DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850
Division of Clinical Improvement and Quality

IMPORTANT NOTICE – PLEASE READ CAREFULLY

Sent Via email to: **mfafreedi@yahoo.com**
(Confirmation of successful transmission of email constitutes proof of receipt.)

August 29, 2024

Jong Lee, DVM, PhD, Director
Mohammad Afreedi, Owner
Lab USA, Inc.
108R Merrimack Street
Haverhill, MA 01830

CLIA Number: 22D1042991

RE: NOTICE OF IMPOSITION OF SANCTIONS – CONDITIONS OUT – IMMEDIATE JEOPARDY

Dear Director and Owner:

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 Title 42 of the Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Laboratories are required to be in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

We are writing to notify you of the determination by the Centers for Medicare & Medicaid Services (CMS) that Lab USA, Inc. ("the laboratory") located at the above address is not in compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Condition-level requirements and has not removed the finding of immediate jeopardy. Therefore, CMS is imposing the following sanctions:

- Revocation of the laboratory's CLIA certificate
- Suspension of the laboratory's CLIA certificate
- A Directed Portion of a Plan of Correction
- Cancelation of the laboratory's approval to receive Medicare and Medicaid payments for all laboratory services

Background

A CLIA routine recertification survey was conducted by CMS' agents, the Massachusetts Department of Public Health (the "State Agency"). The survey was completed on May 21, 2024. In addition, a revisit survey of your laboratory was completed on July 15, 2024, and August 12, 2024. Based on these surveys, the laboratory was found to be out of compliance with three (3) CLIA Condition-level requirements, in addition to numerous CLIA Standard-level requirements.

By letter dated May 24, 2024, the State Agency provided the laboratory with a listing of all deficiencies identified during the survey on Form CMS-2567, Statement of Deficiencies. The State Agency's May 24, 2024, letter also notified the laboratory that the seriousness of the deficiencies resulted in the finding of immediate jeopardy to health and safety and requested that the laboratory take immediate action to remove jeopardy and bring any non-compliance Condition-level requirements into compliance. The State Agency gave the laboratory ten (10) days from the date of the May 24, 2024, letter to submit a credible allegation of compliance and acceptable evidence of correction for the cited deficiencies.

On June 7, 2024, the State Agency received a submission from the laboratory in response to its May 24, 2024, letter. The State Agency reviewed the submission and determined that it did not constitute a credible allegation of compliance and acceptable evidence of correction and did not demonstrate that the laboratory had come into Condition-level compliance and removed immediate jeopardy.

By letter dated June 13, 2024, the State Agency notified the laboratory of its determination and provided the laboratory ten (10) calendar days to provide a response with evidence of correction, or that it was referring the case to CMS with recommendations for sanction action against your laboratory's CLIA certificate. A second submission dated June 25, 2024, was received and determined to not constitute as a credible allegation of compliance and acceptable evidence of correction. On July 15, 2024, a revisit survey was conducted and verified that immediate jeopardy remains. The State Agency referred the case to CMS with a recommendation for sanctions action against the laboratory's CLIA certificate. We reviewed the Form CMS-2567, Statement of Deficiencies issued following the survey and related correspondence and concurred with the State Agency's findings.

CMS' Notice of Proposed Sanctions

By letter dated July 23, 2024, CMS notified the laboratory of proposed sanctions against the laboratory's CLIA certificate based on the findings of immediate jeopardy, the laboratory's failure to meet all CLIA Condition-level requirements, 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 during the CLIA recertification survey completed on May 21, 2024, and revisit surveys on July 15, 2024 and August 12, 2024. This letter described the proposed sanctions and gave the laboratory ten (10) days from the date of the July 23, 2024, letter, or until August 2, 2024, to submit, in writing, any information or evidence as to why these sanctions should not be imposed. CMS also met with the laboratory director and owner on August 7, 2024, to provide an opportunity to clarify the response requirements and to answer any questions. CMS provided the laboratory an extension until August 9, 2024, to submit the response and evidence of compliance.

Your laboratory responded with a submission on August 9, 2024. The submission consisted of mainly the same documentation previously submitted to the State Agency in their request for an allegation of compliance. New documentation submitted on August 9, 2024, "Proficiency Testing Program" does not specifically outline the investigative steps taken or evidence of steps to prevent recurrence. In addition, submitted 2567b plan of correction notes completion date of 8/6/2024 for investigation and performance of corrective actions; no documentation was presented on the corrective actions. No documentation was submitted on an update to API Proficiency Test enrollment.

