R. § 493.1101 Condition: Facility Administration
- D5002 - 42 C.F.R. § 493.1201 Condition: Bacteriology ;
- D5004 - 42 C.F.R. § 493.1202 Condition: Mycobacteriology;
- D5006 - 42 C.F.R. § 493.1203 Condition: Mycology;
- D5008 - 42 C.F.R. § 493.1204 Condition: Parasitology;
- D5010 - 42 C.F.R. § 493.1205 Condition: Virology;
- D5012 - 42 C.F.R. § 493.1207 Condition: Syphilis serology;
- D5014 - 42 C.F.R. § 493.1208 Condition: General immunology;
- D5016 - 42 C.F.R. § 493.1210 Condition: Routine chemistry;
- D5018 - 42 C.F.R. § 493.1211 Condition: Urinalysis;
- D5020 - 42 C.F.R. § 493.1212 Condition: Endocrinology;
- D5022 - 42 C.F.R. § 493.1213 Condition: Toxicology;
- D5024 - 42 C.F.R. § 493.1215 Condition: Hematology;
- D5026 - 42 C.F.R. § 493.1217 Condition: Immunohematology;
- D5028 - 42 C.F.R. § 493.1219 Condition: Histopathology;
- D5030 - 42 C.F.R. § 493.1220 Condition: Oral pathology;
- D5032 - 42 C.F.R. § 493.1221 Condition: Cytology;
- D5034 - 42 C.F.R. § 493.1225 Condition: Clinical cytogenetics;
- D5040 - 42 C.F.R. § 493.1226 Condition: Radiobioassay;
- D5042 - 42 C.F.R. § 493.1227 Condition: Histocompatibility;
- D5200 - 42 C.F.R. § 493.1230 Condition: General laboratory systems;
- D5300 - 42 C.F.R. § 493.1240 Condition: Preanalytic systems;

- D5400 - 42 C.F.R. § 493.1250 Condition: Analytic systems;
- D5800 - 42 C.F.R. § 493.1290 Condition: Postanalytic systems;
- D5980 - 42 C.F.R. § 493.1355 Condition: Laboratories performing PPM procedures;
laboratory director;
- D5990 - 42 C.F.R. § 493.1355 Condition: Laboratories performing PPM procedures;
testing personnel;
- D6000 - 42 C.F.R. § 493.1403 Condition: Laboratories performing moderate complexity
testing; laboratory director;
- D6033 - 42 C.F.R. § 493.1409 Condition: Laboratories performing moderate complexity
testing; technical consultant;
- D6056 - 42 C.F.R. § 493.1415 Condition: Laboratories performing moderate complexity
testing; clinical consultant;
- D6063 - 42 C.F.R. § 493.1421 Condition: Laboratories performing moderate complexity
testing; testing personnel;
- D6076 - 42 C.F.R. § 493.1441 Condition: Laboratories performing high complexity testing;
laboratory director;
- D6108 - 42 C.F.R. § 493.1447 Condition: Laboratories performing high complexity testing;
technical supervisor;
- D6134 - 42 C.F.R. § 493.1453 Condition: Laboratories performing high complexity testing;
clinical consultant;
- D6141 - 42 C.F.R. § 493.1459 Condition: Laboratories performing high complexity testing;
general supervisor;
- D6153 - 42 C.F.R. § 493.1467 Condition: Laboratories performing high complexity testing;
cytology general supervisor
- D6162 - 42 C.F.R. § 493.1481 Condition: Laboratories performing high complexity testing;
cytotechnologist;
- D6168 - 42 C.F.R. § 493.1487 Condition: Laboratories performing high complexity testing;
testing personnel;
- D8100 - 42 C.F.R. § 493.1771 Condition: Inspection requirements applicable to all CLIA-
certified and CLIA-exempt laboratories.

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

The CLIA regulations at 42 C.F.R. § 493.2 defines unsuccessful PT performance as failure to attain the minimum satisfactory score for an analyte, test, subspecialty or specialty for two consecutive or two out of three consecutive testing events. Based on the survey findings, your laboratory is not in compliance with the Condition of successful participation in proficiency testing (PT) based on unsatisfactory performance in proficiency testing (PT) for the events listed below:

<u>PT Provider</u>	<u>Testing Event</u>	<u>Analyte/specialty/subspecialty</u>	<u>Score</u>
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[LIST UNSATISFACTORY EVENTS]

[USE THE FOLLOWING FOR BOTH OPTIONS:

Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program. You must take steps to bring any unmet Conditions into compliance immediately.

You are directed to submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited. Please document your allegation of compliance using the enclosed CMS-2567, Statement of Deficiencies, in the columns labeled "Provider Plan of Correction" and "Completion Date" located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed CMS-2567 documented with a credible allegation of compliance to our office WITHIN 10 DAYS FROM RECEIPT of this notice. You must also submit documented evidence that verifies that the corrections were made. We may conduct a follow-up onsite survey in approximately 30-45 days to verify the corrections if we find your allegation of compliance to be credible and the submitted evidence to be acceptable. If your laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey. (Your allegation of compliance will be included in the public record of the inspection.)

A credible allegation of compliance is a statement or documentation that is:

- 1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
- 2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
- 3) Indicates resolution of the problems.

For your information, acceptable evidence of correction must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- 3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

CLIA regulations at 42 C.F.R. § 493.1838 allow a laboratory at the first occurrence of unsuccessful PT performance to undertake training of its personnel, or obtain necessary technical assistance, or both, if appropriate to the circumstances. If your laboratory determines that training/technical assistance is the appropriate corrective action, evidence must be submitted to document that the training and/or technical assistance have been undertaken and were effective in correcting the problems that caused the unsuccessful PT performance. In particular, the evidence must include documentation that your laboratory has taken action to correct actual or

potential patient outcome during the period of PT failure. See the requirements for acceptable evidence of correction above.

If you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be still out of compliance with any CLIA Condition-level requirements at the time of the follow-up visit, the [STATE AGENCY NAME] will recommend to the [RO NAME] Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. These may include alternative sanctions (Civil Money Penalty of up to \$3,000 per day of noncompliance or per violation per 42 C.F.R. § 493.1834, Directed Plan of Correction per 42 C.F.R. § 493.1832, State Onsite Monitoring per 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of your laboratory's CLIA certificate and cancellation of you laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/surveys may be conducted by the [STATE AGENCY NAME] at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have questions regarding this letter, please contact me at [PHONE #].

Sincerely,

[NAME, TITLE]
[STATE AGENCY NAME]

Enclosure: CMS-2567, Statement of Deficiencies

01 RO (4/20/07) – Terminate CLIA certificate – failed to meet state requirements

IMPORTANT NOTICE – PLEASE READ CAREFULLY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA number: [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: TERMINATION OF CLIA NUMBER – CEASE ALL PATIENT LABORATORY TESTING IMMEDIATELY

Dear Director and Owner(s):

CLIA records show that the above CLIA number was issued to [LABORATORY NAME] effective [DATE] based on a signed application dated [DATE]. We have determined this CLIA number was issued to [LABORATORY NAME] in error as it has failed to meet all necessary requirements.

CLIA regulations at 42 C.F.R. § 493.1101(c) require that a laboratory be in compliance with applicable Federal, State and local laboratory requirements. [NAME OF STATE] law requires that in order to legally perform any testing on [NAME OF STATE] patient specimens, a laboratory must be licensed under the State's laboratory licensure program.

Medicare records indicate that your laboratory is performing and billing for patient testing. We have also been informed by the State Agency Name that [LABORATORY NAME] is not licensed in [NAME OF STATE] to perform patient testing.

Accordingly, CMS is taking action to terminate your laboratory's CLIA certification. [LABORATORY NAME] is directed to cease all patient laboratory testing immediately. You are also directed to return to the [NAME] Regional Office at the address below the CLIA certificate that was issued erroneously for the period [BEGIN DATE TO END DATE OF CLIA CERTIFICATE].

In order to resume testing, your laboratory must reapply for a CLIA certificate when it can show evidence that it has met the necessary State licensure requirements. Your lab must pay the appropriate CLIA fees and be surveyed for compliance with all CLIA requirements prior to resuming patient testing.

You are advised that under 42 U.S.C. § 263a(l), any person who intentionally violates the requirements of CLIA or its regulations shall be imprisoned or fined, or both.

If you have any questions regarding this letter, please contact **[STAFF NAME]** of my staff at **[PHONE NUMBER]**.

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

cc: **[STATE AGENCY NAME]**

02 RO (4/20/07) – Terminate CLIA certificate – lab not operational

IMPORTANT NOTICE – PLEASE READ CAREFULLY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile
constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA number: [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: TERMINATION OF CLIA NUMBER – LABORATORY NOT OPERATIONAL

Dear Director and Owner(s):

CLIA records show that the above CLIA number was issued to [LABORATORY NAME] effective [DATE] for the period [BEGIN DATE TO END DATE OF CLIA CERTIFICATE].

We have received information that [LABORATORY NAME] is no longer operating in the location at [ADDRESS OF LABORATORY]. We called the telephone number of record and were advised that it was not the number for [LABORATORY NAME]. Our records do not indicate that your laboratory has reported a change of address.

As evidence indicates that your laboratory is no longer operational, this letter serves as advance notice that we will take action on [DATE OF THIS NOTICE + 10 DAYS] to terminate [LABORATORY NAME]'s CLIA certificate. If we do not hear from you by then, we will terminate your laboratory's CLIA certificate effective [DATE], the date we were informed that the laboratory vacated the above location. You are also directed to return to the [NAME OF RO] Regional Office, at the address below, the CLIA certificate of [CERTIFICATE TYPE] that was issued for the period [BEGIN DATE TO END DATE OF CLIA CERTIFICATE].

Once your laboratory's CLIA certificate is terminated, your laboratory may no longer perform CLIA laboratory testing, including waived and provider performed microscopy testing. Please be advised that no person may perform laboratory examinations or other procedures on materials derived from the human body unless there is **in effect** a certificate issued by the Secretary of the Health and Human Services applicable to the category of examinations or procedures which includes such examination or procedure. See 42 U.S.C. § 263a(b). Please also be advised that any person who intentionally violates the mandates of CLIA shall be subject to imprisonment, or fines, or both. See 42 U.S.C. § 263(a)(l).

If you have any questions regarding this letter, please contact **[STAFF NAME]** of my staff at **[PHONE NUMBER]**.

Sincerely,

[NAME/TITLE]

[BRANCH NAME]

[DIVISION NAME]

cc: **[STATE AGENCY NAME]**

03 RO (4/20/07) – Denial of CLIA Application – gives appeal rights of reconsideration for prospective laboratory

IMPORTANT NOTICE – PLEASE READ CAREFULLY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA number: [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: DENIAL OF APPLICATION FOR CLIA CERTIFICATION

Dear Director and Owner(s):

Our agent at the [STATE AGENCY NAME] (State agency) has referred your application for CLIA certification to our office with recommendations to deny the application. **[STATE REASON FOR DENIAL. EXAMPLES:**

The owner, operator or director previously owned, operated or directed another laboratory which was revoked within the last two years.

The director does not meet the qualification requirements as specified in the CLIA regulations at 42 C.F.R. § 493._____ for **[CHOOSE ONE: moderate, high]** complexity testing.

The laboratory has not met the prerequisite state licensure requirements for the state of _____.

The owner, operator or director has a prior history of non-compliance. **[Give details.]**

Your laboratory is located in the same location as **[NAME OF REVOKED LABORATORY]**, a laboratory whose CLIA certificate CMS revoked effective **[REVOCATION DATE]** Evidence submitted indicates that this was a change of ownership for the revoked laboratory.

We have reviewed the case and agree with the State agency's recommendation to deny your CLIA application. **[ADD THE FOLOWING FOR THE LAST EXAMPLE:** CLIA policy dictates that when a change of ownership occurs, the existing CLIA number should be assigned automatically to the new owner. In this instance, **[NAME OF APPLICANT LABORATORY]** must assume **[NAME OF REVOKED LABORATORY]**'s CLIA number. However, as **[NAME OF REVOKED LABORATORY]**'s CLIA certificate has been revoked, **[NAME OF APPLICANT LABORATORY]** would not be able to operate under a CLIA number that has been revoked. We are therefore denying your application for a CLIA certificate.

[GIVE APPEAL RIGHTS FOR PROSPECTIVE LABORATORY AS FOLLOWS:]

If you do not believe this determination to deny your application for a CLIA certificate is correct, you may request a reconsideration with CMS in accordance with 42 Code of Federal Regulations § 498.22. A written request for reconsideration must be filed no later than sixty days after the date this letter is received. The date of receipt will be presumed to be 5 days after the date of this notice unless there is showing that it was, in fact, received earlier or later. Such a request may be made to:

[NAME OF RO MANAGER]
[NAME OF BRANCH]
[NAME OF DIVISION OF DIVISION]
Centers for Medicare & Medicaid Services
[STREET ADDRESS]
[CITY, STATE ZIP]

The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reason for disagreement. You may submit any written evidence and statements that are relevant and material to the matters at issue.

If you have any questions regarding this letter, please contact **[STAFF NAME]** of my staff at **[PHONE NUMBER]**.

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

cc: **[STATE AGENCY NAME]**

04 RO (4/20/07) – Loss of Accreditation – notifies lab of CLIA certificate status

IMPORTANT NOTICE – PLEASE READ CAREFULLY

[TODAY’S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA number: [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: LOSS OF ACCREDITATION FROM [NAME OF AO]

Dear Director and Owner(s):

The [NAME OF AO] has advised us by letter dated [AO NOTICE DATE] that it has made the determination to [CHOOSE ONE: deny, revoke, withdraw] accreditation for [NAME OF LABORATORY] effective [LOSS OF ACCREDITATION DATE]. [NAME OF AO]’s decision to [CHOOSE ONE: deny, revoke, withdraw] the laboratory’s accreditation was based on [GIVE REASONS].

Laboratories with a CLIA certificate of accreditation, such as [NAME OF LABORATORY], must be accredited by a CMS approved accrediting organization for all laboratory services provided. As a result of the loss of accreditation from [NAME OF AO], [NAME OF LABORATORY] is no longer deemed to meet the CLIA requirements. In addition, the CLIA certificate of accreditation issued to the laboratory for the period [BEGIN DATE TO END DATE OF CERTIFICATE] is no longer applicable.

CLIA regulations at 42 C.F.R. § 493.551(c) permit the laboratory to retain its certificate of accreditation for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by the Centers for Medicare & Medicaid Services (CMS), whichever is earlier. Accordingly, your laboratory may retain its certificate of accreditation until no later than 45 days after [LOSS OF ACCREDITATION DATE], or until [LOSS OF ACCREDITATION DATE + 45 CALENDAR DAYS].

Your laboratory is reminded that no person may perform laboratory examinations or other procedures on materials derived from the human body unless there is **in effect** a certificate issued by the Secretary of the Health and Human Services applicable to the category of examinations or procedures which includes such examination or procedure. (See 42 U.S.C. § 263a (b)). Any person who intentionally violates CLIA requirements is subject to sanctions, including imprisonment, fines, or both. (42 U.S.C. § 263(a)(I)).

Based on the history of non-compliance with [NAME OF AO], it is necessary for our agents at the [STATE AGENCY NAME] to conduct a survey of [NAME OF LABORATORY] to determine whether your laboratory is in compliance with all CLIA requirements. To facilitate the

process and avoid any gap in certification, we recommend your laboratory apply for a certificate of compliance and remit the applicable CLIA fees as soon as possible. To apply for a CLIA certificate of compliance, please contact the State agency at:

**[STATE AGENCY NAME
SA ADDRESS
SA PHONE NUMBER]**

If compliance cannot be determined or an application for a CLIA certificate of compliance is not received by **[LOSS OF ACCREDITATION DATE + 45 CALENDAR DAYS]**, we may take action to suspend and/or revoke your laboratory's CLIA certificate of accreditation and, if applicable, cancel Medicare payment for tests performed. (42 C.F.R. § 493.61(c)). **[ADD THIS SENTENCE IF A HOSPITAL LABORATORY: If the laboratory's CLIA certificate is revoked, [NAME OF HOSPITAL]'s eligibility to participate in the Medicare program as a provider of hospital services may also be affected since the Condition of Participation related to Laboratory Services at 42 C.F.R. § 482.27 will no longer be met.]** Should this action be necessary, we will notify you at the time of action and provide your laboratory with an explanation of your appeal rights.

If you have any questions regarding this letter, please contact **[STAFF NAME]** of my staff at **[PHONE NUMBER]**.

Sincerely,

**[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]**

cc: **[HOSPITAL ADMINISTRATIVE, IF APPLICABLE]**

[NAME OF AO]

[STATE AGENCY NAME]

[CMS CO]

05 RO (4/20/07) – Testing Without a Valid CLIA Certificate – notice to cease/desist from testing

IMPORTANT NOTICE – PLEASE READ CAREFULLY

[TODAY’S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA number: NONE

RE: TESTING WITHOUT A CLIA CERTIFICATE

Dear [NAME]:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and in Title 42 Code of Federal Regulations, Part 493 (42 C.F.R. Part 493). Compliance with these regulations is a condition of certification for the CLIA program.

It has come to our attention that you have been performing laboratory testing without a valid CLIA certificate.

Please be advised that no person may perform laboratory examinations or other procedures on materials derived from the human body unless there is **in effect** a certificate issued by the Secretary of the Health and Human Services applicable to the category of examinations or procedures which includes such examination or procedure. See 42 U.S.C. § 263a(b). It is illegal for any facility to perform patient testing, including waived and provider performed microscopy testing, without appropriate CLIA certification. Please be advised that any person who intentionally violates the mandates of CLIA shall be subject to imprisonment, or fines, or both. See 42 U.S.C. § 263(a)(l).

You are hereby directed to cease all patient laboratory testing including waived and provider performed microscopy testing. In order to resume testing, you must first apply for and be issued a valid CLIA certificate. To apply for CLIA certification, please contact our agents at

[STATE AGENCY NAME
SA ADDRESS
SA PHONE NUMBER]

If you have any questions regarding this letter, please contact **[STAFF NAME]** of my staff at **[PHONE NUMBER]**.

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

cc: **[STATE AGENCY NAME]**

06 RO (4/20/07) – LBA Cease & Desist Letter – RO notifies facility to cease LBA testing till CLIA certified

IMPORTANT NOTICE – ACTION NECESSARY

[TODAY'S DATE] Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[NAME] CLIA number: NONE
[ADDRESS]
[CITY], [STATE] [ZIP]

RE: TESTING WITHOUT A CLIA CERTIFICATE

Dear [NAME]:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and in Title 42 Code of Federal Regulations, Part 493 (42 C.F.R. Part 493). Compliance with these regulations is a condition of certification for the CLIA program.

It has come to our attention that your facility is performing [**CHOOSE ONE:** the laboratory test “Live Blood Cell Analysis” **OR** an “Unestablished Laboratory Test”] without a CLIA certificate.

CLIA defines a laboratory as:

A facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of health of, human beings. These examinations also include procedures to determine measure or otherwise describe the presence or absence of various substances or organisms in the body.

You are performing laboratory testing as defined by CLIA without the appropriate CLIA certification. You are, therefore, in violation of CLIA and are performing laboratory testing illegally.

Please be advised that no person may perform laboratory examinations or other procedures on materials derived from the human body unless there is in effect a certificate issued by the Secretary applicable to the category of examinations or procedures which includes such examination or procedure. See 42 U.S.C. § 263a(b). Therefore, **YOU ARE REQUIRED TO CEASE ALL CLIA LABORATORY TESTING IMMEDIATELY.** See 42 U.S.C. § 263a(l). Please be advised that any person who intentionally violates this mandate of CLIA shall be subject to imprisonment, or fines, or both. See 42 U.S.C. § 263a(l).

[**CHOOSE ONE:** Live Blood Cell Analysis **OR** The Unestablished Laboratory Test is categorized by default as a high complexity laboratory test. 42 C.F.R. 493 Subpart C identifies the requirements for applying for and receiving a CLIA certificate of compliance. Please pay particular attention to 42 C.F.R. § 493.43(c) for application requirements. If you elect to apply for CLIA certification, a CLIA application may be obtained from:

[**STATE AGENCY NAME**
SA ADDRESS
SA PHONE NUMBER]

Unless an application is received and approved, and a CLIA registration certificate is issued to your facility, you may not perform any laboratory testing. We reiterate that it is illegal for you to perform any laboratory testing as you are not CLIA certified.

If you elect to permanently cease all patient laboratory testing, **we are enclosing an attestation for your completion and signature.** Please complete, sign and return by [**DATE OF NOTICE + 10 CALENDAR DAYS**] to this office at:

Centers for Medicare & Medicaid Services
CLIA Program
[**RO ADDRESS**]
Attention: [**STAFF NAME**]

If we do not receive a notarized copy of the enclosed attestation or you fail to cease all laboratory testing and fail to obtain appropriate CLIA certification, pursuant to 42 C.F.R. § 493.1840(a)(2) and § 493.1840(a)(6), we will refer your case to the United States Department of Health and Human Services' Office of Inspector General for investigation and criminal prosecution. In the future, if you are found to be in violation of CLIA, you may be subject to civil money penalties of up to \$3,000 per day of violation.

If you have any questions regarding this letter, please contact [**STAFF NAME**] of my staff at [**PHONE NUMBER**].

Sincerely,

[**NAME/TITLE**]
[**BRANCH NAME**]
[**DIVISION NAME**]

Enclosure: Attestation of Cease Testing

cc: [**STATE AGENCY NAME**]

Centers for Medicare & Medicaid Services

CLIA Program

ATTESTATION OF CEASE TESTING

By means of my signature on this attestation, I, [NAME], located at [ADDRESS], am attesting to the fact that I have been notified by letter dated [NOTICE DATE] that since I do not possess a valid CLIA certificate, it is illegal for me to perform any laboratory testing including Live Blood Cell Analysis whether or not any fees are charged for the tests. I understand that **any person who intentionally violates this mandate of CLIA shall be subject to imprisonment, or fines, or both.** See 42 U.S.C. § 263a(l).

I am also attesting that all laboratory testing which includes microscopic examination of human specimens ([CHOOSE ONE: Live Blood Cell Analysis OR Unestablished Laboratory Test]) has ceased as of the date of _____. **I understand that if I am found to be in violation of the above CLIA statute, I may be subject to a civil money penalty of up to \$3,000 per day of violation.**

I understand that under section 353 of the Public Health Service Act, I may face imprisonment or fines if convicted of intentionally violating CLIA requirements by conducting testing without a valid CLIA certificate.

Signature

Date

Name

Name of Facility

Address

City, State, Zip

Contact Telephone Number

NOTARIZATION REQUIRED

07 RO (4/20/07) – Federal Survey – standards out - POC request

IMPORTANT NOTICE – ACTION NECESSARY

[**TODAY'S DATE**]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[**DIRECTOR NAME**], M.D., Director

[**OWNER NAME**], Owner(s)

[**LAB NAME**]

CLIA number: [**CLIA NUMBER**]

[**ADDRESS**]

[**CITY**], [**STATE**] [**ZIP**]

RE: STANDARD-LEVEL DEFICIENCIES

Dear Director and Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

A representative from the Centers for Medicare & Medicaid Services (CMS), [**RO NAME**] Regional Office conducted a [**CHOOSE SURVEY TYPE**: an initial, a routine recertification, a complaint] survey of your laboratory that was completed on [**SURVEY DATE**]. Enclosed is form CMS-2567, Statement of Deficiencies, listing the deficiencies found during the survey. The deficiency statement references the CLIA regulations at 42 C.F.R. § 493.

You are required to respond within 10 days of receipt of this notice. Please indicate your corrective actions on the right side of the form CMS-2567 in the column labeled "Provider Plan of Correction", keying your responses to the deficiencies on the left. Additionally, indicate your anticipated completion dates in the column labeled "Completion Date."

Please return the completed form CMS-2567, dated and signed by the director, within 10 days of receipt of this notice.

Regulations at 42 C.F.R. § 493.1816 state that if a laboratory has deficiencies that are not at the Condition level, the laboratory must submit a plan of correction that is acceptable to CMS in content and time frames. Further, regulations at 42 C.F.R. § 493.1816 require all deficiencies to be corrected within 12 months after the last day of the survey. Please note that depending on the nature and seriousness of the deficiency, the acceptable time frame for correction may be less than 12 months.

If your laboratory does not respond timely to this request, or if your laboratory submits a Plan of Correction that is not acceptable in content and time frames, or if your laboratory does not

demonstrate compliance with all CLIA requirements by the specified completion date, we will impose principal sanctions, i.e., suspension, limitation and/or revocation of your laboratory's CLIA certificate and concurrent cancellation of your laboratory's approval for Medicare payments per 42 C.F.R. § 493.1816.

Your laboratory will also be required to provide acceptable evidence of correction for the cited deficiencies. For your information, acceptable evidence of correction must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- 3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/surveys may be conducted by CMS or its agent at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have any questions regarding this letter, please contact **[STAFF NAME]** of my staff at **[PHONE NUMBER]**.

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

Enclosure: CMS-2567, Statement of Deficiencies

IMPORTANT NOTICE – ACTION NECESSARY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA number: [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: CONDITION-LEVEL DEFICIENCIES

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

A representative from the Centers for Medicare & Medicaid Services (CMS), [RO NAME] Regional Office conducted a [CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint] survey of your laboratory that was completed on [SURVEY DATE]. As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. Specifically, the following Conditions were not met: [DELETE CONDITIONS THAT DO NOT APPLY.]

- D2000 - 42 C.F.R. § 493.801 Condition: Enrollment and testing of [proficiency testing] samples;
- D2016 - 42 C.F.R. § 493.803 Condition: Successful participation [proficiency testing]
- D3000 - 42 C.F.R. § 493.1101 Condition: Facility Administration
- D5002 - 42 C.F.R. § 493.1201 Condition: Bacteriology ;
- D5004 - 42 C.F.R. § 493.1202 Condition: Mycobacteriology;
- D5006 - 42 C.F.R. § 493.1203 Condition: Mycology;
- D5008 - 42 C.F.R. § 493.1204 Condition: Parasitology;
- D5010 - 42 C.F.R. § 493.1205 Condition: Virology;
- D5012 - 42 C.F.R. § 493.1207 Condition: Syphilis serology;
- D5014 - 42 C.F.R. § 493.1208 Condition: General immunology;
- D5016 - 42 C.F.R. § 493.1210 Condition: Routine chemistry;
- D5018 - 42 C.F.R. § 493.1211 Condition: Urinalysis;
- D5020 - 42 C.F.R. § 493.1212 Condition: Endocrinology;
- D5022 - 42 C.F.R. § 493.1213 Condition: Toxicology;
- D5024 - 42 C.F.R. § 493.1215 Condition: Hematology;

- D5026 - 42 C.F.R. § 493.1217 Condition: Immunohematology;
- D5028 - 42 C.F.R. § 493.1219 Condition: Histopathology;
- D5030 - 42 C.F.R. § 493.1220 Condition: Oral pathology;
- D5032 - 42 C.F.R. § 493.1221 Condition: Cytology;
- D5034 - 42 C.F.R. § 493.1225 Condition: Clinical cytogenetics;
- D5040 - 42 C.F.R. § 493.1226 Condition: Radiobioassay;
- D5042 - 42 C.F.R. § 493.1227 Condition: Histocompatibility;
- D5200 - 42 C.F.R. § 493.1230 Condition: General laboratory systems;
- D5300 - 42 C.F.R. § 493.1240 Condition: Preanalytic systems;
- D5400 - 42 C.F.R. § 493.1250 Condition: Analytic systems;
- D5800 - 42 C.F.R. § 493.1290 Condition: Postanalytic systems;
- D5980 - 42 C.F.R. § 493.1355 Condition: Laboratories performing PPM procedures;
laboratory director;
- D5990 - 42 C.F.R. § 493.1355 Condition: Laboratories performing PPM procedures;
testing personnel;
- D6000 - 42 C.F.R. § 493.1403 Condition: Laboratories performing moderate complexity
testing; laboratory director;
- D6033 - 42 C.F.R. § 493.1409 Condition: Laboratories performing moderate complexity
testing; technical consultant;
- D6056 - 42 C.F.R. § 493.1415 Condition: Laboratories performing moderate complexity
testing; clinical consultant;
- D6063 - 42 C.F.R. § 493.1421 Condition: Laboratories performing moderate complexity
testing; testing personnel;
- D6076 - 42 C.F.R. § 493.1441 Condition: Laboratories performing high complexity testing;
laboratory director;
- D6108 - 42 C.F.R. § 493.1447 Condition: Laboratories performing high complexity testing;
technical supervisor;
- D6134 - 42 C.F.R. § 493.1453 Condition: Laboratories performing high complexity testing;
clinical consultant;
- D6141 - 42 C.F.R. § 493.1459 Condition: Laboratories performing high complexity testing;
general supervisor;
- D6153 - 42 C.F.R. § 493.1467 Condition: Laboratories performing high complexity testing;
cytology general supervisor
- D6162 - 42 C.F.R. § 493.1481 Condition: Laboratories performing high complexity testing;
cytotechnologist;
- D6168 - 42 C.F.R. § 493.1487 Condition: Laboratories performing high complexity testing;
testing personnel;
- D8100 - 42 C.F.R. § 493.1771 Condition: Inspection requirements applicable to all CLIA-
certified and CLIA-exempt laboratories.

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program. You must take steps to bring any unmet Conditions into compliance immediately.

You are directed to submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited. Please document your allegation of compliance using the

enclosed CMS-2567, Statement of Deficiencies, in the columns labeled “Provider Plan of Correction” and “Completion Date” located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed CMS-2567 documented with a credible allegation of compliance to our office WITHIN 10 DAYS FROM RECEIPT of this notice. You must also submit documented evidence that verifies that the corrections were made. We may conduct a follow-up onsite survey in approximately 30-45 days to verify the corrections if we find your allegation of compliance to be credible and the submitted evidence to be acceptable. If your laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey. (Your allegation of compliance will be included in the public record of the inspection.)

A credible allegation of compliance is a statement or documentation that is:

- 1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
- 2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
- 3) Indicates resolution of the problems.

For your information, acceptable evidence of correction must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- 3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be still out of compliance with any CLIA Condition-level requirements at the time of the follow-up visit, we will impose. These may include alternative sanctions (Civil Money Penalty of up to \$3,000 per day of noncompliance per 42 C.F.R. § 493.1834, Directed Plan of Correction per 42 C.F.R. § 493.1832, State Onsite Monitoring per 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of your laboratory's CLIA certificate and cancellation of you laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the

laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/surveys may be conducted by CMS or its agent at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have any questions regarding this letter, please contact **[STAFF NAME]** of my staff at **[PHONE NUMBER]**.

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

Enclosure: CMS-2567, Statement of Deficiencies

09A RO (4/20/07) – Sanction proposal – standards out – POC unacceptable, SA referred to RO for sanction

IMPORTANT NOTICE – PLEASE READ CAREFULLY

[**TODAY'S DATE**] Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[**DIRECTOR NAME**], M.D., Director

[**OWNER NAME**], Owner(s)

[**LAB NAME**]

CLIA number: [**CLIA NUMBER**]

[**ADDRESS**]

[**CITY**], [**State**] [**ZIP**]

RE: PROPOSED SANCTIONS – STANDARDS NOT MET

IMPOSITION NOTICE TO FOLLOW IF PROPOSED SANCTIONS ARE IMPOSED

Dear Director and Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The [**STATE AGENCY NAME**] (State agency) conducted [**CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint**] survey of your laboratory that was completed on [**SURVEY DATE**]. Based on this survey, [**NAME OF LABORATORY**] was found to be out of compliance with [**NUMBER**] CLIA standards. The State agency provided the laboratory a listing of all deficiencies identified during the survey on Form CMS-2567, Statement of Deficiencies, sent as an enclosure to its [**DATE OF SA LETTER**] letter.

In its [**DATE OF SA LETTER**] letter, the State agency notified the laboratory to take action to correct the cited deficiencies. The State agency gave the laboratory ten days from the date of the [**DATE OF SA LETTER**] letter to submit a plan of correction and supporting evidence to document compliance with all CLIA requirements. Your laboratory submitted a plan of correction dated [**DATE OF SUBMISSION**].

The State agency reviewed the [**DATE OF SUBMISSION**] submission and determined that it did not constitute an acceptable plan of correction. The State agency notified your laboratory of this determination by its letter dated [**DATE OF SA POC REVIEW LETTER**] and gave your laboratory another opportunity to submit an amended plan of correction and additional evidence of correction. Your laboratory sent in a second submission on [**DATE OF SECOND SUBMISSION**] which the State agency reviewed and again determined to be not acceptable. The State agency notified your laboratory by letter dated [**DATE OF SA WARNING**]

LETTER] that it was referring the case to the CMS Regional Office with recommendations to not recertify **[NAME OF LABORATORY]** into the CLIA program. We have reviewed the case and concur with the State agency in its findings and recommendations.

Proposed Sanctions

Accordingly, pursuant to 42 C.F.R. §§ 493.1806 and 493.1840(a)(3), based on the laboratory's non-compliance with CLIA standard-level requirements and based on the failure by the owner(s) and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the **[DATE OF SURVEY]** survey, we are taking action to impose the following sanctions against **[NAME OF LABORATORY]**'s CLIA certificate:

- 42 U.S.C. § 263a(i)(3), 42 C.F.R. §§ 493.1806, 493.1840(a)(3) and 493.1840(e) – Principal Sanction: **Revocation** of the laboratory's CLIA certificate. If imposed, the laboratory has 60 days to appeal the determination to revoke the laboratory's CLIA certificate. If a timely hearing request is received, revocation of the laboratory's CLIA certificate will become effective following the administrative hearing decision, if our determination of non-compliance is upheld.
- 42 C.F.R. §§ 493.1807(a), 493.1808(a), 493.1842 and 493.1844(d)(3) – Principal Sanction: **Cancellation of the laboratory's approval to receive Medicare payments** for any laboratory services performed on or after **[DATE OF NOTICE + 15 CALENDAR DAYS]**. If imposed, this sanction will be effectuated even if the laboratory files a timely appeal.

Moreover, in accordance with Section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), if the sanction of cancellation of the laboratory's approval to receive Medicare payments is imposed, payment under the Medicaid program, Title XIX of the Social Security Act, will no longer be available to the laboratory for any laboratory services performed on or after **[DATE OF NOTICE + 15 CALENDAR DAYS]**. See 42 C.F.R. § 440.2(b).

The laboratory is advised that the above sanctions cannot be avoided by the closure, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

[USE THE FOLLOWING PARAGRAPH IF APPLICABLE:

As the current certificate of **[NAME OF LABORATORY]**'s CLIA certificate expired on **[EXPIRATION DATE]**, we will administratively extend the laboratory's CLIA certificate solely for the purpose of finalizing the current sanction action. The laboratory's CLIA certificate cannot be renewed for Medicare and Medicaid purposes as the laboratory has not shown itself to be in compliance with CLIA requirements. (Compliance with all CLIA requirements and CLIA certification is a requirement for Medicare and Medicaid payments.)]

If the laboratory's CLIA certificate is revoked, 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) prohibit the owner(s) or operator(s) (including director – see 42 C.F.R. § 493.2) from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. This prohibition applies to the owner(s) as well as the director at the time that the deficiencies were found which led to the current sanction actions. If the sanctions become

effective as referenced above, in accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the actions against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year in which the actions are imposed. In addition, pursuant to 42 C.F.R. § 493.1844(g)(1), we will notify the general public by means of a notice published in a local newspaper, if the above sanctions are imposed.

You have ten days from the date of this notice, or until [DATE OF NOTICE + 10 CALENDAR DAYS], to submit in writing any evidence or information as to why the sanctions detailed above should not be imposed. If we do not receive a timely submission or if we determine that the submission is unpersuasive, we will notify you in writing that we will proceed to impose the above-referenced sanctions. We will provide you with the laboratory's appeal rights at that time.

Instructions for sending in Your Response

Your laboratory's response should be sent to:

[NAME OF RO MANAGER]
[NAME OF BRANCH]
[NAME OF DIVISION]
Centers for Medicare & Medicaid Services
[STREET ADDRESS]
[CITY, STATE ZIP]

A copy of any response the laboratory makes should also be sent to the State agency at the following address:

[STATE AGENCY NAME AND ADDRESS]
Attention: [STAFF NAME]

If you have any questions regarding this letter, please contact [STAFF NAME] of my staff at [PHONE NUMBER].

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

cc: [Director name] Via certified mail, return receipt # _____
[Address other than lab address]
[City, State, Zip]

[State Agency Name]

09B RO (4/20/07) – Sanction proposal – standards out – POC unacceptable, SA referred to RO for sanction

IMPORTANT NOTICE – PLEASE READ CAREFULLY

[DATE]

[NAME OF LABORATORY]

CLIA number: **[CLIA NUMBER]**

Attn: **[NAME]**

[ADDRESS]

Dear **[NAME]**:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, and bill for services provided to Medicare beneficiaries or Medicaid recipients under Titles XVIII and XIX of the Social Security Act, it must comply with all CLIA Requirements [42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493)].

The **[NAME OF STATE AGENCY]** (state agency) conducted **[CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint]** survey of **[NAME OF LABORATORY]** on **[DATE]**. The state agency requested a plan of correction on **[DATE]**. The plan of correction was received by the state agency on **[DATE]** and was determined unacceptable. Since that time, the state agency had made several attempts at obtaining an acceptable plan of correction. The following is a summary of those attempts:

[PROVIDE DETAILS]

If a laboratory fails to submit an acceptable plan of correction, and subsequent requests for an acceptable plan of correction are unsuccessful, the Centers for Medicare & Medicaid Services (CMS) may cancel the laboratory's approval to receive Medicare payment for its services in accordance with 42 C.F.R. § 493.1842(a)(2)(ii). In addition, CMS may consider the laboratory's failure to comply with reasonable requests for information pursuant to 42 C.F.R. § 493.1840(a)(4) and may initiate a principal sanction, i.e., suspension, limitation, or revocation of the CLIA certificate, on the basis of this failure.

Based on the failure of **[NAME OF LABORATORY]** to submit an acceptable plan of correction, CMS will impose the following sanctions:

[EXAMPLE:

- 42 C.F.R. § 493.1842(a)(2)(ii) - **Principal sanction: cancellation of [Name of Laboratory]'s approval to receive Medicare payments for laboratory services effective [DATE].** In addition, under section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), payment under the Medicaid program, Title XIX of the Social Security Act, will no longer be available to your laboratory for any laboratory services performed on or after **[DATE]**. You may submit written evidence or other information against the cancellation of the laboratory's approval to receive Medicare and Medicaid payments in accordance with 42 C.F.R. § 493.1842(b). The information must be received within 10 days of receipt of this notice.

- 42 C.F.R. § 493.1840(d)(2)(ii) - **Principal sanction: suspension of your CLIA certificate, effective [DATE]**. Under suspension, your laboratory may not legally perform patient laboratory testing. Your laboratory will be allowed to remain in operation, and may perform other procedures (i.e., quality control, personnel recruitment, training, proficiency testing, etc.).
- 42 C.F.R. § 493.1840(a)(4) - **Principal sanction: revocation of your CLIA certificate, pending a decision from an Administrative Law Judge, if an appeal is filed**. Under revocation, the laboratory will be required to cease all operations. Also, as required under 42 C.F.R. § 493.1840(a)(8), the present owner(s) and/or operator(s) of the [NAME OF LABORATORY] will be prohibited from owning or operating a laboratory for at least two years from the date of revocation. In accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the revocation of your CLIA certificate, should this sanction be imposed, will appear in the Laboratory Registry for the calendar year of your revocation.]