We have carefully reviewed the entire submission for August 9, 2024, and determined that your response has no effect on our determination to impose sanctions. Additionally, the laboratory's submission does not constitute a credible allegation of compliance and acceptable evidence of correction. The evidence submitted shows that the laboratory continues to be out of compliance with CLIA requirements as cited during the May 21, 2024, and July 15, 2024**,** surveys. In addition, in a subsequent revisit survey conducted by the State Agency on August 12, 2024, it was determined that the laboratory continues to be out of compliance and that Immediate Jeopardy continues to exist.

Your laboratory's August 9, 2024, 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 results.

As you were advised by the State Agency in its May 24, 2024, and June 7, 2024, 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 May 24, 2024, and June 7, 2024, letters, and in CMS' July 23, 2024, Notice of Proposed Sanctions, 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 individuals found to have been affected by the deficient practice:
2) How the laboratory has identified other individuals 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) are why the laboratory's August 9, 2024, submission does not constitute a credible allegation of compliance and acceptable evidence of correction.

D2000 ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801
The laboratory has not made systemic changes or implemented a plan to ensure the deficient practice of failing to enroll in proficiency testing (PT) for all tests performed does not recur.

D5400 ANALYTIC SYSTEMS CFR(s): 493.1250
The laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1251 through 493.1283 for each specialty and subspecialty performed. The cumulative effect of this lack of oversight resulted in the laboratory's inability to ensure accuracy and reliability of patient test results in the specialties of Microbiology, Hematology, Diagnostic Immunology, and Chemistry. Refer to D5401, D5403, D5409, D5421, D5429, D5435, D5439, D5441, D5455, D5471, D5481, D5783, and D5791.

D6076 LABORATORY DIRECTOR CFR(s): 493.1441
The deficiencies cited during this CLIA revisit had been cited at the last two CLIA surveys (refer to D5439), the laboratory director failed to provide overall management and direction in accordance with §493.1445 of this subpart and did not ensure that deficiencies cited were corrected and remained corrected through the implementation of appropriate monitoring mechanisms. The cumulative effect of this lack of oversight resulted in the laboratory's inability to ensure accuracy and reliability of patient test results in the specialties of Microbiology, Hematology, Diagnostic Immunology.

In addition, many standard-level deficiencies remained.

Imposed Sanctions

Accordingly, pursuant to 42 C.F.R. §§ 493.1806, 493.1812, 493.1814, and 493.1840(a)(3), **based on the laboratory's failure to meet all CLIA Condition-level requirements, 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 May 21, 2024, July 15, 2024, and August 12, 2024, which led to the determination of Immediate Jeopardy**, we are taking action to impose the following sanctions against Lab USA, Inc.'s CLIA certificate as proposed in our July 23, 2024 letter:

- 42 C.F.R. §§ 493.1806(b), 493.1840(a)(3), and 493.1840(e) – Principal Sanction: **Revocation of the laboratory's CLIA certificate effective September 4, 2024**. The laboratory has sixty (60) calendar 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. *See* 42 C.F.R. § 493.1840(e)(1).

If the 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. The laboratory cannot solicit or accept specimens for laboratory examination or other procedures during the revocation. Additionally, 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.

- 42 C.F.R. §§ 493.1806(b), 493.1812, 493.1840(a)(3), and 493.1840(d)(2)(i) – Principal Sanction: **Suspension of the laboratory's CLIA certificate effective September 4, 2024**, based on the finding of immediate jeopardy. Pursuant to 42 C.F.R. §§ 493.1840(d)(2)(i) and 493.1844(d)(2)(ii), 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. If the ALJ upholds this suspension imposed because of immediate jeopardy, it will become a revocation. *See* 42 C.F.R. § 493.1844(d)(4)(ii).

  When the CLIA certificate is suspended, the laboratory is not permitted to perform any testing for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, 42 U.S.C.A. § 263a, **including waived testing and provider performed microscopy procedures, regardless of whether or not the laboratory charges for the testing.**[1]

- 42 C.F.R. §§ 493.1806(c)(1), 493.1832(b)(2), 493.1844(d)(1), and 493.1844(g)(1) – Alternative Sanction: **Directed Portion of a Plan of Correction effective September 4, 2024** – The laboratory is directed to submit to this office by September 10, 2024, 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 May 17, 2022. We request that this list be provided as an electronic file, in an EXCEL database format if possible. CMS may use this list to advise the laboratory's clients of the nature of its non-compliance and the nature and effective date of sanctions imposed against the laboratory's CLIA certificate. An appeal will not delay the due date for this submission or client notification by CMS.

- 42 C.F.R. §§ 493.1807(a), 493.1808, 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 September 4, 2024**. 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 for all laboratory services 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 September 2, 2024. *See* 42 C.F.R. § 440.2(b).