CMS is required to notify the general public when principal sanctions are imposed. In addition, if the above mentioned sanctions are imposed and your laboratory continues testing, please be informed that under 42 C.F.R. § 493.1806(e) and section 353(l) of the Public Health Service Act, any individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

If you believe this determination is not correct, you may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are set out in regulations at 42 C.F.R. § 493.1844. A written request for hearing must be filed no later than 60 days from the date of receipt of this letter.

You may submit a hearing request directly (accompanied by a copy of this letter) to:

Departmental Appeals Board
 Civil Remedies Division
 Attention: Oliver Potts
 Cohen Building, Room G-644
 330 Independence Ave, SW
 Washington, D.C. 20201

A copy of the hearing request should be sent to:

[NAME OF RO MANAGER]
 [NAME OF BRANCH]
 [NAME OF DIVISION]
 Centers for Medicare & Medicaid Services
 [STREET ADDRESS]
 [CITY, STATE ZIP]

A request for hearing should identify the specific issues, and the findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. You may be represented by counsel at a hearing at your own expense. If no request for a hearing is received by [DATE], your CLIA certificate will be revoked [DATE]. If a hearing is conducted and CMS's determination is upheld, your laboratory may be assessed a fee to cover the government's costs related to the hearing, per 42 C.F.R. § 493.643(d)(2).

Please contact **[NAME]** at **[PHONE/EMAIL]** with any questions concerning this letter.

Sincerely,

[NAME/TITLE]
[OFFICE NAME]

cc: **[LIST ALL CC'S]**

10A RO (4/20/07) – Sanction Proposal – Conditions out – AOC not credible – SA referred to RO for sanction

IMPORTANT NOTICE – ACTION NECESSARY

[TODAY'S DATE] Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of
facsimile constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA number: [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: PROPOSED SANCTIONS – CONDITIONS NOT MET

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The [STATE AGENCY NAME] (State agency) conducted [CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint] survey of your laboratory that was completed on [SURVEY DATE]. Based on this survey, [NAME OF LABORATORY] was found to be out of compliance with [NUMBER] CLIA Conditions:

[LIST CONDITIONS.]

In addition, other standards were also found to be not met. The State agency provided the laboratory a listing of all deficiencies identified during the survey on Form CMS-2567, Statement of Deficiencies, sent as an enclosure to its [DATE OF SA LETTER] letter.

In its [DATE OF SA LETTER] letter, the State agency notified the laboratory to take immediate action to bring any unmet Condition-level requirements into compliance. The State agency gave the laboratory ten days from receipt of the [DATE OF SA LETTER] letter to submit a credible allegation of compliance and acceptable evidence of correction for the cited deficiencies. Your laboratory submitted an allegation of compliance dated [DATE OF SUBMISSION].

The State agency reviewed the [DATE OF SUBMISSION] submission and determined that it did not constitute a credible allegation of compliance and acceptable evidence of correction. The State agency notified your laboratory of this determination by its letter dated [DATE OF SA

AOC REVIEW LETTER] and that it was referring the case to the Regional Office of the Centers for Medicare & Medicaid Services (CMS) with recommendations to not recertify **[NAME OF LABORATORY]** into the CLIA program. We have reviewed the case and concur with the State agency in its findings and recommendations.

Proposed Sanctions

Accordingly, pursuant to 42 C.F.R. §§ 493.1806 and 493.1840(a)(3), based on the laboratory's failure to meet all CLIA Conditions, and based on the failure by the owner(s) and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the **[DATE OF SURVEY]** survey, we are taking action to impose the following sanctions against **[NAME OF LABORATORY]**'s CLIA certificate:

- 42 U.S.C. § 263a(i)(3), 42 C.F.R. §§ 493.1806, 493.1840(a)(3) and 493.1840(e) – Principal Sanction: **Revocation** of the laboratory's CLIA certificate. If imposed, the laboratory has 60 days to appeal the determination to revoke the laboratory's CLIA certificate. If a timely hearing request is received, revocation of the laboratory's CLIA certificate will become effective following the administrative hearing decision, if our determination of non-compliance is upheld.
- 42 C.F.R. §§ 493.1806(c)(3), 493.1810(c)(2)(ii), 493.1810(d) and 493.1834 – Alternative Sanction: **Civil Money Penalty** in the amount of \$3,000 per day for each day of non-compliance effective **[DATE OF NOTICE + 15 CALENDAR DAYS]**. If the laboratory requests a hearing, the civil money penalty amount will not be collected until after the hearing decision is rendered. However, if imposed, the \$3,000/day will begin to accrue on **[DATE OF NOTICE + 15 CALENDAR DAYS]** and will continue to accrue until it can be verified that the laboratory is in compliance with all Condition-level requirements or the laboratory's CLIA certificate is revoked.

In determining the amount of the penalty, CMS has taken into account the following factors: (1) the laboratory was found to be out of compliance with **[NUMBER]** CLIA Condition-level requirements as well as numerous standard-level CLIA requirements at the survey completed on **[SURVEY DATE]**; (2) the laboratory has failed to correct the deficiencies after being provided an opportunity to do so; **[EXAMPLES OF OTHER REASONS:** (3) the laboratory failed to meet the requirement for successful testing of proficiency testing samples; (4) the laboratory failed to establish and verify performance specifications for each testing method prior to testing and reporting patient results; (5) the laboratory director failed to establish and maintain quality control and quality assessment programs to assure the accuracy of patient test results; and (6) the laboratory has expressed no rational reason for its failure to achieve compliance with all applicable Condition-level CLIA requirements.]

- 42 C.F.R. §§ 493.1806(c)(1), 493.1832, 493.1844(d)(1) and 493.1844(g)(1) – Alternative Sanction: **Directed Portion of a Plan of Correction** effective **[DATE OF NOTICE + 15 CALENDAR DAYS]**. If imposed, the laboratory will be directed to submit to this office within ten calendar days from the date of the imposition notice a list of the names and addresses of all physicians and other clients who have used some or all of the laboratory's services since **[DATE OF PRIOR SURVEY OR OTHER DATE AS APPROPRIATE]**.

This list may be used to advise the laboratory's clients of the nature of its non-compliance and the nature and effective date of any sanctions imposed against the laboratory.

- 42 C.F.R. §§ 493.1807(a), 493.1808(a), 493.1842 and 493.1844(d)(3) – Principal Sanction: **Cancellation of the laboratory's approval to receive Medicare payments** for any laboratory services performed on or after **[DATE OF NOTICE + 15 CALENDAR DAYS]**. If imposed, this sanction will be effectuated even if the laboratory files a timely appeal.

Moreover, in accordance with Section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), if the sanction of cancellation of the laboratory's approval to receive Medicare payments is imposed, payment under the Medicaid program, Title XIX of the Social Security Act, will no longer be available to the laboratory for any laboratory services performed on or after **[DATE OF NOTICE + 15 CALENDAR DAYS]**. See 42 C.F.R. § 440.2(b).

The laboratory is advised that the above sanctions cannot be avoided by the closure, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

[USE THE FOLLOWING PARAGRAPH IF APPLICABLE:]

As the current certificate of **[NAME OF LABORATORY]**'s CLIA certificate expired on **[EXPIRATION DATE]**, we will administratively extend the laboratory's CLIA certificate solely for the purpose of finalizing the current sanction action. The laboratory's CLIA certificate cannot be renewed for Medicare and Medicaid purposes as the laboratory has not shown itself to be in compliance with CLIA requirements. (Compliance with all CLIA requirements and CLIA certification is a requirement for Medicare and Medicaid payments.)

If the laboratory's CLIA certificate is revoked, 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) prohibit the owner(s) or operator(s) (including director – see 42 C.F.R. § 493.2) from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. This prohibition applies to the owner(s) as well as the director at the time that the deficiencies were found which led to the current sanction actions.

If the sanctions become effective as referenced above, in accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the actions against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year in which the actions are imposed. In addition, pursuant to 42 C.F.R. § 493.1844(g)(1), we will notify the general public by means of a notice published in a local newspaper, if the above sanctions are imposed.

You have ten days from the date of this notice, or until [DATE OF NOTICE + 10 CALENDAR DAYS], to submit in writing any evidence or information as to why the sanctions detailed above should not be imposed. If we do not receive a timely submission or if we determine that the submission is unpersuasive, we will notify you in writing that we will proceed to impose the above-referenced sanctions. We will provide you with the laboratory's appeal rights at that time.

Instructions for sending in Your Response

Your laboratory's response should be sent to:

[NAME OF RO MANAGER]
[NAME OF BRANCH]
[NAME OF DIVISION]
Centers for Medicare & Medicaid Services
[STREET ADDRESS]
[CITY, STATE ZIP]

A copy of any response the laboratory makes should also be sent to the State agency at the following address:

[STATE AGENCY NAME]
[STATE AGENCY ADDRESS]
Attention: **[STAFF NAME]**

If you have questions regarding this letter, please contact **[STAFF NAME]** at **[PHONE NUMBER]**.

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

cc: **[Director name]** Via certified mail, return receipt # _____
[Address other than lab address]
[City, State, Zip]
[State Agency Name]

10B RO (4/20/07) – Sanction Proposal – Conditions out – AOC not credible – alternative sanctions of Directed Plan of Correction and State Onsite Monitoring

[DATE]

[NAME OF LABORATORY]

CLIA number: [CLIA NUMBER]

Attn: [NAME]

[ADDRESS]

Dear [NAME]:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, and bill for services provided to Medicare beneficiaries or Medicaid recipients under Title XVIII and XIX of the Social Security Act, it must comply with all CLIA Requirements (42 C.F.R. § 493).

Federal regulations require surveys to determine whether or not a laboratory is in compliance with the applicable regulations. [NAME OF STATE AGENCY] (State agency) conducted [CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint] survey of [NAME OF LABORATORY] on [DATE], resulting in the finding of Condition-level noncompliance. On [DATE], the state agency requested your laboratory to correct the cited deficiencies. Your laboratory submitted an allegation of compliance documented on the Provider Plan of Correction column of the CMS-2567, Statement of Deficiencies. The State agency reviewed your laboratory's submission and informed you on [DATE] that the plan of correction was not acceptable and did not constitute a credible allegation of compliance. Therefore, an on-site revisit could not be performed.

The Centers for Medicare & Medicaid Services, (CMS) has reviewed the survey report and determined that your laboratory is not in compliance with the CLIA Conditions. These deficiencies have been found to be of such a serious nature as to substantially limit your laboratory's capability to render adequate services, and prevent it from being in compliance with the CLIA Conditions. Specifically, your laboratory does not meet the following CLIA Condition(s):

[EXAMPLE:

- 42 C.F.R. § 493.803 Condition: Successful Participation;
- 42 C.F.R. § 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; and
- 42 C.F.R. § 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.]

Based on the serious nature of the deficiencies cited and the failure of [NAME OF LABORATORY] to provide a credible allegation of compliance, CMS will impose the following alternative sanctions by the authority of 42 C.F.R. § 493.1804(b)(2):

[EXAMPLE:

42 C.F.R. § 493.1832, **Sanction: Directed Plan of Correction**, effective [DATE]. When CMS imposes a directed plan of correction, CMS directs the laboratory to take specific corrective action within specific time frames in order to achieve compliance.

In order to correct the CLIA Condition 42 C.F.R. § 493.803 Successful Participation, your laboratory must:

Cease patient testing in the failed specialty of hematology and demonstrate satisfactory performance in two supplemental proficiency testing events. These testing events can be requested from any approved proficiency testing company. Results of the supplemental proficiency testing must be submitted to the state agency no later than [DATE].

In addition, in accordance with 42 C.F.R. § 493.1838, the laboratory must show documentation of training and technical assistance for all personnel involved in patient testing for the failed specialty. Documentation of training must be submitted to the state agency no later than [DATE].

In order to achieve compliance for the CLIA Condition, Laboratories Performing Moderate Complexity Testing, Technical Consultant at 42 C.F.R. § 493.1409, your laboratory must:

Obtain the services of a qualified Technical Consultant to assist and review the laboratory's performance. Any prospective candidate must hold a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and possess at least four (4) years of laboratory experience in the specialty of Hematology.

Submit the name of the Technical Consultant to the State agency no later than [DATE] and obtain that agency's approval prior to entering into any contractual arrangement with such an individual.

The duties of the Technical Consultant will include:

- a) The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation;
- b) Establish a quality control program appropriate for the testing performed; establish the parameters for acceptable levels of analytic performance; and ensure that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;
- c) Document review of control material test results for the all laboratory testing on at least a weekly basis;
- d) Develop written protocols to monitor and verify test results for accuracy and reliability;
- e) Implement procedures for the review of proficiency testing to include documentation of remedial actions for any unacceptable analyte and test event scores;
- f) Resolve technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;
- g) Ensure that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

- h) Identify training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; document training of all individuals performing patient testing with respect to the above requirements, including orientation to quality control requirements, troubleshooting and record keeping;
- i) Evaluate the competency of all testing personnel assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently through:
 - (i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
 - (ii) Monitoring the recording and reporting of test results;
 - (iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
 - (iv) Direct observation of performance of instrument maintenance and function checks;
 - (v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
 - (vi) Assessment of problem solving skills.
- j) Evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.
- k) Retain documentation of all corrective actions for review by CMS and/or the State agency.

42 C.F.R. § 493.1836, **Sanction: State onsite monitoring**, effective [DATE]. CMS will require the state agency to provide intermittent monitoring of the plan of correction to ensure that the laboratory makes the improvements necessary to bring it into compliance. When CMS imposes the sanction of onsite monitoring, the sanction continues until CMS determines that the laboratory has the capability to ensure compliance with all Condition-level requirements.]

You may submit to CMS written evidence or other information against the imposition of alternative sanctions in accordance with 42 C.F.R. § 493.1810(b). The information must be received within 10 days of receipt of this notice.

The alternative sanction of a Directed Plan of Correction is intended to assist your laboratory to come into compliance with CLIA requirements. However, it remains the responsibility of the laboratory to provide a complete response to the cited deficiencies that would constitute a credible allegation of compliance and acceptable evidence of correction.

Your laboratory must take action to correct all Condition-level deficiencies or, under the authority of 42 C.F.R. § 493.1804(b)(2), CMS will take action to impose principal sanctions against your laboratory's CLIA certificate. In addition, failure to comply with the alternative sanction of a Directed Plan of Correction is basis for suspension, limitation or revocation of your laboratory's CLIA certificate pursuant to 42 C.F.R. § 493.1840(a)(7).

Your laboratory is directed to document compliance with the Directed Plan of Correction and indicate acceptable corrective action for each deficiency cited on the enclosed CMS-2567, Statement of Deficiencies, using the Provider Plan of Correction column. Indicate the appropriate completion dates on the right side of the form, keying your responses to the deficiencies on the left. In addition, you must provide acceptable evidence that the corrective actions have been implemented.

Acceptable evidence of correction must include:

- Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
- How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

Please send the plan of correction and evidence of correction to: **[STATE AGENCY ADDRESS]**. In addition, please forward a copy to this office. The State agency must receive your response by **[DATE]**.

If your plan of correction and evidence of correction is determined to constitute a credible allegation of compliance and acceptable evidence of correction, CMS will determine if compliance can be certified on the basis of the evidence presented, or if a revisit will be required to verify whether the laboratory has, in fact, achieved compliance.

A credible allegation of compliance is a statement or documentation that is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required; is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and indicates that the problem has been resolved.

If a revisit is conducted and the findings from the revisit indicate your laboratory is back in compliance with all CLIA Conditions, principal sanctions will not be imposed. If on the revisit, the laboratory is found out of compliance, CMS will impose the following principal sanctions:

42 C.F.R. § 493.1807(a), Sanction: cancel your laboratory's approval to receive Medicare payments for laboratory services effective **[DATE]**. In addition, under section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. 440.30(c), payment under the Medicaid program, Title XIX of the Social Security Act, will no longer be available to your laboratory for any laboratory services performed on or after **[DATE]**.

42 C.F.R. § 493.1840(a)(3) and (a)(7), Sanction: revocation of your CLIA certificate, pending a decision from an Administrative Law Judge, if an appeal is filed. Under revocation, the laboratory will be required to cease all patient testing. Also under revocation, 42 C.F.R. § 493.1840(a)(8), will prohibit the present owner and operator from owning or operating a laboratory for at least two years from the date of revocation. In accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the revocation of

your CLIA certificate, should this sanction be imposed, will appear in the Laboratory Registry for the calendar year of your revocation.

CMS is required to notify the general public when principal sanctions are imposed. In addition, if the above mentioned sanctions are imposed and your laboratory continues testing, please be informed that under 42 C.F.R. § 493.1806(e), any individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

If you believe this determination is not correct, you may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are set out in regulations at 42 C.F.R. § 493.1844. A written request for hearing must be filed no later than 60 days from the date of receipt of this letter.

You may submit a hearing request directly (accompanied by a copy of this letter) to:

Departmental Appeals Board
Civil Remedies Division
Attention: Oliver Potts
Cohen Building, Room G-644
330 Independence Avenue, S.W.
Washington, D.C. 20201

A copy of the hearing request should be sent to:

[NAME OF RO MANAGER]
[NAME OF BRANCH]
[NAME OF DIVISION]
Centers for Medicare & Medicaid Services
[STREET ADDRESS]
[CITY, STATE ZIP]

A request for hearing should identify the specific issues, and the findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. You may be represented by counsel at a hearing at your own expense. If the laboratory remains out of compliance on the revisit, and if no request for a hearing is received by **[DATE]**, your laboratory's CLIA certificate will be revoked **[DATE]**. If a hearing is conducted and CMS' determination is upheld, your laboratory may be assessed a fee to cover the government's costs related to the hearing, per 42 C.F.R. § 493.643(d)(2).

Please contact **[STAFF NAME]** at **[PHONE/EMAIL]** with any questions concerning this letter.

Sincerely,

[NAME/TITLE]
[OFFICE NAME]

cc: **[DIRECTOR NAME]** Via certified mail, return receipt # _____
[ADDRESS OTHER THAN LAB ADDRESS]
[CITY, STATE, ZIP]

[STATE AGENCY NAME]

IMPORTANT NOTICE – ACTION NECESSARY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile
constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA number: [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: PROPOSED SANCTIONS – CONDITIONS NOT MET – IMMEDIATE JEOPARDY

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The [STATE AGENCY NAME] (State agency) conducted [CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint] survey of your laboratory that was completed on [SURVEY DATE]. Based on this survey, [NAME OF LABORATORY] was found to be out of compliance with [NUMBER] CLIA Conditions:

[LIST CONDITIONS.]

In addition, other standards were also found to be not met.

The serious nature of the deficiencies resulted in a determination of immediate jeopardy to patient health and safety. The State agency notified [NAME OF LABORATORY] by letter dated [DATE OF SA LETTER] that conditions within the laboratory pose an immediate jeopardy situation. The State agency provided the laboratory a listing of all deficiencies identified during the survey on Form CMS-2567, Statement of Deficiencies, sent as an enclosure to its [DATE OF SA LETTER] letter.

In the [DATE OF SA LETTER] letter, the State agency notified the laboratory to take immediate action to remove jeopardy and bring any unmet Condition-level requirements into compliance. The State agency gave the laboratory ten days from the date of the [DATE OF SA LETTER] letter to submit a credible allegation of compliance and acceptable evidence of correction for the cited deficiencies. Your laboratory submitted an allegation of compliance dated [DATE OF SUBMISSION].

The State agency reviewed the [DATE OF SUBMISSION] submission and determined that it did not constitute a credible allegation of compliance and acceptable evidence of correction. The State agency notified your laboratory of this determination by its letter dated [DATE OF SA AOC REVIEW LETTER] and that it was referring the case to the CMS Regional Office with recommendations to not [CHOOSE ONE: certify, recertify] [NAME OF LABORATORY] into the CLIA program. We have reviewed the case and concur with the State agency in its findings and recommendations.

Proposed Sanctions

Accordingly, pursuant to 42 C.F.R. §§ 493.1806 and 493.1840(a)(3), based on the laboratory's failure to meet all CLIA Conditions, and based on the failure by the owner(s) and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the [DATE OF SURVEY] survey, we are taking action to impose the following sanctions against [NAME OF LABORATORY]'s CLIA certificate:

- 42 U.S.C. § 263a(i)(3), 42 C.F.R. §§ 493.1806, 493.1840(a)(3) and 493.1840(e) – Principal Sanction: **Revocation** of the laboratory's CLIA certificate effective [DATE OF NOTICE + 60 CALENDAR DAYS]. If imposed, the laboratory has 60 days to appeal the determination to revoke the laboratory's CLIA certificate. If a timely hearing request is received, revocation of the laboratory's CLIA certificate will become effective following the administrative hearing decision, if our determination of non-compliance is upheld.
- 42 C.F.R. §§ 493.1806, 493.1812, 493.1840(a)(3) and 493.1840(d)(2)(i) – Principal Sanction: **Suspension** of the laboratory's CLIA certificate effective [DATE OF NOTICE + 8 CALENDAR DAYS] based on the finding of immediate jeopardy. The suspension will take effect regardless of whether a hearing is filed and will remain in effect until the laboratory's CLIA certificate is revoked.
- 42 C.F.R. §§ 493.1806(c)(3), 493.1810(c)(2)(i), 493.1810(d) and 493.1834 – Alternative Sanction: **Civil Money Penalty** in the amount of \$10,000 per day for each day of non-compliance effective [DATE OF NOTICE + 5 CALENDAR DAYS]. If the laboratory requests a hearing, the civil money penalty amount will not be collected until after the hearing decision is rendered. However, the \$10,000/day will begin to accrue on [DATE OF NOTICE + 5 CALENDAR DAYS] and will continue to accrue until it can be verified that the laboratory is in compliance with all Condition-level requirements or the laboratory's CLIA certificate is suspended.

In determining the amount of the penalty, CMS has taken into account the following factors: (1) the laboratory was found to be out of compliance with [NUMBER] CLIA Condition-level requirements as well as numerous standard-level CLIA requirements at the survey completed on [SURVEY DATE]; (2) the deficiencies cited at the [SURVEY DATE] survey were so serious as to result in the determination of immediate jeopardy to patient health and safety; (3) the laboratory has failed to remove jeopardy after being provided an opportunity to do so; [EXAMPLES OF OTHER REASONS: (4) the laboratory failed to meet the requirement for successful testing of proficiency testing samples; (5) the laboratory failed to establish and verify performance specifications for each testing method prior to testing and reporting patient results; (6) the laboratory

accepted and tested patient specimens which were hemolyzed and serum samples having had prolonged contact with red blood cells, i.e., the integrity of the patient specimens had been compromised, yet the laboratory tested and reported panic values indicating life-threatening conditions; (7) the laboratory director failed to establish and maintain quality control and quality assessment programs to assure the accuracy of patient test results; and (8) the laboratory has expressed no rational reason for its failure to achieve compliance with all applicable Condition-level CLIA requirements.]

- 42 C.F.R. §§ 493.1806(c)(1), 493.1832, 493.1844(d)(1) and 493.1844(g)(1) – Alternative Sanction: **Directed Portion of a Plan of Correction** effective [DATE OF NOTICE + 5 CALENDAR DAYS]. The laboratory will be directed to submit to this office within ten calendar days from the date of the imposition notice a list of the names and addresses of all physicians and other clients who have used some or all of the laboratory’s services since [DATE OF PRIOR SURVEY OR OTHER DATE AS APPROPRIATE]. This list may be used to advise the laboratory’s clients of the nature of its non-compliance and the nature and effective date of any sanctions imposed against the laboratory.
- 42 C.F.R. §§ 493.1807(a), 493.1808(a), 493.1842 and 493.1844(d)(3) – Principal Sanction: **Cancellation of the laboratory’s approval to receive Medicare payments** for any laboratory services performed on or after [DATE OF NOTICE + 5 CALENDAR DAYS]. This sanction will be effectuated even if the laboratory files a timely appeal.

Moreover, in accordance with Section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), payment under the Medicaid program, Title XIX of the Social Security Act, will no longer be available to the laboratory for any laboratory services performed on or after [DATE OF NOTICE + 5 DAYS]. See 42 C.F.R. § 440.2(b).

The laboratory is advised that the above sanctions cannot be avoided by the closure, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

When the laboratory's CLIA certificate is suspended, the laboratory will not be permitted to perform any patient testing including waived and provider performed microscopy testing and regardless of whether or not the laboratory charges for the testing. (The laboratory may continue to perform parallel testing on patient specimens if needed to implement corrective actions. However, the laboratory may not report any patient test results during the period when its CLIA certificate is suspended.)

Also, under revocation, 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) prohibit the owner(s) or operator(s) (including director – see 42 C.F.R. § 493.2) from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. This prohibition applies to the owner(s) as well as the director at the time that the deficiencies were found which led to the current sanction actions.

When the sanctions become effective as referenced above, in accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the actions against the laboratory’s CLIA certificate will appear in the Laboratory Registry for the calendar year in which the actions are imposed. In addition, pursuant to 42 C.F.R. § 493.1844(g)(1), we will notify the general public by means of a notice published in a local newspaper, when the above sanctions are imposed.

Appeal Rights

If [NAME OF LABORATORY] does not believe this determination to impose these actions against its CLIA certificate is correct, the laboratory may request a hearing before an administrative law judge (ALJ) of the Departmental Appeals Board in accordance with 42 C.F.R. § 493.1844(a)(1)-(2) and 42 C.F.R. §§ 498.40 through 498.78. A written request for hearing must be filed no later than sixty days after the date of this letter is received (see 42 C.F.R. § 493.1844(f)). Such a request may be made directly (accompanied by a copy of this letter) to:

Departmental Appeals Board
Civil Remedies Division
Attention: Oliver Potts
Cohen Building, Room G-644
330 Independence Ave, SW
Washington, D.C. 20201

A copy of the hearing request should be sent to:

[NAME OF RO MANAGER]
[NAME OF BRANCH]
[NAME OF DIVISION]
Centers for Medicare & Medicaid Services
[STREET ADDRESS]
[CITY, STATE ZIP]

The request for hearing must contain a statement as to the specific issues and findings of fact and conclusions of law in this determination with which the laboratory disagrees and the basis for the laboratory's contention that the specific issues and/or findings and conclusions are incorrect. Evidence and arguments may also be presented at the hearing, where counsel may represent the laboratory at its own expense. **If a hearing is conducted and CMS' determination is upheld, the laboratory will be assessed a fee to cover the government's cost related to the hearing.** See 42 C.F.R. § 493.643(d)(2).

As noted above, if a timely request for hearing is filed, i.e., by [DATE OF NOTICE + 60 CALENDAR DAYS], CMS does not collect the Civil Money Penalty or revoke any type of CLIA certificate until after an ALJ hearing that upholds CMS' sanction determination. However, suspension of the laboratory's CLIA certificate will go into force effective [DATE OF NOTICE + 8 CALENDAR DAYS], and the Directed Portion of a Plan of Correction and cancellation of all Medicare and Medicaid payment are effective [DATE OF NOTICE + 5 CALENDAR DAYS], regardless of whether a hearing is requested. See 42 C.F.R. §§ 493.1844(d)(1)-(3) and 493.1844(h)(1).

Please be advised that the determination that a laboratory's deficiencies pose immediate jeopardy is not subject to appeal. Please also be advised that the determination as to which alternative sanction or sanctions to impose, including the amount of a Civil Money Penalty to impose per day or per violation, is not subject to appeal. See 42 C.F.R. § 493.1844(c)(4) and (c)(6). Please note that in accordance with 42 U.S.C. § 263a(i)(2), CMS is authorized to suspend the CLIA certificate of a laboratory before holding a hearing where the failure to comply with CLIA

requirements presents an imminent and serious risk to human health, as has been determined in the case of **[NAME OF LABORATORY]**. As further provided under this section of the statute, if the laboratory requests a hearing, it is entitled to have the hearing commence within 60 days of the effective date of the suspension. The laboratory must specify in any request for a hearing to challenge the suspension of its CLIA certificate whether it wishes the hearing to commence within 60 days.

You have ten days from the date of this notice, or until [DATE OF NOTICE + 10 CALENDAR DAYS], to submit in writing any evidence and/or information as to why the sanctions detailed above should not be imposed. Your laboratory's response should be sent to:

[NAME OF RO MANAGER]
[NAME OF BRANCH]
[NAME OF DIVISION]
Centers for Medicare & Medicaid Services
[STREET ADDRESS]
[CITY, STATE ZIP]

A copy of any response the laboratory makes should also be sent to the State agency at the following address:

[STATE AGENCY NAME]
[STATE AGENCY ADDRESS]
Attention: **[STAFF NAME]**

If you have questions regarding this letter, please contact **[STAFF NAME]** at **[PHONE NUMBER]**.

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

cc: **[DIRECTOR NAME]** Via certified mail, return receipt # _____
[ADDRESS OTHER THAN LAB ADDRESS]
[CITY, STATE, ZIP]

[STATE AGENCY NAME]

12 RO (4/20/07) – Sanction Proposal – Subsequent Unsuccessful PT – SA PT desk review finds subsequent unsuccessful and referred immediately to RO for sanction

IMPORTANT NOTICE – ACTION NECESSARY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of
Facsimile constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA number: [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

**RE: PROPOSED SANCTIONS DUE TO SUBSEQUENT OCCURRENCE OF
UNSUCCESSFUL PARTICIPATION IN PROFICIENCY TESTING – IMPOSITION
NOTICE TO FOLLOW IF PROPOSED SANCTIONS ARE IMPOSED**

Dear Director and Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. Part 493). Compliance with these regulations is a requirement for certification for the CLIA program.

Subpart H of 42 C.F.R Part 493 requires each laboratory certified to test specimens under the CLIA regulations to successfully participate in an approved proficiency testing program. The CLIA regulations at 42 C.F.R. § 493.2 define, as set out in Subpart H, unsuccessful proficiency testing performance as failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two out of three consecutive testing events.

Determination of Non-Compliance: Finding of Unsuccessful Participation in Proficiency Testing - Subsequent Occurrence

Evidence obtained by the [STATE AGENCY NAME] (the State agency) during a desk review conducted on [DATE OF CMS-2567 FOR PT DESK REVIEW] of proficiency testing results submitted to CLIA from your laboratory's proficiency testing program shows your laboratory has a repeat history of unsatisfactory proficiency testing performance for the tests and events listed below which constitutes a subsequent occurrence of unsuccessful participation in proficiency testing for these tests:

<u>Testing Event</u>	<u>PT Provider</u>	<u>Test</u>	<u>Score</u>
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[LIST UNSATISFACTORY EVENTS.]

Based on the repeat proficiency testing failures listed above, your laboratory is not in compliance with [NUMBER] CLIA Conditions. The enclosed Form CMS-2567, Statement of Deficiencies, specifically documents the laboratory's failure to meet the Condition-level requirements at: **[DELETE ANY DIRECTOR CONDITION THAT DOES NOT APPLY.]**

D2016 - 42 C.F.R. § 493.803	Condition: Successful participation [proficiency testing]
D6000 - 42 C.F.R. § 493.1403	Condition: Laboratories performing moderate complexity testing; laboratory director;
D6076 - 42 C.F.R. § 493.1441	Condition: Laboratories performing high complexity testing; laboratory director;

In addition, other standards were found to be not met.

Proposed Sanctions Based on Unsuccessful Participation in Proficiency Testing – Subsequent Occurrence

Pursuant to 42 C.F.R. §§ 493.1804(b)(1)(ii), 493.1806(a), and 493.1840(a)(3), we propose to take sanction actions against the laboratory's CLIA certificate based on Condition-level non-compliance as evidenced by:

- (1) The repeat history of proficiency testing failures in the [**CHOOSE as appropriate:** specialty, subspecialty] of [**SPECIALTY OR SUBSPECIALTY NAME**] for the analyte [**ANALYTE NAME**], which constitutes a subsequent occurrence of unsuccessful participation in proficiency testing; and
- (2) The laboratory director's failure to fulfill his responsibility for monitoring proficiency testing to ensure that the laboratory is in compliance with the CLIA Condition of successful participation in proficiency testing.

We propose to take the following sanction actions against the laboratory's CLIA certificate:

- 42 C.F.R. §§ 493.803(b), 493.1804(b)(1)(ii), 493.1806, and 493.1840(a)(3) – Principal Sanction: **Limitation** of the laboratory's CLIA certificate for the [**CHOOSE as appropriate:** analyte, specialty, subspecialty] [**NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY**] for not less than six months effective [**LIMITATION DATE**]. When a laboratory's CLIA certificate is limited in a specific [**CHOOSE as appropriate:** analyte, specialty, subspecialty], the laboratory will not be permitted to perform any patient testing in that [**CHOOSE as appropriate:** analyte, specialty, subspecialty.]

NOTE: The laboratory may continue to perform parallel testing on patient specimens in the [**CHOOSE as appropriate:** analyte, specialty, subspecialty] of [**NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY**] if needed to implement corrective actions, however, the laboratory may not report any patient test results in the [**CHOOSE as appropriate:** analyte, specialty, subspecialty] of [**NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY**] during the period when its CLIA certificate is limited in the [**CHOOSE as appropriate:** analyte, specialty, subspecialty] of [**NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY**].

The laboratory has sixty (60) days in which to appeal the determination to limit its certificate in the [CHOOSE as appropriate: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY]. If the laboratory chooses not to file an appeal, limitation of its CLIA certificate in the [CHOOSE as appropriate: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] will become effective [LIMITATION DATE]. If a timely hearing request is received, limitation of the laboratory's CLIA certificate in the [CHOOSE as appropriate: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] will be effective with the date of the administrative hearing decision, if our determination of non-compliance is upheld.

As noted below, pursuant to 42 C.F.R. §§ 493.1840(a)(4) and 493.1844(d)(2)(ii)(B), limitation of the laboratory's CLIA certificate will not be delayed even if a hearing is filed if the laboratory fails to comply with the terms of the Directed Plan of Correction (see proposed sanction of a Directed Plan of Correction below).

- 42 C.F.R. §§ 493.1804(b)(1)(ii), 493.1804(b)(2), 493.1806(c)(1), 493.1832, and 493.1844(h)(2) – Alternative Sanction: **Directed Plan of Correction** effective [CMP EFFECTIVE DATE]. If this sanction is imposed, the laboratory is directed to (1) address any actual or potential negative patient outcome during the period of unsuccessful proficiency testing performance for the [CHOOSE as appropriate: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] and submit acceptable evidence that this has been done within ten (10) calendar days from the date of the notice of imposition; (2) demonstrate that the laboratory has established an effective oversight mechanism to prevent recurrences of proficiency testing failure for all testing including testing in the [CHOOSE as appropriate: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] and submit acceptable evidence that such a mechanism has been implemented within ten (10) calendar days from the date of the notice of imposition; and (3) demonstrate satisfactory performance in two consecutive proficiency testing events for the [CHOOSE as appropriate: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] before the limitation of the laboratory's certificate in the [CHOOSE as appropriate: analyte, specialty or subspecialty] of [NAME OF ANALYTE, SPECIALTY OR SUBSPECIALTY] can be lifted. The laboratory may obtain the two consecutive proficiency testing events from any proficiency testing program approved by CMS for the calendar year.

Acceptable evidence of correction to be submitted to meet the requirements of the Directed Plan of Correction must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) have been taken;
- 3) What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur; and,
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

Please note that pursuant to 42 C.F.R. §§ 493.1840(a)(4) and 493.1844(d)(2)(ii)(B), if the laboratory fails to comply with the terms of the Directed Plan of Correction above, it will

constitute failure to comply with a reasonable request from CMS for information and work on materials necessary to determine continued eligibility for its CLIA certificate or continued compliance with performance standards set by CMS, and will result in the limitation taking effect [DATE OF NOTICE + 15 CALENDAR DAYS], regardless of whether a hearing is filed. In addition, pursuant to 42 C.F.R. § 493.1840(a)(7), failure to comply with alternative sanctions is a basis for limitation, suspension, or revocation of any type of CLIA certificate.

- 42 C.F.R. §§ 493.1804(b)(1)(ii), 493.1804(b)(2), 493.1806(c)(3), 493.1810(d), 493.1814, 493.1834, and 493.1844(h)(2) – Alternative Sanction: **Civil Money Penalty** effective [CMP EFFECTIVE DATE]. If this sanction is imposed, it will be in the amount of **\$3,000 per day** of non-compliance until compliance is met or until the principal sanction of Limitation of the laboratory's CLIA Certificate in the analyte [ANALYTE NAME] (see proposed sanction of Limitation of the laboratory's certificate above) is imposed, whichever is earlier. If the laboratory does not appeal and the limitation is effective on [LIMITATION EFFECTIVE DATE], the **total Civil Money Penalty would be [TOTAL CMP AMOUNT]**. You are advised that if the laboratory requests a timely hearing, the Civil Money Penalty amount will not be collected but will continue to run until the hearing decision is rendered.

In determining the amount of the penalty, CMS has taken into account the following factors: (1) the laboratory has a history of proficiency testing failures in the [CHOOSE as appropriate: analyte, specialty, subspecialty] OF [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] for [LIST PT TESTING EVENTS]*; (2) CLIA records show that the laboratory also had proficiency testing failures for the analytes of [NAME OF FAILED ANALYTES] for the [PT TESTING EVENTS]; (3) the laboratory director has failed to fulfill his responsibility for monitoring proficiency testing to ensure that the laboratory is in compliance with the CLIA Condition of successful participation in proficiency testing; (4) the failure in proficiency testing indicates a high potential for inaccurate patient test results as proficiency testing samples are tested in the same manner as patient samples; and (5) the laboratory has failed to have an effective quality assessment mechanism in place to ensure successful participation in proficiency testing and thereby to ensure accurate and reliable patient test results.

* We note that on [DATE OF SA DESK REVIEW NOTICE OF 1ST UNSUCCESSFUL], the State agency notified your laboratory of a first occurrence of unsuccessful participation in proficiency testing for the analyte of [ANALYTE NAME], based on unsatisfactory results for the [PT EVENTS]. Your laboratory submitted an allegation of compliance and evidence of correction on [DATE OF AOC FOR 1ST UNSUCCESSFUL] which was deemed to be acceptable. [LIST OTHER SA DESK REVIEW NOTIFICATIONS OF 1ST UNSUCCESSFULS IF APPLICABLE.] The subsequent occurrence of unsuccessful participation in PT indicates that the laboratory failed to either implement corrections as alleged or monitor for the effectiveness of its corrective actions.

- 42 C.F.R. §§ 493.1804(b)(1)(ii), 493.1804(b)(2), 493.1807(b), 493.1808(b), 493.1826, 493.1844(d)(1), and 493.1844(h)(2) – Medicare Alternative Sanction: **Suspension of the laboratory’s approval to receive Medicare payments** for any services performed in the [CHOOSE as appropriate: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] effective [LIMITATION DATE].

The laboratory must agree in writing (in return for not having its Medicare approval cancelled immediately) to not charge Medicare beneficiaries or their private insurance carriers for the services for which Medicare payment is suspended, i.e., in the [CHOOSE as appropriate: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY]. Failure to provide this written agreement will result in the cancellation of the laboratory’s approval to receive Medicare payment for all laboratory services effective [LIMITATION DATE].

As a consequence of the suspension of the approval to receive Medicare for services performed in [CHOOSE as appropriate: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY], under section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), payment under the Medicaid program, Title XIX of the Social Security Act, will also no longer be available to the laboratory for all laboratory services performed in the [CHOOSE as appropriate: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] effective [LIMITATION DATE]. See 42 C.F.R. § 440.2(b). Pursuant to 42 C.F.R. § 493.807, the suspension period for Medicare and Medicaid approval for these services is for a period of not less than six months.