[1] The laboratory may continue to perform parallel testing on specimens if needed to implement corrective actions. However, the laboratory may not report any test results during the period when its CLIA certificate is suspended.

The above sanctions cannot be avoided by the closure of the laboratory, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing. CMS will not change a laboratory's CLIA certificate type while an enforcement action is pending. In addition, a laboratory's CLIA certificate will remain active while an enforcement action is pending.

Appeal Rights

If Lab USA, Inc. 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 (DAB) in accordance with 42 C.F.R. §§ 493.1844(a)(1)-(2) and 42 C.F.R. §§ 498.40 through 498.78. A request for hearing must be filed no later than **sixty (60) calendar days** after the date this letter is received (see 42 C.F.R. § 493.1844(f)). You should file your request for an appeal (accompanied by a copy of this letter) to the Department Appeals Board Electronic Filing System website (DAB E-file) at https://dab.efile.hhs.gov. Instructions for filing an appeal can be found on the DAB E-file website.

The Civil Remedies Division (CRD) recommends that parties with the capability to file documents electronically utilize DAB E-File. However, paper filing of documents in cases where electronic filing is allowed remains available for parties unable to file electronically. If a party is unable to use DAB E-File, it must send appeal-related documents to CRD using a postal or commercial delivery service at the following address:

Department of Health and Human Services
Departmental Appeals Board, MS 6132
Civil Remedies Division
330 Independence Avenue, S.W.
Cohen Building — Room G-644
Washington, D.C. 20201

Please send a copy of your appeal to:

DCLIQEnforcement@cms.hhs.gov

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 a hearing is conducted and CMS' determination is upheld, the laboratory may be assessed a fee to cover the government's cost related to the hearing.** *See* 42 C.F.R. § 493.643(d)(2).

How to File: When using DAB E-File for the first time, you will need to create an account by a) clicking Register on the DAB E-File home page; b) entering the requested information on the Register New Account form; and c) clicking Register Account at the bottom of the form. Each representative authorized to represent you must register separately to use the DAB E-File on your behalf.

The e-mail address and password given during registration must be entered on the login screen when accessing DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he/she is a party or an authorized representative. You can file a new appeal by a) clicking the File New Appeal link on the Manage Existing Appeals screen; then b) clicking Civil Remedies Division on the File New Appeal screen; and c) entering and uploading the requested information and documents on the File New Appeal-Civil Remedies Division form.

The Civil Remedies Division (CRD) requires all hearing requests to be signed and accompanied by the notice letter from CMS that addresses the action taken and your appeal rights. All submitted documents must be in Portable Document Format (PDF). Documents uploaded to DAB E-File on any day on or before 11:59p.m. ET will be considered to have been received on that day. You will be expected to accept electronic service of any appeal-related documents filed by CMS or that the CRD issues on behalf of the Administrative Law Judge (ALJ) via DAB E-File. Further instructions are located at: *https://dab.efile.hhs.gov/appeals/to_cr_instructions*. Please contact the Civil Remedies Division at 202-565-9462 if you have questions regarding the DAB E-Filing System. If you experience technical issues with the DAB E-Filing System, please contact E-File System Support at: *OSDABImmediateOffice@hhs.gov* or call 202-565-0146 before 4:00p.m. EST.

If you do not have access to a computer or internet service, you may call the Civil Remedies Division at 202-565-9462 to request a waiver from e-filing and provide an explanation as to why you cannot file electronically, or you may mail a written request for a waiver along with your written request for a hearing. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter via fax or by mailing to the address listed above.

Please be advised 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, is not subject to appeal. See 42 C.F.R. §§ 493.1844(c)(4), (c)(6) and (c)(7). 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.

If a timely request for hearing is filed, i.e., by October 28, 2024, CMS does not revoke any type of CLIA certificate until after an ALJ hearing that upholds CMS' determination of non-compliance and imposition of sanction(s). **However, the Directed Portion of a Plan of Correction to submit the laboratory's client list, imposition of suspension of the CLIA certificate, and the cancellation of the laboratory's approval to receive all Medicare and Medicaid payment** are effective **September 4, 2024,** 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).

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 posting the information on the Survey & Certification website at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Termination-Notices.html.

Please contact Lakeisha Jones and Jelani Sanaa by e-mail at DCLIQEnforcement@cms.hhs.gov with any questions concerning this letter.

Sincerely,

Gregg S. Brandush, RN, JD
Division Director
Centers for Medicare & Medicaid Services (CMS)
Division of Clinical Laboratory Improvement and Quality

cc:
Massachusetts Department of Public Health