Please be advised that the imposition of sanctions cannot be avoided by closure of your laboratory, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

Instructions for Sending in Your Response

The laboratory has ten (10) calendar days from the date of this notice, or until [NOTICE DATE + 10 CALENDAR DAYS], to submit in writing any evidence or information as to why the proposed sanctions for a subsequent occurrence of unsuccessful participation in proficiency testing for the [CHOOSE as appropriate: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] and noncompliance with the Conditions of successful participation in proficiency testing and laboratory director should not be imposed. If we do not receive a timely submission or if we determine that the submission is unpersuasive, we will notify you in writing that we will proceed to impose the above-referenced sanctions. We will provide information regarding the laboratory’s appeal rights at that time.

All responses, including written evidence as to why the proposed sanctions for a subsequent occurrence of unsuccessful participation in proficiency testing for the [CHOOSE as appropriate: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] should not be imposed should be sent to:

[Name of RO Manager]
[Name of Branch]

[Name of Division]
Centers for Medicare & Medicaid Services
[Street address]
[City, State, Zip]

If you have questions regarding this letter, please contact **[STAFF NAME]** at **[PHONE NUMBER]**.

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

Enclosure: Form CMS-2567, Statement of Deficiencies

cc: **[STATE AGENCY NAME]**

13 RO (4/20/07) – Sanction Proposal – Improper PT Referral - SA survey finds improper PT referral and referred to RO immediately for sanction

IMPORTANT NOTICE – PLEASE READ CAREFULLY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA number: [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: PROPOSED SANCTIONS – IMPROPER PROFICIENCY TESTING REFERRAL

Dear Director/Owner(s):

For a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a requirement for certification for the CLIA program.

The [STATE AGENCY NAME] (State agency) conducted [CHOOSE SURVEY TYPE: an initial, a routine recertification, a complaint] survey of your laboratory that was completed on [SURVEY DATE]. Based on this survey, your laboratory was found to be out of compliance with two CLIA Conditions: [DELETE ANY DIRECTOR CONDITION THAT DOES NOT APPLY]

D2000: 42 C.F.R. § 493.801	Enrollment and Testing of [Proficiency Testing] Samples; and,
D6000: 42 C.F.R. § 493.1403	Laboratories performing moderate complexity testing; laboratory director.
D6076: 42 C.F.R. § 493.1441	Condition: Laboratories performing high complexity testing; laboratory director.

The Condition of proficiency testing is specifically supported by deficiency D2013 at 42 C.F.R. § 493.801(b)(4) for improper proficiency testing referral by reporting proficiency testing results obtained from another laboratory. The Form CMS-2567, Statement of Deficiencies, which details the cited deficiencies, is enclosed for your reference.

The State agency has referred your case to CMS for sanction action due to the improper proficiency testing referral. CMS has reviewed your case and concurs with the State agency in its findings and recommendations.

Accordingly, **due to the improper referral of your laboratory's proficiency testing samples to another laboratory for analysis, and your laboratory's failure to meet the Condition(s) of laboratory director, [MODERATE AND/OR HIGH] complexity testing**, CMS is proposing to impose the following sanctions against your laboratory's CLIA certificate:

- 42 U.S.C. § 263a(i)(3), 42 C.F.R. § 493.801(b)(4), § 493.1806(a) and (b), § 493.1840(a)(3) and (6), § 493.1840(b), and § 493.1840(e) – Principal Sanction: **Revocation** of your laboratory's CLIA certificate. The laboratory has 60 days in which to appeal the determination to revoke its CLIA certificate. If the laboratory chooses not to request an appeal, revocation of its CLIA certificate (if imposed) will become effective **[DATE OF THIS NOTICE + 60 CALENDAR DAYS]**. If a timely hearing request is received, revocation of the laboratory's CLIA certificate will become effective following the administrative hearing decision, if our determination of non-compliance is upheld.
- 42 C.F.R. § 493.1804(b)(2), § 493.1806(c)(3), § 493.1834, and § 493.1840(b) – Alternative Sanction: **Civil Money Penalty** effective **[DATE OF NOTICE + 15 CALENDAR DAYS]** in the amount of \$3,000 per occurrence for each instance in which your laboratory engaged in improper proficiency testing referral activities. The record shows that **[NUMBER]** instances of improper proficiency testing referral occurred **[CITE THE INSTANCES, e.g., (API Q2/[Year] event chemistry proficiency testing sample 6, API Q2/2000 event chemistry proficiency testing sample 7, API Q2/[Year] event chemistry proficiency testing sample 8, API Q2/[Year] event chemistry proficiency testing sample 9, and API Q2/[Year] event chemistry proficiency testing sample 10)]**. At \$3,000 per occurrence, this amounts to a total Civil Money Penalty of **[NUMBER x \$3,000]**. (See Form CMS-2567 under D2013 for details about these occurrences.)

In determining the amount of the penalty, CMS has taken into account that the laboratory was found to have engaged in improper proficiency testing referral activities in **[NUMBER]** separate instances resulting in the determination by CMS that the laboratory was out of compliance with **[NUMBER]** Condition-level requirements of CLIA.

- 42 C.F.R. § 493.1804(b)(2), § 493.1806(c)(1), § 493.1814, § 493.1832(b)(2), and § 493.1844(g)(1) – Alternative Sanction: **Directed Portion of a Plan of Correction** effective **[DATE OF NOTICE + 15 CALENDAR DAYS]**. When this sanction is imposed, you will be directed to submit to this office within ten calendar days from the date of the notice of imposition a list of the names and addresses of all physicians and other clients who have used some or all of your laboratory's services from **[DATE OF PRIOR SURVEY OR OTHER DATE AS APPROPRIATE]** to the present date. This list may be used to advise your clients of the nature of your laboratory's non-compliance and the nature and effective date of any sanction actions imposed against your laboratory.
- 42 C.F.R. § 493.1807(a), § 493.1808(a), § 493.1842, and § 493.1844(d)(3) – Principal Sanction: **Cancellation of your laboratory's approval to receive Medicare payments** for any services performed effective **[DATE OF NOTICE + 15 CALENDAR DAYS]**. When this sanction is imposed, under Section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), payment under the Medicaid program, Title XIX of the Social Security Act, will no longer be available to your laboratory for all services effective **[DATE OF NOTICE + 15 CALENDAR DAYS]**.

The laboratory is advised that the above sanctions cannot be avoided by the closure, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

When your laboratory's CLIA certificate is revoked, your laboratory will be required to cease all patient testing, including waived testing or provider performed microscopy procedures, regardless of whether the laboratory charges for such testing. Also, pursuant to 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), the owner(s) and operator (including the director) of the laboratory will be prohibited from owning or operating (including directing) any laboratory for at least two years from the date of the revocation. This prohibition applies to the owner(s) as well as director at the time your laboratory was found to have been improperly referring its proficiency testing specimens.

Appeal Rights

If **[NAME OF LABORATORY]** does not believe this determination to impose these additional actions against its CLIA certificate is correct, the laboratory may request a hearing before an administrative law judge (ALJ) of the Department Appeals Board in accordance with 42 C.F.R. § 493.1844(a)(1) - (2) and 42 C.F.R. Part 498. A written request for hearing must be filed no later than sixty days after the date of this letter, or by **[DATE OF THIS NOTICE + 60 CALENDAR DAYS]** (see 42 C.F.R. § 493.1844(f)). Such a request may be made directly (accompanied by a copy of this letter) to:

Departmental Appeals Board
Civil Remedies Division
Attention: Oliver Potts
Cohen Building, Room G-644
330 Independence Ave, SW
Washington, D.C. 20201

A copy of the hearing request should be sent to:

[NAME OF RO MANAGER]
[NAME OF BRANCH]
[NAME OF DIVISION]
Centers for Medicare & Medicaid Services
[STREET ADDRESS]
[CITY, STATE ZIP]

The request for hearing must contain a statement as to the specific issues and findings of fact and conclusions of law in this determination with which the laboratory disagrees and the basis for the laboratory's contention that the specific issues and/or findings and conclusions are incorrect. Evidence and arguments may also be presented at the hearing, where counsel may represent the laboratory at its own expense. **If a hearing is conducted and CMS' determination is upheld, the laboratory will be assessed a fee to cover the government's cost related to the hearing.** See 42 C.F.R. § 493.643(d)(2).

If a timely request for hearing is filed, i.e., by **[DATE OF THIS NOTICE + 60 CALENDAR DAYS]**, CMS does not collect a Civil Money Penalty or revoke any type of CLIA certificate until after an ALJ hearing that upholds CMS' sanction determination. However, the Directed Portion of a Plan of Correction to submit the laboratory's client list and the cancellation of all Medicare and Medicaid payment are effective **[DATE OF THIS NOTICE + 15 CALENDAR DAYS]** regardless of whether a hearing is requested. See 42 C.F.R. §§ 493.1844(d)(1), 493.1844(d)(2)(i), 493.1844(d)(3), and 493.1844(h)(2).

Please be advised that the determination as to which alternative sanction or sanctions to impose, including the amount of a Civil Money Penalty to impose per day or per violation, is not subject to appeal. See 42 C.F.R. § 493.1844(c)(4) and (c)(7).

You have ten days from the date of this notice, or until [DATE OF NOTICE + 10 CALENDAR DAYS], to submit in writing any evidence or information as to why the sanctions detailed above should not be imposed. If we do not receive a timely submission or if we determine that the submission is unpersuasive, we will notify you in writing that we will proceed to impose the above-referenced sanctions.

If you have questions regarding this letter, please contact **[STAFF NAME]** at **[PHONE NUMBER]**.

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

Enclosure: Form CMS-2567, Statement of Deficiencies

cc: **[DIRECTOR NAME]** Via certified mail, return receipt # _____
[ADDRESS OTHER THAN LAB ADDRESS]
[CITY, STATE, ZIP]

[STATE AGENCY NAME]

14 RO (4/20/07) – Sanction Proposal – Standards Out – POC Unacceptable – response to sanction proposal notice not acceptable, sanctions imposed

IMPORTANT NOTICE – PLEASE READ CAREFULLY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA number: [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: IMPOSITION OF SANCTIONS – STANDARDS NOT MET

Dear Director/Owner(s):

[NAME OF LABORATORY] was notified by our letter dated [DATE OF PROPOSED SANCTION NOTICE] of proposed sanctions against the laboratory's CLIA certificate based on the laboratory's failure to meet all CLIA standard-level requirements, and based on the failure by the owner(s) and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the survey completed on [SURVEY DATE]. The laboratory was given ten days from the date of the [DATE OF PROPOSED SANCTION NOTICE] letter to submit information or written evidence as to why these sanctions should not be imposed.

Your laboratory responded with a submission on [DATE]. The submission included [LIST WHAT WAS INCLUDED IN THE SUBMISSION].

We have carefully reviewed the entire [DATE OF SUBMISSION] submission and determined that your laboratory's plan of correction is not acceptable. The evidence submitted shows that the laboratory continues to be out of compliance with CLIA standard-level requirements as cited during the [SURVEY DATE] survey.

As you were advised by the State agency in its [DATES OF SA LETTERS] letters, the laboratory's plan of correction must be substantiated by acceptable evidence of correction, which must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice:
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken:
- 3) What measure has been put into place or what systemic changes the laboratory has made to ensure that the deficient practice does not recur; and
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

For your information, the following details by deficiency tag (D-tag) why **[NAME OF LABORATORY]**'s **[DATE OF SUBMISSION]** submission does not constitute acceptable evidence of correction.

[PROVIDE REVIEW OF SUBMISSION AND WHY NOT ACCEPTABLE.]

IMPOSED SANCTIONS

Accordingly, as the laboratory has failed to meet all CLIA standard-level requirements and based on the failure the owner(s) and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the survey completed on **[SURVEY DATE]**, we are taking action to impose sanctions against **[NAME OF LABORATORY]**'s CLIA certificate as proposed in our **[DATE OF SANCTION PROPOSAL NOTICE]** letter, with effective dates as follows:

- **Revocation** of the laboratory's CLIA certificate effective **[DATE OF THIS NOTICE + 60 DAYS]**. The laboratory has 60 days to appeal the determination to revoke the laboratory's CLIA certificate. If a timely hearing request is received, revocation of the laboratory's CLIA certificate will become effective following the administrative hearing decision, if our determination of non-compliance is upheld.
- **Cancellation of the laboratory's approval to receive Medicare payments** for any services performed on or after **[DATE]**. As a result, under section 1902 (a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), payment for all laboratory services under the Medicaid program, Title XIX of the Social Security Act, is no longer available to the laboratory for any laboratory services performed on or after **[DATE]**. See 42 C.F.R. § 440.2(b).

Appeal Rights

If **[NAME OF LABORATORY]** does not believe this determination to impose these actions against its CLIA certificate is correct, the laboratory may request a hearing before an administrative law judge (ALJ) of the Departmental Appeals Board in accordance with 42 C.F.R. § 493.1844(a)(1)-(2) and 42 C.F.R. §§ 498.40 through 498.78. A written request for hearing must be filed no later than sixty days after the date of this letter is received (see 42 C.F.R. § 493.1844(f)). Such a request may be made directly (accompanied by a copy of this letter) to:

Departmental Appeals Board
Civil Remedies Division
Attention: Oliver Potts
Cohen Building, Room G-644
330 Independence Ave, SW
Washington, D.C. 20201

A copy of the hearing request should be sent to:

[NAME OF RO MANAGER]
[NAME OF BRANCH]
[NAME OF DIVISION]

Centers for Medicare & Medicaid Services
[STREET ADDRESS]
[CITY, STATE ZIP]

The request for hearing must contain a statement as to the specific issues and findings of fact and conclusions of law in this determination with which the laboratory disagrees and the basis for the laboratory's contention that the specific issues and/or findings and conclusions are incorrect. Evidence and arguments may also be presented at the hearing, where counsel may represent the laboratory at its own expense. **If a hearing is conducted and CMS' determination is upheld, the laboratory will be assessed a fee to cover the government's cost related to the hearing.** See 42 C.F.R. § 493.643(d)(2).

If a timely request for hearing is filed, i.e., by [DATE OF THIS NOTICE + 60 CALENDAR DAYS], CMS does not revoke any type of CLIA certificate until after an ALJ hearing that upholds CMS' sanction determination. However, cancellation of all Medicare and Medicaid payment is effective [DATE], regardless of whether a hearing is requested. See 42 C.F.R. §§ 493.1844(d)(3) and 493.1844(h)(2).

The laboratory is reminded that the above sanctions cannot be avoided by the closure, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

When a laboratory's CLIA certificate is revoked, it is required to cease all patient laboratory testing, including waived and provider performed microscopy testing and regardless of whether or not the laboratory charges for the testing. Also, under revocation, 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) prohibit the owner(s) or operator(s) (including director – see 42 C.F.R. § 493.2) from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. This prohibition applies to the owner(s) as well as the director at the time that the deficiencies were found which led to the current sanction actions.

In accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the actions against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year in which the actions are imposed. In addition, pursuant to 42 C.F.R. § 493.1844(g)(1), we will notify the general public by means of a notice published in a local newspaper.

If you have questions regarding this letter, please contact **[STAFF NAME]** at **[PHONE NUMBER]**.

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

Enclosure: Form CMS-2567, Statement of Deficiencies

cc: **[DIRECTOR NAME]** Via certified mail, return receipt # _____
[ADDRESS OTHER THAN LAB ADDRESS]
[CITY, STATE, ZIP]

[STATE AGENCY NAME]

IMPORTANT NOTICE – PLEASE READ CAREFULLY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile
constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA # [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: IMPOSITION OF SANCTIONS – CONDITIONS OUT

Dear Director/Owner(s):

[NAME OF LABORATORY] was notified by our letter dated [DATE OF PROPOSED SANCTION NOTICE] of proposed sanctions against the laboratory's CLIA certificate based on the laboratory's failure to meet all CLIA Conditions, and based on the failure by the owner(s) and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the survey completed on [SURVEY DATE]. The laboratory was given ten days from the date of the [DATE OF PROPOSED SANCTION NOTICE] letter to submit information or written evidence as to why these sanctions should not be imposed.

Your laboratory responded with a submission on [DATE]. The submission included [LIST WHAT WAS INCLUDED IN THE SUBMISSION].

We have carefully reviewed the entire [DATE OF SUBMISSION] submission and determined that your laboratory's allegation of compliance is not credible and evidence of correction is not acceptable. The evidence submitted shows that the laboratory continues to be out of compliance with CLIA Condition-level requirements as cited during the [SURVEY DATE] survey.

As you were advised by the State agency in its [DATES OF SA LETTERS] letters, a credible allegation of compliance, as defined by the CLIA requirements at 42 C.F.R. § 493.2, is a statement or document that is:

- 1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
- 2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
- 3) Indicates resolution of the problem.

It is important to note that for it to be credible, the allegation of compliance must be complete and address each of the deficiencies. For each deficiency, the allegation of compliance must include a corrective action date that is realistic in terms of the action being accomplished

between the date of the survey and the planned date of completion. In addition, the allegation of compliance must contain information that indicates resolution of the problems.

As you were also advised by the State agency in its **[DATES OF SA LETTERS]** letters, the laboratory's allegation of compliance must be substantiated by acceptable evidence of correction, which must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice:
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken:
- 3) What measure has been put into place or what systemic changes the laboratory has made to ensure that the deficient practice does not recur; and,
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

For your information, the following details by deficiency tag (D-tag) why **[NAME OF LABORATORY]**'s **[DATE OF SUBMISSION]** submission does not constitute a credible allegation of compliance and acceptable evidence of correction.

[PROVIDE REVIEW OF SUBMISSION AND WHY NOT ACCEPTABLE.]

IMPOSED SANCTIONS

Accordingly, as the laboratory has failed to meet all CLIA Conditions and based on the failure of the owner(s) and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the survey completed on **[SURVEY DATE]**, we are taking action to impose sanctions against **[NAME OF LABORATORY]**'s CLIA certificate as proposed in our **[DATE OF SANCTION PROPOSAL NOTICE]** letter, with effective dates as follows:

- **Revocation** of the laboratory's CLIA certificate effective **[DATE OF THIS NOTICE + 60 CALENDAR DAYS]**. The laboratory has 60 days to appeal the determination to revoke the laboratory's CLIA certificate. If a timely hearing request is received, revocation of the laboratory's CLIA certificate will become effective following the administrative hearing decision, if our determination of non-compliance is upheld.
- **Civil Money Penalty** of \$3,000 per day for each day of non-compliance effective **[BEGIN DATE]** and will continue to accrue until it can be verified that the laboratory is in compliance with all Condition-level requirements or the laboratory's CLIA certificate is revoked.
- **Directed Portion of a Plan of Correction** effective **[Date]** – The laboratory is directed to submit to this office by **[DATE OF NOTICE + 10 CALENDAR DAYS]** a list of the names and addresses of all physicians and other clients who have used some or all of the laboratory's services since **[DATE OF PRIOR SURVEY OR OTHER DATE AS APPROPRIATE]**. We request that this list be provided as an electronic file, in an EXCEL database format if possible. This list may be used to advise the laboratory's

clients of the nature of its non-compliance and the nature and effective date of sanction actions imposed against the laboratory.

- **Cancellation of the laboratory's approval to receive Medicare payments** for any services performed on or after [DATE]. As a result, under section 1902 (a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), payment for all laboratory services under the Medicaid program, Title XIX of the Social Security Act, is no longer be available to the laboratory for any laboratory services performed on or after [DATE]. See 42 C.F.R. § 440.2(b).

Appeal Rights

If [NAME OF LABORATORY] does not believe this determination to impose these actions against its CLIA certificate is correct, the laboratory may request a hearing before an administrative law judge (ALJ) of the Departmental Appeals Board in accordance with 42 C.F.R. § 493.1844(a)(1)-(2) and 42 C.F.R. §§ 498.40 through 498.78. A written request for hearing must be filed no later than sixty days after the date of this letter is received (see 42 C.F.R. § 493.1844(f)). Such a request may be made directly (accompanied by a copy of this letter) to:

Departmental Appeals Board
Civil Remedies Division
Attention: Oliver Potts
Cohen Building, Room G-644
330 Independence Ave, SW
Washington, D.C. 20201

A copy of the hearing request should be sent to:

[NAME OF RO MANAGER]
[NAME OF BRANCH]
[NAME OF DIVISION]
Centers for Medicare & Medicaid Services
[STREET ADDRESS]
[CITY, STATE ZIP]

The request for hearing must contain a statement as to the specific issues and findings of fact and conclusions of law in this determination with which the laboratory disagrees and the basis for the laboratory's contention that the specific issues and/or findings and conclusions are incorrect. Evidence and arguments may also be presented at the hearing, where counsel may represent the laboratory at its own expense. **If a hearing is conducted and CMS' determination is upheld, the laboratory will be assessed a fee to cover the government's cost related to the hearing.** See 42 C.F.R. § 493.643(d)(2).

Please be advised that the determination as to which alternative sanction or sanctions to impose, including the amount of a Civil Money Penalty to impose per day or per violation, is not subject to appeal. See 42 C.F.R. § 493.1844(c)(4).

If a timely request for hearing is filed, i.e., by [DATE OF THIS NOTICE + 60 CALENDAR DAYS], CMS does not collect the Civil Money Penalty or revoke any type of CLIA certificate

until after an ALJ hearing that upholds CMS' sanction determination. However, the Directed Portion of a Plan of Correction and cancellation of all Medicare and Medicaid payments are effective [DATE], regardless of whether a hearing is requested. See 42 C.F.R. §§ 493.1844(d)(1)-(3) and 493.1844(h)(2). Please be advised that failure to comply with an alternative sanction is independent basis for suspension, limitation or revocation of any type of CLIA certificate.

The laboratory is reminded that the above sanctions cannot be avoided by the closure, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

When a laboratory's CLIA certificate is revoked, it is required to cease all patient laboratory testing, including waived and provider performed microscopy testing and regardless of whether or not the laboratory charges for the testing. Also, under revocation, 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) prohibit the owner(s) or operator(s) (including director – see 42 C.F.R. § 493.2) from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. This prohibition applies to the owner(s) as well as the director at the time that the deficiencies were found which led to the current sanction actions.

In accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the actions against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year in which the actions are imposed. In addition, pursuant to 42 C.F.R. § 493.1844(g)(1), we will notify the general public by means of a notice published in a local newspaper.

If you have any questions regarding this letter, please contact [STAFF NAME] of my staff at [TELEPHONE NUMBER].

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

cc: [DIRECTOR NAME] Via certified mail, return receipt # _____
[ADDRESS OTHER THAN LAB ADDRESS]
[CITY, STATE, ZIP]

[STATE AGENCY NAME]

16 RO (4/20/07) – sanction imposition IJ – IJ not removed – sanctions imposed

IMPORTANT NOTICE – PLEASE READ CAREFULLY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA # [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: IMPOSITION OF SANCTIONS – CONDITIONS OUT – IMMEDIATE JEOPARDY

Dear Director/Owner(s):

[NAME OF LABORATORY] was notified by our letter dated [DATE OF PROPOSED SANCTION NOTICE] of proposed sanctions against the laboratory's CLIA certificate based on the findings of immediate jeopardy and the laboratory's failure to meet all CLIA Conditions, and based on the failure by the owners and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the survey completed on [SURVEY DATE]. The laboratory was given ten days from the date of the [DATE OF PROPOSED SANCTION NOTICE] letter to submit information or written evidence as to why these sanctions should not be imposed.

Your laboratory responded with a submission on [DATE]. The submission consisted of [LIST WHAT WAS INCLUDED IN THE SUBMISSION].

We have carefully reviewed the entire [DATE OF SUBMISSION] submission and determined that your laboratory's allegation of compliance is not credible and evidence of correction is not acceptable. The evidence submitted shows that the laboratory continues to be out of compliance with CLIA requirements as cited during the [SURVEY DATE] survey and immediate jeopardy continues to exist.

Your laboratory's [DATE OF SUBMISSION] submission provides additional evidence of poor laboratory practice beyond what was cited at the survey and leads us to question the effectiveness of the laboratory's oversight mechanisms and the competency of personnel. The submission also fails to provide assurance of the laboratory's ability to provide accurate and reliable patient results.

As you were advised by the State agency in its [DATES OF SA LETTERS] letters, a credible allegation of compliance, as defined by the CLIA requirements at 42 C.F.R. § 493.2, is a statement or document that is:

- 1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
- 2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and

- 3) Indicates resolution of the problem.

It is important to note that for it to be credible, the allegation of compliance must be complete and address each of the deficiencies. For each deficiency, the allegation of compliance must include a corrective action date that is realistic in terms of the action being accomplished between the date of the survey and the planned date of completion. In addition, the allegation of compliance must contain information that indicates resolution of the problems.

As you were also advised by the State agency in its **[DATES OF SA LETTERS]** letters, the laboratory's allegation of compliance must be substantiated by acceptable evidence of correction, which must include:

- 1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- 2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- 3) What measure has been put into place or what systemic changes the laboratory has made to ensure that the deficient practice does not recur; and,
- 4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

For your information, the following details by deficiency tag (D-tag) why **[NAME OF LABORATORY]**'s **[DATE OF SUBMISSION]** submission does not constitute a credible allegation of compliance and acceptable evidence of correction.

[PROVIDE REVIEW OF SUBMISSION AND WHY NOT ACCEPTABLE.]

IMPOSED SANCTIONS

Accordingly, as the laboratory has failed to meet all CLIA Conditions and based on the failure of the owners and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the survey completed on **[Survey date]** which led to the determination of immediate jeopardy, we are taking action to impose the following sanctions against **[NAME OF LABORATORY]**'s CLIA certificate as proposed in our **[DATE OF SANCTION PROPOSAL NOTICE]** letter:

- **Revocation** of the laboratory's CLIA certificate effective **[DATE APPEAL PERIOD EXPIRES]**.
- **Suspension** of the laboratory's CLIA certificate effective **[DATE]**.
- **Civil Money Penalty** of \$10,000 per day for each day of non-compliance effective **[BEGIN DATE]** until **[END DATE]**, the date of suspension of the laboratory's CLIA certificate.
- **Directed Portion of a Plan of Correction** effective **[DATE]** – The laboratory is directed to submit to this office by **[DATE OF NOTICE + 10 CALENDAR DAYS]** a list of the names and addresses of all physicians and other clients who have used some or all of the

laboratory's services since **[DATE OF PRIOR SURVEY OR OTHER DATE AS APPROPRIATE]**. We request that this list be provided as an electronic file, in an EXCEL database format if possible. This list may be used to advise the laboratory's clients of the nature of its non-compliance and the nature and effective date of sanction actions imposed against the laboratory.

- **Cancellation of the laboratory's approval to receive Medicare payments** for any services performed on or after **[DATE]**. As a result, under section 1902 (a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), payment for all laboratory services under the Medicaid program, Title XIX of the Social Security Act, is no longer be available to the laboratory for any laboratory services performed on or after **[DATE]**. See 42 C.F.R. § 440.2(b).

Please refer to our **[DATE OF SANCTION PROPOSAL NOTICE]** letter for the laboratory's appeal rights and instructions on how to file an appeal. For an appeal request to be timely, it must be requested by no later than **[DATE APPEAL PERIOD EXPIRES]** as noted in the **[DATE OF SANCTION PROPOSAL NOTICE]** letter. If an appeal request is not filed, revocation of **[NAME OF LABORATORY]'s** CLIA certificate will be effective **[DATE APPEAL PERIOD EXPIRES]**.

We remind the laboratory that the determination that a laboratory's deficiencies pose immediate jeopardy is not subject to appeal. In addition, the determination as to which alternative sanction or sanctions to impose, including the amount of a Civil Money Penalty to impose per day or per violation, is not subject to appeal. See 42 C.F.R. § 493.1844(c)(4), (c)(6) and (c)(7).

If a timely request for hearing is filed, revocation of the laboratory's CLIA certificate will become effective following the administrative hearing decision, if our determination of non-compliance is upheld. However, suspension of the laboratory's CLIA certificate remains effective **[DATE OF SUSPENSION]**, and the Directed Portion of a Plan of Correction and cancellation of all Medicare and Medicaid payment remain effective **[DATE]**, regardless of whether a hearing is requested. See 42 C.F.R. 493.1844(d)(1)-(3) and 493.1844(h)(1). Please be advised that failure to comply with an alternative sanction is independent basis for suspension, limitation or revocation of any type of CLIA certificate.

In addition, if a timely hearing request is filed, the civil money penalty amount will not be collected until after the hearing decision is rendered. However, the \$10,000 per day accrues from **[CMP BEGIN DATE]** until the suspension of the laboratory's CLIA certificate.

The laboratory is reminded that the above sanctions cannot be avoided by the closure, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

We also remind the laboratory that as its CLIA certificate is suspended effective [Date], it is not permitted to perform any patient laboratory testing, including waived testing and regardless of whether or not the laboratory charges for the testing. (The laboratory may continue to perform parallel testing on patient specimens if needed to implement corrective actions.) However, the laboratory may not report any patient test results during the period when its CLIA certificate is suspended.

Also, under revocation, 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) prohibit the owner(s) or operator(s) (including director – see 42 C.F.R. § 493.2) from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. This prohibition applies to the owner(s) as well as the director at the time that the deficiencies were found which led to the current sanction action.

In accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the actions against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year in which the actions are imposed. In addition, pursuant to 42 C.F.R. § 493.1844(g)(1), we will notify the general public by means of a notice published in a local newspaper.

If you have any questions regarding this letter, please contact [**STAFF NAME**] of my staff at [**TELEPHONE NUMBER**].

Sincerely,

[**NAME/TITLE**]
[**BRANCH NAME**]
[**DIVISION NAME**]

cc: [**DIRECTOR NAME**] Via certified mail, return receipt # _____
[**ADDRESS OTHER THAN LAB ADDRESS**]
[**CITY, STATE, ZIP**]

[**STATE AGENCY NAME**]

17 RO (4/20/07) – Sanction Imposition – Subsequent Unsuccessful PT– evidence does not refute subsequent unsuccessful, sanctions imposed

IMPORTANT NOTICE – ACTION NECESSARY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA # [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: IMPOSITION OF SANCTIONS – UNSUCCESSFUL PARTICIPATION IN
PROFICIENCY TESTING – SUBSEQUENT OCCURRENCE

Dear Director and Owner(s):

By letter dated February 15, 2006, we proposed sanctions against [NAME OF LABORATORY] as a result of a subsequent occurrence of unsuccessful participation in proficiency testing in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY], which resulted in the determination of noncompliance with the Condition-level requirements of successful participation in proficiency testing and laboratory director. We provided the laboratory ten (10) days to submit in writing any evidence or information as to why these proposed sanctions should not be imposed.

In response, we received on [DATE SUBMISSION RECEIVED], the laboratory's submission under cover letter dated [SUBMISSION DATE]. The laboratory's [SUBMISSION DATE] submission consisted of [LIST WHAT WAS SUBMITTED].

Imposition of Sanctions Based on Unsuccessful Participation in Proficiency Testing – Subsequent Occurrence

Based on careful review of the laboratory's [SUBMISSION DATE] submission, we find no evidence to refute the subsequent occurrence of unsuccessful participation in proficiency testing in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY], which resulted in the determination of noncompliance with the Condition-level requirements of successful participation in proficiency testing and laboratory director.

As detailed on the form CMS-2567 under the Condition-level requirements at deficiency tag [LIST D-TAGS: I.E., D2016, D6000, D6076] the laboratory has a repeat history of unsatisfactory proficiency testing performance in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] constituting a subsequent occurrence of unsuccessful participation in proficiency testing as follows:

Proficiency Testing Event

PT Provider

Test

Score

[LIST UNSATISFACTORY EVENTS.]

The laboratory's [SUBMISSION DATE] submission provides no evidence to indicate that unsatisfactory proficiency testing performance for [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] did not occur for the [LIST PT EVENTS]. Accordingly, we are imposing the sanctions proposed in our [DATE OF SANCTION PROPOSAL NOTICE] letter against the laboratory's CLIA certificate, amended as follows:

- 42 C.F.R. §§ 493.803(b), 493.807, 493.1804(b)(1)(ii), 493.1806, and 493.1840(a)(3) – Principal Sanction: **Limitation** of the laboratory's CLIA certificate for the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] for not less than six months effective [LIMITATION DATE]. When a laboratory's CLIA certificate is limited in a specific [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty], the laboratory is not permitted to perform any patient testing in that [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty].*

The laboratory has sixty (60) days from the date of this notice, or until [DATE OF THIS NOTICE + 60 CALENDAR DAYS], in which to appeal the determination to limit its certificate in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY]. If the laboratory chooses not to file an appeal, limitation of its CLIA certificate in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] will become effective [LIMITATION DATE]. If a timely hearing request is received, limitation of the laboratory's CLIA certificate in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] will be effective with the date of the administrative hearing decision, if our determination of non-compliance is upheld.

[ADD THE FOLLOWING PARAGRAPH IF LIMITING AT ANALYTE LEVEL.]

Note: The laboratory must agree in writing to the limitation at the analyte level (i.e., [NAME OF ANALYTE]) so that the limitation is not imposed at the [CHOOSE AS APPROPRIATE: specialty, subspecialty] level (i.e., [NAME OF SPECIALTY OR SUBSPECIALTY]). See agreement enclosed.

*The laboratory is reminded that it may continue to perform parallel testing on patient specimens in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] if needed to implement corrective actions, however, the laboratory may not report any patient test results in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] during the period when its CLIA certificate is limited in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY].

- 42 C.F.R. §§ 493.1804(b)(1)(ii), 493.1804(b)(2), 493.1806(c)(1), 493.1832 and 493.1844(h)(2) – Alternative Sanction: **Directed Plan of Correction** effective [LIMITATION DATE] as stated in our [DATE OF SANCTION PROPOSAL NOTICE] letter, and amended as follows. The laboratory is directed to address any actual or potential negative patient outcome during the period of unsuccessful proficiency testing performance for the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] and submit acceptable evidence that this has been done within ten (10) calendar days from the date of this notice; (2) demonstrate that the laboratory has established an effective oversight mechanism to prevent recurrences of proficiency testing failure for all testing including testing in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] and submit acceptable evidence that such a mechanism has been implemented within ten (10) calendar days from this notice; and (3) demonstrate satisfactory performance in two consecutive proficiency testing events for the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] before the limitation of the laboratory's certificate in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] can be lifted. The laboratory may obtain the two consecutive proficiency testing events from any proficiency testing program approved by CMS for the calendar year.
- 42 C.F.R. §§ 493.804(b)(1)(ii), 493.1804(b)(2), 493.1806(c)(3), 493.1810(d), 493.1814, 493.1834, and 493.1844(h)(2) – Alternative Sanction: **Civil Money Penalty** effective [CMP EFFECTIVE DATE] (as stated in our notice dated [DATE OF SANCTION PROPOSAL NOTICE]) in the amount of \$3,000 per day of non-compliance until compliance is met (i.e., compliance with the Directed Plan of Correction above) or until the principal sanction of Limitation of the laboratory's CLIA certificate in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] is imposed (see imposed sanction of Limitation of the laboratory's certificate above). As you were advised in our [DATE OF SANCTION PROPOSAL NOTICE] letter, if the laboratory requests a hearing, the Civil Money Penalty amount will not be collected until after the hearing decision is rendered.
- 42 C.F.R. §§ 493.1804(b)(1)(ii), 493.1804(b)(2), 493.1807(b), 493.1808(b), 493.1826, 493.1844(d)(1), and 493.1844(h)(2) – Medicare Alternative Sanction: **Suspension of the laboratory's approval to receive Medicare payments** for any services performed in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] effective [LIMITATION DATE].

The laboratory must agree in writing (in return for not having its Medicare approval cancelled immediately) to not charge Medicare beneficiaries or their private insurance carriers for the services for which Medicare payment is suspended, i.e., in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY]. For your convenience, we are enclosing a statement to this effect for the laboratory's owner(s) to sign to be returned within ten (10) days from the date of this notice, or by [NOTICE DATE + 10 CALENDAR DAYS]. Failure to provide this written agreement by [NOTICE DATE + 10 CALENDAR DAYS] will

result in the cancellation of the laboratory's approval to receive Medicare payment for all laboratory services effective [**LIMITATION DATE**].

As a consequence of the suspension of the approval to receive Medicare, under section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), payment under the Medicaid program, Title XIX of the Social Security Act, will also no longer be available to the laboratory for all laboratory services performed in the [**CHOOSE AS APPROPRIATE**: analyte, specialty, subspecialty] of [**NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY**] effective [**LIMITATION DATE**]. See 42 C.F.R. § 440.2(b). Pursuant to 42 C.F.R. § 493.807, the suspension period for Medicare and Medicaid approval is for a period of not less than six months.

The laboratory is reminded that pursuant to 42 C.F.R. § 493.1840(a)(7), failure to comply with alternative sanctions is also a basis for limitation, suspension, or revocation of any type of CLIA certificate.

If a laboratory's CLIA certificate is revoked, it will be required to cease all patient laboratory testing, including waived testing or provider performed microscopy procedures, regardless of whether the laboratory charges for such testing. Also under revocation, 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 1840(a)(8) prohibit the owners or operators (including the laboratory director – see 42 C.F.R. § 493.2) from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. This prohibition applies to the owners and operators, as well as the laboratory director at the time the deficiencies were found which lead to the current sanction actions.

In accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the above imposed sanctions against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year in which the actions are imposed. In addition, pursuant to 42 C.F.R. § 493.1844(g)(1), we will notify the general public by means of a notice published in a local newspaper.

Appeal Rights

If [**NAME OF LABORATORY**] does not believe this determination to impose these actions against its CLIA certificate is correct, the laboratory may request a hearing before an administrative law judge (ALJ) of the Department Appeals Board in accordance with 42 C.F.R. § 493.1844(a)(1)-(2) and 42 C.F.R. Part 498. A written request for hearing must be filed no later than sixty (60) days from the date of this notice, or by [**DATE OF THIS NOTICE + 60 CALENDAR DAYS**] (see 42 C.F.R. § 493.1844(f)). Such a request may be made directly (accompanied by a copy of this letter) to:

Departmental Appeals Board
Civil Remedies Division
Attention: Oliver Potts
Cohen Building, Room G-644
330 Independence Ave, SW
Washington, D.C. 20201

A copy of the hearing request should be sent to:

[NAME OF RO MANAGER]
[NAME OF BRANCH]
[NAME OF DIVISION]
Centers for Medicare & Medicaid Services
[STREET ADDRESS]
[CITY, STATE ZIP]

The request for hearing must contain a statement as to the specific issues and findings of fact and conclusions of law in this determination with which the laboratory disagrees and the basis for the laboratory's contention that the specific issues and/or findings and conclusions are incorrect. Evidence and arguments may also be presented at the hearing, where counsel may represent the laboratory at its own expense. **If a hearing is conducted and CMS' determination is upheld, the laboratory will be assessed a fee to cover the government's cost related to the hearing.** See 42 C.F.R. § 493.643(d)(2).

As noted above, if a timely request for hearing is filed, i.e., by [DATE OF THIS NOTICE + 60 CALENDAR DAYS], CMS does not limit a laboratory's CLIA certificate or collect the Civil Money Penalty until after an ALJ hearing.

Please be advised that the determination as to which alternative sanction or sanctions to impose, including the amount of a Civil Money Penalty imposed per day or per violation, is not subject to appeal. See 42 C.F.R. § 493.1844(c)(4) and (c)(7). Pursuant to 42 C.F.R. § 1844(d)(1), the effective date of an alternative sanction (other than a civil money penalty) is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending. As noted above, failure to comply with alternative sanctions is basis for suspension, limitation, or revocation of any type of CLIA certificate. See 42 C.F.R. § 493.1840(a)(7).

If you have any questions regarding this letter, please contact [STAFF NAME] of my staff at [TELEPHONE NUMBER].

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

Enclosure: Agreement

cc: [DIRECTOR NAME] Via certified mail, return receipt # _____
[ADDRESS OTHER THAN LAB ADDRESS]
[CITY, STATE, ZIP]

[STATE AGENCY NAME]

AGREEMENT

I am the [**CHOOSE AS APPROPRIATE**: owner, director] of [**NAME OF LABORATORY**] located at [**LABORATORY ADDRESS**], CLIA number [**CLIA NUMBER**].

I understand and agree that the sanction of suspension of [**NAME OF LABORATORY**]'s approval to receive Medicare payment for the analyte [**NAME OF ANALYTE**] is imposed effective [**LIMITATION DATE**] for a period of six months.

By my signature below, [**NAME OF LABORATORY**] agrees (in return for not having its Medicare approval cancelled immediately or its Medicare approval suspended on [**LIMITATION DATE**] for the [**CHOOSE AS APPROPRIATE**: specialty, subspecialty] of [**NAME OF SPECIALTY, SUBSPECIALTY**]) not to charge Medicare beneficiaries or their private insurance carriers for laboratory services in the analyte of [**NAME OF ANALYTE**] for the duration of the six-month suspension of Medicare for this analyte as stated above.

[**NAME OF LABORATORY**] also agrees to the limitation of its CLIA certification for the analyte of [**NAME OF ANALYTE**], due to unsuccessful participation in proficiency testing, for the duration of the six-month suspension of Medicare for this analyte as stated above in order that limitation is not imposed for the [**CHOOSE AS APPROPRIATE**: specialty, subspecialty] of [**NAME OF SPECIALTY, SUBSPECIALTY**]. This means [**NAME OF LABORATORY**] agrees to not perform any patient testing (for both Medicare and non-Medicare patients) in the analyte of [**NAME OF ANALYTE**] during this same six-month period. After the six-month period, [**NAME OF LABORATORY**] agrees to notify CMS to apply for reinstatement and be granted CMS approval prior to resuming testing in and receiving Medicare/Medicaid reimbursement for this analyte.

[**NAME OF LABORATORY**] understands and agrees that the alternative sanction of a Civil Money Penalty in the amount of \$3,000 per day of non-compliance until compliance is met or until the principal sanction of Limitation of the laboratory's CLIA certificate in the analyte of [**NAME OF ANALYTE**] has been imposed effective [**CMP EFFECTIVE DATE**]. [**NAME OF LABORATORY**] also understands that pursuant to 42 C.F.R. § 493.1840(a)(7), failure to pay the Civil Money Penalty once it becomes final will be the basis for suspension or revocation of its CLIA certificate.

I understand that failure to provide this written agreement by [**NOTICE DATE + 10 DAYS**] will result in the automatic cancellation of the laboratory's approval to receive Medicare payment for all laboratory services effective [**LIMITATION DATE**]. I also understand that signing this agreement does not affect the laboratory's appeal rights in connection with this sanction action.

In addition, I understand that pursuant to 42 C.F.R. § 493.1840(a)(7) violation of this agreement will result in the immediate revocation of [**NAME OF LABORATORY**]'s CLIA certificate under 42 C.F.R. § 493.1840(a)(1) and pursuant to 42 C.F.R. § 493.1826(a)(1)(ii) in the immediate cancellation of the laboratory's approval to receive Medicare payments for all laboratory services.

Signature

Date

Print Name and Title

Contact address other than laboratory address

Contact telephone number

Contact FAX number

IMPORTANT NOTICE – PLEASE READ CAREFULLY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA # [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: IMPOSITION OF SANCTIONS – IMPROPER PROFICIENCY TESTING REFERRAL

Dear Director and Owner(s):

You were notified by our letter dated [DATE OF SANCTION PROPOSAL NOTICE] of proposed sanctions against your laboratory's CLIA certificate. You were given ten days from the date of the letter in which to submit information or written evidence as to why these proposed sanctions should not be imposed.

On [DATE], we received your response dated [DATE]. We have carefully reviewed and considered your response and find that your submission has no effect on our sanction determination, as it does not remove the basis of our sanction action.

We remind you that the basis for our sanction determination against your laboratory's CLIA certificate is the improper referral of your laboratory's proficiency testing samples to another laboratory for analysis. Based on the CLIA requirements, the referral of your laboratory's proficiency testing samples alone, with or without the direct communication of the other laboratory's test result to your laboratory, requires CMS to take sanction actions as proposed. Your [DATE] submission does not show that your laboratory did not engage in improper referral of your laboratory's proficiency testing samples to another laboratory for analysis. [ADD IF APPLICABLE: In fact, your submission confirms the validity of the information we had already received from [NAME OF AO], your laboratory's former accrediting organization, and from the [NAME OF STATE AGENCY] (the State agency).]

[FOLLOWING 4 PARAGRAPHS ARE OPTIONAL:]

A recent decision by the HHS Departmental Appeals Board (DAB) (Lackawanna Medical Group Laboratory v. CMS, Decision No. CR957) underscores the special care a laboratory must take in managing and overseeing its proficiency testing. In this case, the laboratory alleged that its quality control program required that when it sent samples for parallel testing at another laboratory, it included proficiency test samples with its regular patient workload. The laboratory only reported the results of its own testing of proficiency testing samples to the proficiency testing program and not the results of parallel testing by the other laboratory.

The DAB ruled that sending proficiency testing samples to another laboratory, either intentionally or unintentionally, constitutes a violation of 42 C.F.R. § 493.801(b)(4) and the statute at 42 U.S.C. § 263a(i)(4). Because of this, the DAB concluded that CMS “is required to revoke” the laboratory’s CLIA certificate. The DAB added that:

“The regulation establishes an absolute bar to sending proficiency test samples to another laboratory for testing if the sending laboratory is certified to do the same testing. . .The statute and regulations allow for no exceptions to the prohibition. Thus, the motives of the laboratory that sends proficiency test samples to another laboratory for analysis that the sending laboratory is certified to perform, are irrelevant.

The fact that the sending laboratory never reports the analysis of the proficiency samples to the proficiency program is not mentioned by the statutes or regulations as an exception or defense to the prohibition, and is also irrelevant.”]

In the case of your laboratory, a review of the proficiency test results obtained from the other laboratory indicates close agreement with those proficiency test results derived by your laboratory and reported to the proficiency test provider. There is a strong possibility that if the test results had differed significantly, knowledge of the other laboratory’s test results would have affected and, perhaps, changed the proficiency testing results your laboratory reported. The close agreement between the test results precluded any need for your testing person to immediately communicate the other laboratory’s test results to your laboratory.

[INCLUDE HERE ANY FURTHER DETAILS]

Sanctions Imposed

Accordingly, we are taking action to impose sanctions as proposed in our **[DATE OF SANCTION PROPOSAL NOTICE]** letter, with effective dates as follows:

- **Revocation** of the laboratory’s CLIA certificate effective **[DATE APPEAL PERIOD EXPIRES]**.
- **Civil Money Penalty** of \$3,000 per occurrence for each instance in which the laboratory engaged in improper proficiency testing referral activities for a total of **[NUMBER OF OCCURRENCES X \$3,000.00]**.
- **Directed Portion of a Plan of Correction** effective **[DATE]** – The laboratory is directed to submit to this office within ten calendar days from the date of this notice, or by **[DATE OF NOTICE + 10 CALENDAR DAYS]**, a list of the names and addresses of all physicians and other clients who have used some or all of the laboratory’s services from **[DATE OF PRIOR SURVEY OR OTHER DATE AS APPROPRIATE]** to the present date. This list may be used to advise the laboratory’s clients of the nature of the laboratory’s non-compliance and the nature and effective date of any sanction actions imposed against the laboratory.
- **Cancellation of your laboratory’s approval to receive Medicare and Medicaid payments** for any services performed on or after **[DATE]**.

Please refer to our **[DATE OF SANCTION PROPOSAL NOTICE]** letter for the laboratory’s appeal rights and instructions on how to file an appeal. For an appeal request to be timely, it must be

requested by no later than **[DATE APPEAL PERIOD EXPIRES]** as noted in the **[DATE OF SANCTION PROPOSAL NOTICE]** letter. If an appeal request is not filed, revocation of **[NAME OF LABORATORY]**'s CLIA certificate will be effective **[DATE APPEAL PERIOD EXPIRES]**.

As you were previously advised, if a timely request for hearing is filed, i.e., by **[DATE APPEAL PERIOD EXPIRES]**, CMS does not collect the Civil Money Penalty or revoke any type of CLIA certificate until after an ALJ hearing that upholds the revocation. However, the cancellation of all Medicare and Medicaid payment and the Directed Portion of a Plan of Correction will be effective **[DATE]**, regardless of whether a hearing is requested. See 42 C.F.R. § 493.1844(d)(1), § 493.1844(d)(3), and § 493.1844(h)(2).

Please be reminded that pursuant to 42 C.R.R. § 493.1844(c)(4) and (c)(7), the determination as to which alternative sanction(s) to impose, including the amount of a Civil Money Penalty to impose per day or per violation, is not subject to appeal. Also, pursuant to 42 C.F.R. § 493.1840(a)(7), failure to comply with alternative sanctions is an additional basis to suspend and/or revoke the laboratory's CLIA certificate.

When **[NAME OF LABORATORY]**'s CLIA certificate is revoked, it is required to cease all patient laboratory testing, including waived testing or provider performed microscopy procedures, regardless of whether the laboratory charges for such testing. Also, pursuant to 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), the owner and operator (including the director) of the laboratory will be prohibited from owning or operating (including directing) any laboratory for at least two years from the date of the revocation.

In accordance with the regulation at 42 C.F.R. § 493.1850(a)(4), information regarding the actions against **[NAME OF LABORATORY]**'s CLIA certificate will appear in the Laboratory Registry for the calendar year in which the action is imposed. Pursuant to 42 C.F.R. § 493.1844(g)(1), we will notify the general public by means of a notice published in a local newspaper in your area when these actions become effective as referenced above. In addition, we will notify the Office of Inspector General that the laboratory referred its proficiency testing samples to another laboratory for analysis, as required by the regulation at 42 C.F.R. § 493.1840(f).

If you have any questions regarding this letter, please contact **[STAFF NAME]** of my staff at **[PHONE NUMBER]**.

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

cc: **[DIRECTOR NAME]** Via certified mail, return receipt # _____
[ADDRESS OTHER THAN LAB ADDRESS]
[CITY, STATE, ZIP]
[STATE AGENCY NAME]

IMPORTANT NOTICE – ACTION NECESSARY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA # [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: SANCTIONS FINAL

Dear Director and Owner(s):

You were notified by letter dated [DATE] of the imposition of sanctions against [NAME OF LABORATORY]. You were advised that the laboratory had sixty (60) days to appeal CMS' determination. The appeal period expired on [DATE] and we did not receive a request for appeal.

Accordingly, the sanction action against [NAME OF LABORATORY] is final. Cancellation of the laboratory's approval to receive Medicare and Medicaid payments effectuated [DATE] remains in effect. The revocation of [NAME OF LABORATORY]'s CLIA certificate is effective [DATE], the date the appeal period expired.

Since the laboratory's CLIA certificate has been revoked, the laboratory is required to cease all patient testing including waived and provided performed microscopy testing and regardless of whether the laboratory charges for the testing. Please be advised that any person who intentionally violates the mandates of CLIA shall be subject to imprisonment, or fines, or both. See 42 U.S.C. § 263a(1).

Due to the revocation of [NAME OF LABORATORY]'s CLIA certificate, you, as the owner(s) and/or director of the laboratory at the time it was found to be in non-compliance, are barred from owning, operating or directing any laboratory, in fact or by proxy, for a period of two years from the date of the revocation, or until [REVOCAION DATE + 2 YEARS]. See U.S.C. § 263a(i)(3) and 42 C.F.R. § 1840(a)(8).

Before you can be reinstated into the CLIA program as an owner, operator, or director of any laboratory, you must first apply for reinstatement [USE IF APPLICABLE: directly to the CMS Regional Office] and the laboratory you seek to own, operate or direct must submit to a survey and be found in compliance with all applicable CLIA requirements prior to being certified to perform any testing. You must provide reasonable assurance that the deficient practices that resulted in the current sanction action will not recur before we can reinstate you into the CLIA program as a laboratory owner, operator or director.

You are directed to provide us with the names, addresses, and CLIA numbers of all laboratories of which you are owner, operator or director as of the revocation date of [REVOCAION DATE]. In addition, you must take action immediately to remove yourself from that position(s) and provide us evidence that this has been accomplished. Please complete, sign, and date the enclosed attestation and return it along with evidence as referenced above to our office within 15 days from the date of this

notice, or by **[NOTICE DATE + 15 CALENDAR DAYS]**. If you do not own, operate, or direct any other laboratory, please so indicate on the attestation, and sign, date, and return to our office by **[NOTICE DATE + 15 CALENDAR DAYS]**.

As required by 42 U.S.C. § 263(a)(n) and 42 C.F.R. § 493.1850(a)(2), information regarding the sanctions imposed against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year of its revocation. A notice of imposed sanctions will also be published in a local newspaper in your area. See 42 C.F.R. § 493.1844(g)(1).

If you have any questions regarding this letter, please contact **[STAFF NAME]** of my staff at **[TELEPHONE NUMBER]**.

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

Enclosures: Attestation

cc: **[DIRECTOR NAME]** Via certified mail, return receipt # _____
[ADDRESS OTHER THAN LAB ADDRESS]
[CITY, STATE, ZIP]

[STATE AGENCY NAME]

20 RO – Sanctions Final – Conditions out, IJ or non-IJ – hearing not requested, dismissed or upheld – sanctions final, option 1) demand CMP – director is owner; and option 2) director is not owner

IMPORTANT NOTICE – PLEASE READ CAREFULLY

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[TODAY'S DATE]

[DIRECTOR NAME], M.D., Director

[OWNER NAME], Owner(s)

[LAB NAME]

[ADDRESS]

CLIA # [CLIA NUMBER]

[CITY], [STATE] [ZIP]

RE: SANCTIONS FINAL [ADD IF DEMANDING CMP WITH THIS LETTER: – CMP CASE NUMBER XXXX-XX-LAB-XXX]

Dear Director and Owner(s):

You were notified by letter dated [DATE] of the imposition of sanctions against [NAME OF LABORATORY]. The sanction action was based on the finding of Condition-level non-compliance [ADD IF APPLICABLE: that resulted in the determination of immediate jeopardy to patient health and safety]. You were advised that the laboratory had sixty (60) days to appeal the sanction determination.

[IF HEARING NOT REQUESTED, USE THE FOLLOWING PARAGRAPH:

The appeal period expired on [DATE] and we did not receive a request for appeal. With the expiration of the appeal period, the sanction action against [NAME OF LABORATORY] is final.]

[IF HEARING DISMISSED, USE FOLLOWING 2 PARAGRAPHS:

By letter dated [DATE], the laboratory requested a hearing. This request was forwarded to the Departmental Appeals Board (DAB) on [DATE].

Subsequently, the laboratory [CHOOSE ONE OR STATE REASON FOR DISMISSAL: withdrew, failed to pursue] the hearing request. Based on [CHOOSE ONE OR STATE REASON FOR DISMISSAL: the withdrawal, failure to pursue], the Administrative Law Judge (ALJ) issued a dismissal order on [DATE]. With the hearing dismissal, our sanction determination against the laboratory is final.]

[IF HEARING UPHeld, USE FOLLOWING 2 PARAGRAPHS:

By letter dated [DATE], the laboratory requested a hearing. This request was forwarded to the Departmental Appeals Board (DAB) on [DATE].

The administrative Law Judge (ALJ) issued a written decision on [DATE] upholding the sanction determination against [NAME OF LABORATORY], including revocation of its CLIA certificate. With the ALJ decision, our sanction determination against the laboratory is final.]

[CONTINUE FOR ALL SITUATIONS AND ADD OR DELETE SANCTIONS AS APPLICABLE TO THE CASE.]

Accordingly, the Directed Portion of a Plan of Correction effectuated by our sanction imposition letter dated [DATE] to submit to this office a list of names and addresses of all physicians, providers, suppliers and other clients (including patients) who have used some or all of the laboratory's services from [DATE] to the present date remains in effect. Cancellation of the laboratory's approval to receive Medicare and Medicaid payments effectuated [DATE] also remains in effect. The Civil Money Penalty totaling [CMP AMOUNT] as imposed by our letter dated [DATE] is now final. The revocation of [NAME OF LABORATORY]'s CLIA certificate is effective [DATE], the date [CHOOSE ONE: the appeal period expired, of the ALJ decision, the ALJ dismissed the case].

[INCLUDE FOLLOWING LANGUAGE IF APPLICABLE: We have yet to receive the laboratory's list as instructed by the Directed Portion of a Plan of Correction. We remind you that this list may be used to advise the laboratory's clients of the nature of the laboratory's non-compliance and the nature and effective dates of any sanction actions imposed against the laboratory.]

[OPTION 1 – USE THE FOLLOWING PARAGRAPH IF DIRECTOR IS NOT OWNER:

Please note that instructions for payment of the Civil Money Penalty will be sent to the owner(s) under separate cover. [SEE LETTER 22 RO – CIVIL MONEY PENALTY DEMAND LETTER.]]

[OPTION 2 – USE THE FOLLOWING 3 PARAGRAPHS IF DIRECTOR IS OWNER:

As noted above, the Civil Money Penalty due is [CMP AMOUNT]. The Civil Money Penalty is due and payable on [NOTICE DATE + 15 DAYS]. Please note that interest is assessed, in accordance with the regulation at 42 C.F.R. § 493.1834(i), on the unpaid balance of the penalty beginning on the due date of [NOTICE DATE + 15 DAYS]. If the Civil Money Penalty is not received by [NOTICE DATE + 15 DAYS], interest will be assessed at the rate of [CURRENT INTEREST RATE] on the outstanding balance for every 30-day period for which it remains unpaid.

Please remit the total due of [CMP AMOUNT] by [NOTICE DATE + 15 DAYS]. Your check should be made out to "CMS Laboratory Program." To assure proper crediting of the payment, please be sure to include the Civil Money Penalty case number [XXXX-XX-LAB-XXX] on the face of the check and remit to:

Centers for Medicare and Medicaid Services
Division of Premium Billing & Collections
Civil Money Penalty

P.O. Box 7520
Baltimore, MD 21207-0520

We are also requesting that a photocopy of the check be sent to:

[NAME OF RO MANAGER]

[NAME OF BRANCH]
[NAME OF DIVISION]
Centers for Medicare & Medicaid Services
[STREET ADDRESS]
[CITY, STATE ZIP]]

[CONTINUE FOR ALL SITUATIONS.]

Since the laboratory's CLIA certificate has been revoked, the laboratory is required to cease all patient laboratory testing, including waived and provided performed microscopy testing and regardless of whether the laboratory charges for the testing. Please be advised that any person who intentionally violates the mandates of CLIA shall be subject to imprisonment, or fines, or both. See 42 U.S.C. § 263a(1).

Due to the revocation of [NAME OF LABORATORY]'s CLIA certificate, you, as the owner(s) and/or director of the laboratory at the time it was found to be in non-compliance, are barred from owning, operating or directing any laboratory, in fact or by proxy, for a period of two years from the date of the revocation, or until [DATE]. See U.S.C. § 263a(i)(3) and 42 C.F.R. § 1840(a)(8).

Before you can be reinstated into the CLIA program as an owner, operator, or director of any laboratory, you must first apply for reinstatement [USE IF APPLICABLE: directly to the CMS Regional Office] and the laboratory you seek to own, operate or direct must submit to a survey and be found in compliance with all applicable CLIA requirements prior to being certified to perform any testing. You must provide reasonable assurance that the deficient practices that resulted in the current sanction action will not recur before we can reinstate you into the CLIA program as a laboratory owner, operator or director.

You are directed to provide us with the names, addresses, and CLIA numbers of all laboratories of which you are owner, operator or director as of the revocation date of [DATE]. In addition, you must take action immediately to remove yourself from that position(s) and provide us evidence that this has been accomplished. Please complete, sign, and date the enclosed attestation and return it along with evidence as referenced above to our office within 15 calendar days from the date of this notice, or by [NOTICE DATE + 15 CALENDAR DAYS]. If you do not own, operate, or direct any other laboratory, please so indicate on the attestation, and sign, date, and return to our office by [NOTICE DATE + 15 CALENDAR DAYS].

As required by 42 U.S.C. § 263(a)(n) and 42 C.F.R. § 493.1850(a)(2), information regarding the sanctions imposed against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year of its revocation. A notice of imposed sanctions will also be published in a local newspaper in your area. See 42 C.F.R. § 493.1844(g)(1). [ADD FOLLOWING SENTENCE IF APPLICABLE: In addition, we will notify the Office of Inspector General that the laboratory engaged in improper proficiency testing referral activities, as required by the regulation at 42 C.F.R. § 493.1840(f).]

If you have any questions regarding this letter, please contact [STAFF NAME] of my staff at [TELEPHONE NUMBER].

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

Enclosures: Director Attestation
Owner Attestation (s)

cc: **[IF DIRECTOR IS NOT OWNER, CC DIRECTOR AT ADDRESS OTHER
THAN LAB ADDRESS:**

[DIRECTOR NAME] Via certified mail, return receipt # _____

[ADDRESS OTHER THAN LAB ADDRESS]

[CITY, STATE, ZIP]]

[STATE AGENCY NAME]

21 RO (4/20/07) – Sanctions Final – subsequent unsuccessful PT, appeal period expired, lab does not file an appeal, sanctions final

IMPORTANT NOTICE – PLEASE READ CAREFULLY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

[NAME], M.D., Director/Owner

[LAB NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

CLIA # [CLIA NUMBER]

RE: SANCTIONS FINAL – CMP CASE NUMBER [XXXX-XX-LAB-XXX]

Dear Director/Owner:

By letter dated [DATE OF SANCTION IMPOSITION NOTICE], we imposed sanctions against [NAME OF LABORATORY] as a result of a subsequent occurrence of unsuccessful participation in proficiency testing for the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY]. We notified your laboratory that it had 60 days, or until [DATE OF SANCTION IMPOSITION NOTICE + 60 CALENDAR DAYS], to appeal the imposition of sanctions. The appeal period has ended and we did not receive an appeal request from you.

Accordingly, the sanction action against [NAME OF LABORATORY] is final. The following sanctions as imposed by our letter dated [DATE OF SANCTION IMPOSITION NOTICE] remain in effect: Limitation of the laboratory's CLIA certificate for the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] for not less than six months effective [LIMITATION DATE]; a Directed Plan of Correction effective [LIMITATION DATE]; a Civil Money Penalty effective [CMP EFFECTIVE DATE] in the amount of \$3,000 per day of non-compliance (i.e., with the Directed Plan of Correction) or until the principal sanction of Limitation of the laboratory's CLIA certificate in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] goes into effect, for a total of [TOTAL CMP AMOUNT]; and Suspension of the laboratory's approval to receive Medicare and Medicaid payments for laboratory services performed in the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] effective [LIMITATION DATE].

[IF APPLICABLE, INDICATE LAB'S COMPLIANCE STATUS WITH DPOC, FOR EXAMPLE: Based on your laboratory's submissions subsequent to our sanction proposal notice, we have determined that your laboratory has complied with parts 1 and 2 of the Directed Plan of Correction and has yet to comply with part 3, i.e., demonstrate satisfactory PT performance in two consecutive proficiency testing events for the [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] of [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY] before the laboratory can resume testing for [CHOOSE AS APPROPRIATE: analyte, specialty, subspecialty] [NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY].] [ADD THE FOLLOWING SENTENCE IF APPROPRIATE: In addition, we acknowledge receipt of the signed agreement from the laboratory that, in return for not having its Medicare approval cancelled immediately, it will not charge Medicare

beneficiaries or their private insurance carriers for the services for which Medicare payment is suspended, i.e., in the [**CHOOSE AS APPROPRIATE**: analyte, specialty, subspecialty] of [**NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY**].]

The Civil Money Penalty is due and payable on [**NOTICE DATE + 15 CALENDAR DAYS**]. Please note that interest is assessed, in accordance with the regulation at 42 C.F.R. § 493.1834(i), on the unpaid balance of the penalty beginning on the due date of [**NOTICE DATE + 15 CALENDAR DAYS**]. If the Civil Money Penalty is not received by [**NOTICE DATE + 15 CALENDAR DAYS**], interest will be assessed at the rate of [**CURRENT INTEREST RATE**] on the outstanding balance for every 30-day period for which it remains unpaid.

Please remit the total due of [**CMP AMOUNT**] by [**NOTICE DATE + 15 CALENDAR DAYS**]. Your check should be made out to “CMS Laboratory Program.” To assure proper crediting of the payment, please be sure to include the Civil Money Penalty case number [**XXXX-XX-LAB-XXX**] on the face of the check and remit to:

Centers for Medicare and Medicaid Services
Division of Premium Billing & Collections
Civil Money Penalty
P.O. Box 7520
Baltimore, MD 21207-0520

We are also requesting that a copy of the check be sent to:

[**NAME OF RO MANAGER**]
[**NAME OF BRANCH**]
[**NAME OF DIVISION**]
Centers for Medicare & Medicaid Services
[**STREET ADDRESS**]
[**CITY, STATE ZIP**]

We caution the laboratory to maintain compliance with the CLIA requirements for successful participation in proficiency testing. Any future repeat proficiency testing failures would be basis for immediate sanction action to limit, suspend, or revoke the laboratory’s CLIA certificate.

After the limitation period of six months, i.e., after [**LIMITATION DATE + 6 MONTHS**], if the laboratory wishes to resume testing for the [**CHOOSE AS APPROPRIATE**: analyte, specialty, subspecialty] of [**NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY**], the laboratory must contact CMS to apply for reinstatement. The laboratory will be requested to submit written evidence that Part 3 of the directed plan of correction has been met and CMS will determine at that time whether an on-site survey is needed to determine whether compliance was sustained prior to reinstatement.

If you have any questions regarding this letter, please contact [**STAFF NAME**] of my staff at [**TELEPHONE NUMBER**].

Sincerely,

[**NAME/TITLE**]

[BRANCH NAME]
[DIVISION NAME]

cc: **[STATE AGENCY NAME]**

IMPORTANT NOTICE – ACTION NECESSARY

[TODAY'S DATE]

Via facsimile to [xxx xxx-xxxx] and first class mail.
(Confirmation of successful transmission of facsimile
constitutes proof of receipt.)

[OWNER NAME], Owner(s)

[LAB NAME]

CLIA # [CLIA NUMBER]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: CIVIL MONEY PENALTY PAYMENT DEMAND LETTER - CASE NUMBER [XXXX-XX-LAB-XXX]

Dear Owner(s):

In accordance with the statutory provisions of section 353(h) of the U.S. Public Health Service Act and the regulations at 42 C.F.R. § 493.1834, a Civil Money Penalty was imposed on [NAME OF LABORATORY], [CLIA NUMBER] for not meeting CLIA requirements. Please refer to the enclosed final sanction letter [ADD IF APPLICABLE: effectuating the ALJ decision of [ALJ DECISION DATE].]

This is to inform you that the Civil Money Penalty imposed by letter dated [DATE OF SANCTION IMPOSITION NOTICE] is due and payable on [NOTICE DATE + 15 CALENDAR DAYS]. The total of the Civil Money Penalty is [CMP AMOUNT]. [USE FOLLOWING SENTENCE IF PER DAY: This total represents the daily amount of [AMOUNT OF CMP PER DAY] for [NUMBER OF DAYS ACCRUED] days of the penalty accrual from [CMP BEGIN DATE] through [CMP END DATE]. [USE FOLLOWING SENTENCE IF PER VIOLATION: This total represents the per violation amount of [AMOUNT] for the total number of [NUMBER] violations.]

The Civil Money Penalty is payable by check. Please note that interest is assessed in accordance with the regulations at 42 C.F.R. § 493.1834(i), on the unpaid balance beginning on the due date of [NOTICE DATE + 15 CALENDAR DAYS]. If the Civil Money Penalty is not received by [NOTICE DATE + 15 CALENDAR DAYS], interest will be assessed at the annual rate of [CURRENT INTEREST RATE] on the outstanding principal balance for every 30-day period for which it remains unpaid. If you are unable to pay the entire amount at this time, please notify this office immediately so that we may determine if you are eligible for installment payments.

Please remit the total due of [CMP AMOUNT] by [NOTICE DATE + 15 CALENDAR DAYS]. Your check should be made out to "CMS Laboratory Program." To assure proper crediting of the payment, please be sure to include the Civil Money Penalty case number [XXXX-XX-LAB-XXX] on the face of the check and remit to:

Centers for Medicare and Medicaid Services
Division of Premium Billing & Collections
Civil Money Penalty
P.O. Box 7520
Baltimore, MD 21207-0520

We are also requesting that a photocopy of the check be sent to:

[NAME OF RO MANAGER]
[NAME OF BRANCH]
[NAME OF DIVISION]
Centers for Medicare & Medicaid Services
[STREET ADDRESS]
[CITY, STATE ZIP]

You must pay all outstanding Civil Money Penalty amounts, including any applicable interest, before you can be reinstated into the CLIA program in the capacity of owner, operator or director of any laboratory after the prohibition period.

If you have any questions regarding this letter, please contact **[STAFF NAME]** of my staff at **[TELEPHONE NUMBER]**.

Sincerely,

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

Enclosure: Sanctions Final Letter

cc: **[STATE AGENCY NAME]**

ATTESTATION

By my signature below, I, _____, [CHOOSE ONE: director, owner] of [NAME OF LABORATORY] located at [ADDRESS], [CLIA NUMBER], am attesting that [NAME OF LABORATORY] has ceased operations as of the revocation date of [REVOCAION DATE]. I understand that effective [REVOCAION DATE] the laboratory may not perform patient laboratory testing, including waived testing and provider performed microscopy procedures, regardless of whether it charges for such testing. I am also attesting to the following (please check one and complete as appropriate):

_____ As of [REVOCAION DATE] that [NAME OF LABORATORY]'s CLIA certificate was revoked; I was owner, operator, and/or director of the following laboratories:

<u>Name</u>	<u>Address</u>	<u>CLIA Number</u>	<u>Position</u>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

_____ I have removed myself from the position of owner, operator and/or director of the above laboratories effective _____ and am submitting evidence of having so removed myself along with this signed attestation by [NOTICE DATE + 15 CALENDAR DAYS].

_____ As of [REVOCAION DATE], the date that [NAME OF LABORATORY]'s CLIA certificate was revoked, I was not the owner, operator, and/or director of any laboratory other than [NAME OF LABORATORY]. I am returning this signed attestation by [NOTICE DATE + 15 CALENDAR DAYS].

[USE FOLLOWING PARAGRAPH FOR DIRECTOR:]

Due to the revocation of [NAME OF LABORATORY], I understand that I am prohibited from owning or operating (including directing), in fact or by proxy, any laboratory, including laboratories performing only waived testing or provider performed microscopy procedures, until at least [REVOCAION DATE + 2 YEARS]. I further understand that before I can be reinstated into the CLIA program as an owner, operator, or director of any laboratory, I must first apply for reinstatement [USE IF APPLICABLE: directly to the CMS Regional Office], and the laboratory I seek to own, operate or direct must submit to a survey and be found in compliance with all applicable CLIA requirements. In addition, I understand that any person who intentionally violates the requirements of CLIA shall be subject to imprisonment, fine, or both. See 42 U.S.C. § 263a(l).]

[USE FOLLOWING PARAGRAPH FOR OWNER:]

Due to the revocation of [NAME OF LABORATORY]'s CLIA certificate, I understand that 1) I am prohibited from owning or operating (including directing), in fact or by proxy, any laboratory, including laboratories performing only waived testing or provider performed microscopy procedures, until at least

[**REVOCAION DATE + 2 YEARS**]; 2) before I can be reinstated into the CLIA program as an owner, operator, or director of any laboratory, I must first apply for reinstatement [**USE IF APPLICABLE:** directly to the CMS Regional Office], and the laboratory I seek to own, operate or direct must submit to a survey and be found in compliance with all applicable CLIA requirements; 3) I must pay all outstanding Civil Money Penalty amounts including any applicable interest before I can be reinstated into the CLIA program in the capacity of owner, operator or director of any laboratory. In addition, I understand that any person who intentionally violates the requirements of CLIA shall be subject to imprisonment, fine, or both. See 42 U.S.C. § 263a(l).]

Signature

Name

Date

Contact address other than laboratory address

Contact telephone number

24 RO (4/20/07) – Sanction – Public Notice Request – sanctions final, request newspaper publication of public notice

[DATE]

[NAME OF CONTACT]

Advertising Placement Coordinator

Newspaper Service Bureau

[ADDRESS]

[CITY, STATE, ZIP CODE]

Dear **[NAME OF CONTACT]**:

With reference to Purchase Order (PO) _____, we are requesting that the enclosed newspaper advertisement be published as follows:

NAME OF PAPER: **[NEWSPAPER NAME]**

DATE TO BE PUBLISHED: **Next available date**

SUBJECT: **[SANCTIONS TO BE PUBLISHED, FOR EXAMPLE: Revocation of CLIA Certificate/Cancellation of Medicare Payment]** for **[NAME OF LABORATORY]**,
CLIA number [CLIA NUMBER]

STAFF PERSON/PHONE NUMBER: **[STAFF NAME] / [TELEPHONE NUMBER]**

ADVERTISING ORDER (AO) NUMBER: **[AO NUMBER]**

In all billing and/or correspondence, please refer to the Purchase Order listed above and the appropriate Advertising Order number for this particular ad. Please mail all invoices as well as proof of publication to the Centers for Medicare and Medicaid Services, ATTN: **[NAME OF ADMINISTRATIVE OFFICER]**, **[RO ADDRESS, CITY, STATE, ZIP]**.

If you have any questions, please contact **[STAFF NAME]** at **[TELEPHONE NUMBER]**. Thank you.

Sincerely yours,

[NAME]

Administrative Officer

Enclosure

[NAME], Manager

[BRANCH]

[DIVISION]

[NEWSPAPER NAME]

ATTENTION: LEGAL ADVERTISING DEPARTMENT

NEWSPAPER NOTICE

Print in Public Notice Section of Newspaper

**CLIA Notice to the Public
Sanctions against [NAME OF LABORATORY]
CLIA certificate number [CLIA NUMBER]**

Notice is hereby given that the Secretary of the United States Department of Health and Human Services imposed under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) the following principal sanctions against the above laboratory located at **[ADDRESS, CITY STATE, ZIP]: [LIST SANCTION SUCH AS** revocation of its CLIA certificate] effective **[DATE]; [LIST SANCTION SUCH AS** suspension or limitation of its CLIA certificate] effective **[DATE]; [LIST SANCTION SUCH AS** cancellation of its approval to receive Medicare payments] effective **[DATE]. [ADD IF APPLICABLE: A Civil Money Penalty was also assessed.] [STATE REASON FOR SANCTION SUCH AS: This action was based on deficiencies cited at a [SURVEY DATE] survey of the laboratory, which resulted in the determination of immediate jeopardy to public health and safety.]**

CLIA regulations prohibit the laboratory's owner, **[OWNER NAME]**, and its director, **[DIRECTOR NAME]**, from owning, operating or directing any laboratory for two years from the date of the revocation, or until **[REVOCATION DATE + 2 YEARS]**.

**[NAME OF RO MANAGER]
[NAME OF BRANCH]
[NAME OF DIVISION]**

25 RO (4/20/07) – Sanction – Client Notification – notice to clients of lab regarding sanctions imposed

IMPORTANT NOTICE – PLEASE READ CAREFULLY

CERTIFIED MAIL - Return Receipt Requested

[DATE]

[NAME OF CLIENT]

[ATTN: NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

RE: Notice of CLIA Sanction Action against [NAME OF LABORATORY], CLIA Number [CLIA NUMBER]

Dear [NAME]:

This notice is being sent to you because you have been identified as a client who ordered patient testing at [NAME OF LABORATORY]. This laboratory was sanctioned recently by the Centers for Medicare and Medicaid Services (CMS) as a result of serious quality problems discovered at a survey conducted on [DATE], which led CMS to determine that the laboratory was out of compliance with [NUMBER] Condition-level CLIA requirements. [ADD IF APPLICABLE: The serious nature of the deficient practices resulted in the determination that the laboratory posed immediate jeopardy to patient health and safety.]

[ADD IF APPLICABLE: Due to the laboratory's continued failure to correct the cited deficiencies, the laboratory's CLIA certificate was suspended effective [DATE] and its approval to receive Medicare and Medicaid payments canceled effective the same date. The laboratory may not legally perform any CLIA laboratory testing for patients while its CLIA certificate is suspended.]

We are writing both to inform you of the current sanction action and to alert you that CLIA laboratory test results you received in the past from [NAME OF LABORATORY] may not be accurate or reliable. We are calling this matter to your attention so that you can take whatever measures, including patient retesting, that you deem appropriate.

[ADD IF APPLICABLE: Currently, a revocation action is pending against the laboratory's CLIA certificate. If revoked, the owner [NAME] and director [NAME] of the laboratory will be prohibited from owning or operating a laboratory for a period of two years from the date of the revocation.]

If you have any questions regarding this notice, please contact [STAFF NAME] of my staff at [PHONE NUMBER/ADDRESS/EMAIL].

Sincerely,

[NAME/TITLE]

[OFFICE]

26 RO (4/20/07) – Sanction PT – Suspension of Medicare Agreement - lab agreement to not charge Medicare beneficiaries or other insurance carriers for lab services for analyte/subspecialty/specialty for which Medicare payment is suspended

AGREEMENT

By my signature below, **[NAME OF LABORATORY]** located at **[ADDRESS]**, agrees (in return for not having its Medicare approval cancelled immediately) not to charge Medicare beneficiaries or their private insurance carriers for laboratory services in the **[CHOOSE ONE AS APPROPRIATE: analyte, specialty, subspecialty]** of **[NAME OF ANALYTE, SPECIALTY, SUBSPECIALTY]** for which Medicare is suspended effective **[MEDICARE SUSPENSION DATE]**.

I understand that failure to provide this written agreement by **[NOTICE DATE + 10 CALENDAR DAYS]** will result in the automatic cancellation of the laboratory’s approval to receive Medicare payment for all laboratory services effective **[MEDICARE SUSPENSION DATE]**. I also understand that signing this agreement does not affect the laboratory’s appeal rights in connection with this sanction action.

In addition, I understand that pursuant to 42 C.F.R.§ 493.1840(a)(7) violation of this agreement will result in the immediate revocation of **[NAME OF LABORATORY]**’s CLIA certificate under 42 C.F.R. § 493.1840(a)(1) and pursuant to 42 C.F.R. § 493.1826(a)(1)(ii) in the immediate cancellation of the laboratory’s approval to receive Medicare payments for all laboratory services.

Signature

Date

Print Name and Title

Contact address other than laboratory address

Contact telephone number

Contact FAX number

Complaint Close-Out

[DATE]

[COMPLAINANT NAME]

[ADDRESS]

[CITY], [STATE] [ZIP]

[Complaint ID – If applicable.]

Dear Complainant(s):

We are writing to inform you that the investigation regarding your concerns of the **[LABORATORY]** was completed on **[DATE]**. The laboratory has been found to be **[COMPLIANT or NON-COMPLIANT]** with CLIA requirements.

If you have further questions regarding this matter please contact me at **[PHONE #]**.

Sincerely,

[SURVEYOR NAME], [TITLE]
[STATE AGENCY NAME]

Or

[NAME/TITLE]
[BRANCH NAME]
[DIVISION NAME]

CC: