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|--|---|
| <b>CMS Manual System</b>                     | <b>Department of Health &amp; Human Services (DHHS)</b>   |
| <b>Pub 100-04 Medicare Claims Processing</b> | <b>Centers for Medicare &amp; Medicaid Services (CMS)</b> |
| <b>Transmittal 3867</b>                      | <b>Date: September 28, 2017</b>                           |
|  | <b>Change Request 10198</b>                               |

**Transmittal 3812, dated July 27, 2017, is being rescinded and replaced by Transmittal 3867, dated, September 28, 2017 to change a CPT code in the attachment from 83518QW to 82044QW. All other information remains the same.**

**SUBJECT: New Waived Tests**

**I. SUMMARY OF CHANGES:** This Change Request (CR) will inform contractors of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration. Since these tests are marketed immediately after approval, the Centers for Medicare & Medicaid Services (CMS) must notify its contractors of the new tests so that the contractors can accurately process claims. There are 17 newly added waived complexity tests. The initial release of this Recurring Update Notification applies to Chapter 16, section 70.8 of the IOM.

**EFFECTIVE DATE: October 1, 2017**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: October 2, 2017**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

| <b>R/N/D</b> | <b>CHAPTER / SECTION / SUBSECTION / TITLE</b> |
|--------------|---|
| N/A          | N/A   |

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Recurring Update Notification**

# Attachment - Recurring Update Notification

|             |                   |                          |                       |
|-------------|-------------------|--------------------------|-----------------------|
| Pub. 100-04 | Transmittal: 3867 | Date: September 28, 2017 | Change Request: 10198 |
|-------------|-------------------|--------------------------|-----------------------|

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**SUBJECT: New Waived Tests**

**EFFECTIVE DATE: October 1, 2017**

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**IMPLEMENTATION DATE: October 2, 2017**

## I. GENERAL INFORMATION

**A. Background:** The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

Listed below are the latest tests approved by the Food and Drug Administration (FDA) as waived tests under CLIA. The Current Procedural Terminology (CPT) codes for the following new tests must have the modifier QW to be recognized as a waived test. However, the tests mentioned on the first page of the attached list (i.e., CPT codes: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

The CPT code, effective date and description for the latest tests approved by the FDA as waived tests under CLIA are the following:

- 87880QW, December 8, 2016, Quidel Sofia Strep A+ FIA (from throat swab only);
- 80305QW, April 28, 2017, Alere Toxicology Services Alere iCup Rx Multi-Drug Urine Test Cup;
- 82044QW, and 82570QW, May 10, 2017, Acon Laboratories, Inc. Mission U120 Urine Chemistry Test System (Mission Urinalysis Reagent Strips (Microalbumin/Creatinine));
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Amphetamine Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Oxazepam Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Cocaine Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Marijuana Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Methamphetamine Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Morphine Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Oxycodone Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Barbiturates Panel Dip;

- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Buprenorphine Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Methylenedioxyamphetamine Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Phencyclidine Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Methadone Panel Dip;
- 87804QW, May 30, 2017, Quidel Sofia 2 {Sofia Influenza A+B FIA}; and
- 82274QW, G0328QW, June 5, 2017, Jant Pharmacal Coporation Accutest ValuPak Immunochemical Fecal Occult Blood Test.

This Recurring Update Notification applies to Chapter 16, section 70.8 of the IOM.

**B. Policy:** The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for laboratory tests in a facility with a valid, current CLIA certificate, laboratory claims are currently edited at the CLIA certificate level.

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

| Number  | Requirement   | Responsibility |   |                            |                                  |             |             |             |       |  |  |  |
|---------|---|----------------|---|----------------------------|----------------------------------|-------------|-------------|-------------|-------|--|--|--|
|         |   | A/B<br>MAC     |   | D<br>M<br>E<br>M<br>A<br>C | Shared-<br>System<br>Maintainers |             |             |             | Other |  |  |  |
|         |   | A              | B |                            | F<br>I<br>S<br>S                 | M<br>C<br>S | V<br>M<br>S | C<br>W<br>F |       |  |  |  |
| 10198.1 | The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.   |                | X |                            |                                  |             |             |             |       |  |  |  |
| 10198.2 | Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention. |                | X |                            |                                  |             |             |             |       |  |  |  |
| 10198.3 | Contractors shall not use the explanatory information under the "Use" column in the attachment as the reason for rejecting a claim.   |                | X |                            |                                  |             |             |             |       |  |  |  |

## III. PROVIDER EDUCATION TABLE

| Number  | Requirement   | Responsibility |   |             |                            |                  |
|---------|---|----------------|---|-------------|----------------------------|------------------|
|         |   | A/B MAC        |   |             | D<br>M<br>E<br>M<br>A<br>C | C<br>E<br>D<br>I |
|         |   | A              | B | H<br>H<br>H |                            |                  |
| 10198.4 | MLN Article: A provider education article related to this instruction will be available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. |                | X |             |                            |                  |

#### IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

| X-Ref Requirement Number | Recommendations or other supporting information: |
|--------------------------|--|
|                          |  |

**Section B: All other recommendations and supporting information: N/A**

#### V. CONTACTS

**Pre-Implementation Contact(s):** Kathleen Todd, 410-786-3385 or kathleen.todd@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

#### VI. FUNDING

##### **Section A: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**ATTACHMENTS: 1**

## TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u>   | <u>TEST NAME</u>   | <u>MANUFACTURER</u> | <u>USE</u>   |
|--|--|---------------------|--|
| 81002  | Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen | Various             | Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections |
| 81025  | Urine pregnancy tests by visual color comparison   | Various             | Diagnosis of pregnancy   |
| 82270<br>82272<br>(Contact your Medicare carrier for claims instructions.) | Fecal occult blood   | Various             | Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening)   |
| 82962  | Blood glucose by glucose monitoring devices cleared by the FDA for home use  | Various             | Monitoring of blood glucose levels   |
| 83026  | Hemoglobin by copper sulfate – non-automated   | Various             | Monitors hemoglobin level in blood   |
| 84830  | Ovulation tests by visual color comparison for human luteinizing hormone   | Various             | Detection of ovulation (optimal for conception)  |
| 85013  | Blood count; spun microhematocrit  | Various             | Screen for anemia  |
| 85651  | Erythrocyte sedimentation rate – non-automated   | Various             | Nonspecific screening test for inflammatory activity, increased for majority of infections, and most cases of carcinoma and leukemia                         |

**This list includes updates from Change Request FFS10198**

## TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u>  | <u>TEST NAME</u>   | <u>MANUFACTURER</u> | <u>USE</u>  |
|---|--|---------------------|---|
| 80047QW, 82330QW, 82374QW, 82435QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW, 85014QW | Abbott i-STAT Chem8+ Cartridge {Whole Blood}   | i-STAT Corporation  | Measures ionized calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, urea nitrogen, and hematocrit in whole blood  |
| 80048QW   | 1. Abaxis Piccolo Blood Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood}           | Abaxis, Inc         | Measures total calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, and urea nitrogen in whole blood  |
|   | 2. Abaxis Piccolo xpress Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood}          | Abaxis, Inc         |   |
| 80051QW   | 1. Abaxis Piccolo Blood Chemistry Analyzer (Electrolyte Metabolic Reagent Disc){Whole Blood}     | Abaxis, Inc.        | Measures carbon dioxide, chloride, potassium, and sodium in whole blood   |
|   | 2. Abaxis Piccolo xpress Chemistry Analyzer (Electrolyte Metabolic Reagent Disc){Whole Blood}    | Abaxis, Inc.        |   |
| 80053QW   | 1. Abaxis Piccolo Blood Chemistry Analyzer (Comprehensive Metabolic Reagent Disc){ Whole Blood}  | Abaxis, Inc.        | Measures alanine amino transferase, aspartate amino transferase, albumin, total bilirubin, total calcium, carbon dioxide, chloride, creatinine, glucose, alkaline phosphatase, potassium, total protein, sodium, and urea nitrogen in whole blood |
|   | 2. Abaxis Piccolo xpress Chemistry Analyzer (Comprehensive Metabolic Reagent Disc){ Whole Blood} | Abaxis, Inc.        |   |

**This list includes updates from Change Request FFS10198**  
 \* Newly added waived test system

**TESTS GRANTED WAIVED STATUS UNDER CLIA**

| <u>CPT CODE(S)</u>   | <u>TEST NAME</u>  | <u>MANUFACTURER</u>              | <u>USE</u>   |
|--|---|----------------------------------|--|
| 80061QW, 82465QW<br>(Contact your Medicare carrier for claims instructions.),<br>83718QW,<br>84478QW           | 1. Abaxis, Piccolo xpress Chemistry Analyzer {Lipid Panel Reagent Disc} (Whole Blood)   | Abaxis, Incorporated             | Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood  |
|  | 2. Infopia USA LipidPro lipid profile and glucose measuring system (LipidPro Lipid Profile test strips)                         | Infopia Co., Ltd.                |  |
|  | 3. Jant Pharmacal Corp, LipidPlus Professional Lipid Profile and Glucose Measuring System (LipidPlus Lipid Profile test strips) | Infopia Co., Ltd.                |  |
|  | 4. Piccolo Point of Care Chemistry Analyzer (Lipid Panel Reagent Disc) (Whole Blood)  | Abaxis, Incorporated             |  |
|  | 5. Polymer Technology Systems CardioChek PA Analyzer {PTS Panels Lipid Panel Test Strips}                                       | Polymer Technology Systems, Inc. |  |
|  | 6. Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Lipid Panel test strips)                     | Polymer Technology Systems, Inc. |  |
|  | 7. Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels Lipid Panel test strips)                          | Polymer Technology Systems, Inc. |  |
| 80061QW, 82465QW<br>(Contact your Medicare carrier for claims instructions.),<br>82962,<br>83718QW,<br>84478QW | 1. Jant Pharmacal LipidPlus Lipid Profile and Glucose Measuring System  | Infopia Co., Ltd.                | Monitoring of blood glucose levels and measures total cholesterol, HDL cholesterol, and triglycerides in whole blood |

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 \* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u>  | <u>TEST NAME</u>  | <u>MANUFACTURER</u>  | <u>USE</u>   |
|---|---|----------------------|--|
| 80061QW, 82465QW<br>(cont.)(Contact your Medicare carrier for claims instructions.),<br>82962,<br>83718QW,<br>84478QW   | 2. Jant Pharmacal Corp, LipidPlus Professional Lipid Profile and Glucose Measuring System | Infopia Co., Ltd     | Monitoring of blood glucose levels and measures total cholesterol, HDL cholesterol, and triglycerides in whole blood                                 |
|   | 3. Infopia USA LipidPro lipid profile and glucose measuring system                        | Infopia Co., Ltd.    |  |
|   | 4. Infopia USA LipidPro Professional Lipid Profile and Glucose Measuring System           | Infopia Co., Ltd     |  |
| 80061QW, 82465QW<br>(Contact your Medicare carrier for claims instructions.),<br>83718QW,<br>84460QW,<br>84478QW  | Cholestech LDX (Lipid Profile – ALT (GPT)){Whole Blood}                                   | Cholestech Corp.     | Measures alanine aminotransferase, total cholesterol, HDL cholesterol, and triglycerides in whole blood  |
| 80061QW, 82465QW<br>82465QW (Contact your Medicare carrier for claims instructions.),<br>82947QW, 82950QW,<br>82951QW, 82952QW,<br>83718QW, 84450QW,<br>84460QW, 84478QW<br>80069QW | Alere Cholestech LDX {Whole Blood}  | Alere, Inc.          | Measures alanine aminotransferase, aspartate aminotransferase, total cholesterol, HDL cholesterol, glucose, and triglycerides in whole blood         |
|   | 1. Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Renal Function Panel){Whole Blood}    | Abaxis, Incorporated | Measures albumin, total calcium, total carbon dioxide, chloride, creatinine, glucose, phosphorus, potassium, sodium and urea nitrogen in whole blood |
|   | 2. Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Renal Function Panel){Whole Blood}   | Abaxis, Incorporated |  |

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\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u>  | <u>TEST NAME</u>   | <u>MANUFACTURER</u>                 | <u>USE</u>   |
|---|--|-------------------------------------|--|
| 80178QW   | ReliaLAB Inc. InstaRead Lithium System {fingerstick or venipuncture whole blood}   | Akers Laboratories, Inc.            | Measures lithium blood levels in whole blood   |
| 80305QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges) categorized as waived complexity. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the currently waived test systems and analytes. | Various                             | Screening test for the presence/detection of any number of drug classes in urine   |
| 81003QW   | Dipstick or tablet reagent urinalysis – automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen categorized as waived complexity. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the currently waived test systems.   | Various                             | Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections   |
| 81003QW, 82044QW, 82570QW   | 1. Siemens Clinitek 50 Urine Chemistry Analyzer  | Siemens Healthcare Diagnostics Inc. | Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; and the semi-quantitative measurement of albumin and creatinine in urine                             |
| 81003QW, 82044QW, 82570QW, 84703QW  | 1. Siemens Clinitek Status Urine Chemistry Analyzer  | Siemens Healthcare Diagnostics      | Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; the semi-quantitative measurement of albumin and creatinine in urine; and the diagnosis of pregnancy |
|   | 2. Siemens, Clinitek Status+ Analyzer  | Siemens Healthcare Diagnostics      |  |

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\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u>  | <u>TEST NAME</u>  | <u>MANUFACTURER</u>              | <u>USE</u>   |
|---|---|----------------------------------|--|
| 81003QW, 82044QW,<br>82570QW,<br>84703QW (cont.)  | 3. Siemens, Clinitek Status Connect System  | Siemens Healthcare Diagnostics   | Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; the semi-quantitative measurement of albumin and creatinine in urine; and the diagnosis of pregnancy |
| 81007QW   | 1. Diatech Diagnostics Uriscreeen (for OTC use)   | Savyon/USA                       | Detects catalase in urine which is associated with urinary tract infections (UTIs). White blood cells and some bacteria associated with UTIs are positive for catalase.  |
|   | 2. Jant Pharmacal Corporation Accutest Uriscreeen (Bacteriuria)   | Savyon Diagnostics Ltd           |  |
| 82010QW   | PTS Bioscanner (for OTC use) - for blood ketones  | Polymer Technology Systems, Inc. | Measures ketones in whole blood  |
| 82010QW,<br>82962   | 1. Abbott Laboratories, Medisense Products Precision™ Xtra™ Advanced Diabetes Management System (K983504) | Abbott Laboratories              | Monitoring of blood glucose levels and measures ketones in whole blood   |
|   | 2. Abbott Medisense Precision Xtra Advanced Diabetes Management System (K040814)                          | Abbott Laboratories              |  |
|   | 3. Nova Biomedical Nova Max Plus Glucose and B-Ketone Monitoring System                                   | Nova Biomedical Corp.            |  |
| 82040QW, 82150QW,<br>82247QW, 82310QW,<br>82565QW, 82947QW,<br>82950QW, 82951QW,<br>82952QW,<br>82977QW, 84075QW,<br>84155 QW, 84450QW,<br>84460QW, 84520QW,<br>84550QW | Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 13 Panel){ Whole Blood}                        | Abaxis, Inc.                     | Quantitative measurement of alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, calcium, creatinine, gamma glutamyltransferase, glucose, total bilirubin, total protein, urea nitrogen and uric acid in whole blood      |

**This list includes updates from Change Request FFS10198**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u>  | <u>TEST NAME</u>  | <u>MANUFACTURER</u>     | <u>USE</u>  |
|---|---|-------------------------|---|
| 82040QW, 82150QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84075QW, 84155 QW, 84450QW, 84460QW, 84520QW, 84550QW | Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}  | Abaxis, Inc.            | Quantitative measurement of alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, calcium, creatinine, gamma glutamyltransferase, glucose, total bilirubin, total protein, urea nitrogen and uric acid in whole blood |
| 82040QW, 82150QW, 82247QW, 82977QW, 84075QW, 84155QW, 84450QW, 84460QW  | 1. Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){ whole blood}                                | Abaxis, Inc.            | Measures alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, gamma glutamyltransferase, total bilirubin and total protein levels in whole blood   |
|   | 2. Abaxis Piccolo xpress Chemistry Analyzer {Liver Panel Plus} (Whole Blood)  | Abaxis, Inc             |   |
| 82040QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84520QW  | Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 1) {Whole Blood}   | Polymedco, Inc.         | Measures albumin, total calcium, creatinine, glucose and total protein levels in whole blood  |
| 82043QW   | HemoCue Albumin 201 System  | HemoCue, Inc.           | Quantitative measurement of albumin in urine by immunoassay   |
| 82044QW, 82570QW  | Acon Laboratories, Inc. Mission U120 Urine Chemistry Test System (Mission Urinalysis Reagent Strips (Microalbumin/Creatinine))* | ACON Laboratories, Inc. | Semi-quantitative measurement of albumin and creatinine in urine  |
| 82120QW, 83986QW  | Litmus Concepts FemExam TestCard (from vaginal swab)  | Litmus Concepts, Inc.   | Qualitative test of a vaginal fluid sample for elevated pH (pH greater than or equal to 4.7) and the presence of volatile amines  |
| 82247QW, 84075QW, 84155QW, 84450QW, 84460QW   | Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 2) {Whole Blood}   | Polymedco, Inc.         | Measures alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, total bilirubin and urea levels in whole blood   |
| 82271QW   | 1. Aerscher Hemaprompt FG   | Aerscher Diagnostics    | Rapid screening test to detect the presence of gastric occult blood   |

**This list includes updates from Change Request FFS10198**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u>  | <u>TEST NAME</u>  | <u>MANUFACTURER</u>        | <u>USE</u>  |
|---|---|----------------------------|---|
| 82271QW (cont.)   | 2. SmithKline Gastrocult  | SmithKline                 | Rapid screening test to detect the presence of gastric occult blood   |
| 82271QW,<br>83986QW   | Beckman Coulter Primary Care Diagnostics Gastrocult®  | Beckman Coulter, Inc.      | Rapid screening test to detect the presence of gastric occult blood and determine the pH (acid-base balance) of gastric aspirates       |
| 82274QW<br>G0328QW  | Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous categorized as waived complexity. . Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the currently waived test systems. | Various                    | Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay                       |
| 82374QW, 82435QW,<br>82550QW, 82565QW,<br>82947QW, 84132QW,<br>84295QW, 84520QW             | 1. Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}   | Abaxis, Inc.               | Measures chloride, creatine kinase, creatinine, glucose, potassium, sodium, total carbon dioxide and urea nitrogen (BUN) in whole blood |
|   | 2. Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}  | Abaxis, Inc                |   |
| 82435QW, 82947QW,<br>82950QW, 82951QW,<br>82952QW, 84132QW,<br>84295QW, 84520QW,<br>85014QW | Abbott i-STAT 6+ Cartridge {Whole Blood}  | i-Stat Corporation         | Measures chloride, glucose, potassium, sodium, urea nitrogen, and hematocrit in whole blood   |
| 82465QW (Contact your Medicare carrier for claims instructions.)                            | 1. Advanced Care  | Johnson & Johnson          | Cholesterol monitoring  |
|   | 2. Boehringer Mannheim Accu-Chek InstantPlus Cholesterol  | Boehringer Mannheim        |   |
|   | 3. ChemTrak AccuMeter   | ChemTrak                   |   |
|   | 4. ENA.C.T Total Cholesterol Test   | ActiMed Laboratories, Inc. |   |
|   | 5. ActiMed Laboratories ENA.C.T. Total Cholesterol Test (PDU)   | ActiMed Laboratories, Inc. |   |

**This list includes updates from Change Request FFS10198**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u>  | <u>TEST NAME</u>  | <u>MANUFACTURER</u>              | <u>USE</u>  |
|---|---|----------------------------------|---|
| 82465QW (cont.)<br>(Contact your Medicare carrier for claims instructions.)                             | 6. Lifestream Technologies Cholesterol Monitor  | Lifestream Technologies, Inc.    | Cholesterol monitoring  |
|   | 7. Lifestream Technologies Personal Cholesterol Monitor   | Lifestream Technologies, Inc.    |   |
|   | 8. Polymer Technology Systems (PTS) MTM Bioscanner 1000 (for OTC use) for cholesterol                   | Polymer Technology Systems, Inc. |   |
|   | 9. PTS Bioscanner Test Strips Cholesterol   | Polymer Technology Systems, Inc. |   |
| 82465QW (Contact your Medicare carrier for claims instructions.),<br>82947QW, 82950QW, 82951QW, 82952QW | 1. Polymer Technology Systems, Inc., CardioChek Home Test System (CardioChek Home Chol+Glu test strips) | Polymer Technology Systems, Inc. | Measures total cholesterol, and glucose in whole blood        |
|   | 2. Polymer Technology Systems, Inc., CardioChek Plus Test System (PTS Panels Chol+Glu test strips)      | Polymer Technology Systems, Inc. |   |
| 82465QW (Contact your Medicare carrier for claims instructions.),<br>83718QW                            | 1. Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL Panel Test Strips)         | Polymer Technology Systems, Inc. | Measures total cholesterol and HDL cholesterol in whole blood |
|   | 2. Polymer Technology Systems, Inc., CardioChek Home Test System (CardioChek Home Chol+HDL test strips) |                                  |   |
|   | 3. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL Panel Test Strips)            | Polymer Technology Systems, Inc. |   |
|   | 4. Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels CHOL+HDL Test Panel Test Strips)       | Polymer Technology Systems, Inc. |   |

**This list includes updates from Change Request FFS10198**

\* Newly added waived test system

**TESTS GRANTED WAIVED STATUS UNDER CLIA**

| <b><u>CPT CODE(S)</u></b>   | <b><u>TEST NAME</u></b>   | <b><u>MANUFACTURER</u></b>       | <b><u>USE</u></b>   |
|---|---|----------------------------------|---|
| 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW (cont.)                             | 5. Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels Chol + Glu Test Panel)                     | Polymer Technology Systems, Inc. | Measures total cholesterol and HDL cholesterol in whole blood           |
|   | 6. Polymer Technology Systems, Inc., CardioChek Plus Test System (PTS Panels Chol+HDL test strips)          | Polymer Technology Systems, Inc. |   |
|   | 7. Roche Diagnostics AccuChek Instant Plus Dual Testing System  | Roche Diagnostics                |   |
| 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 82947QW, 82950QW, 82951QW, 82952QW | 1. Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)        | Polymer Technology Systems, Inc. | Measures total cholesterol, HDL cholesterol, and glucose in whole blood |
|   | 2. Polymer Technology Systems, Inc., CardioChek Home Test System (CardioChek Home Chol+HDL+Glu test strips) | Polymer Technology Systems, Inc. |   |
|   | 3. Polymer Technology Systems, Inc., CardioChek Plus Test System (PTS Panels Chol+HDL+Glu test strips)      | Polymer Technology Systems, Inc. |   |
|   | 4. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)           | Polymer Technology Systems, Inc. |   |

**This list includes updates from Change Request FFS10198**  
 \* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u>   | <u>TEST NAME</u>  | <u>MANUFACTURER</u>      | <u>USE</u>   |
|--|---|--------------------------|--|
| 82465QW (Contact your Medicare carrier for claims instructions.),<br>82947QW, 82950QW,<br>82951QW, 82952QW,<br>83718QW,<br>84478QW,<br>80061QW                 | Cholestech LDX  | Cholestech Corp.         | Measures total cholesterol, glucose, HDL cholesterol, and triglycerides in whole blood   |
| 82465QW (Contact your Medicare carrier for claims instructions.),<br>82947QW, 82950QW,<br>82951QW, 82952QW,<br>83036QW,<br>84478QW                             | Wako APOLOWAKO Analyzer (Whole Blood)   | Wako Chemicals USA, Inc. | Measures total cholesterol, hemoglobin A1c, glucose, and triglycerides in whole blood  |
| 82465QW(Contact your Medicare carrier for claims instructions.),<br>82947QW, 82950QW,<br>82951QW, 82952QW,<br>83718QW, 84478QW,<br>84450QW, 84460QW<br>82523QW | Abaxis Piccolo xpress Chemistry Analyzer {Lipid Panel Plus Reagent Disc} (Whole Blood)} | Abaxis, Inc.             | Measures cholesterol, HDL cholesterol, glucose, alanine aminotransferase, aspartate aminotransferase, and triglycerides in whole blood |
| 82565QW  | Ostex International Osteomark NTX Point of Care Prescription Home Use                   | Ostex International Inc. | Measures normalized cross-linked N-telopeptides of type 1 collagen in urine  |
| 82565QW, 84520QW   | Abbott i-STAT Crea Cartridge {Whole Blood}  | i-Stat Corporation       | Quantitative measurement of creatinine in whole blood  |
|  | Abaxis Piccolo xpress Chemistry Analyzer (Kidney Check Panel){Whole Blood}              | Abaxis, Inc.             | Quantitative measurement of creatinine and urea nitrogen in whole blood  |

**This list includes updates from Change Request FFS10198**  
\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u>   | <u>TEST NAME</u>   | <u>MANUFACTURER</u> | <u>USE</u>  |
|--|--|---------------------|---|
| 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84450QW, 84460QW, 84520QW  | 1. Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 6 Panel){Whole Blood}  | Abaxis, Inc.        | Quantitative measurement of alanine aminotransferase, aspartate aminotransferase, creatinine, gamma glutamyltransferase, glucose and urea nitrogen in whole blood |
|  | 2. Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 6 Panel){Whole Blood} | Abaxis, Inc.        |   |
| 82679QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.), 83002QW | Clearplan Easy Fertility Monitor (for luteinizing hormone and estrone 3 glucuronide) | Unipath Limited     | Detection of luteinizing hormone and estrone 3 glucuronide in urine to identify the optimal time for conception   |
| 82947QW, 82950QW, 82951QW, 82952QW   | 1. HemoCue B-Glucose Photometer  | HemoCue, Inc.       | Measures glucose levels in whole blood  |
| 82947QW, 82950QW, 82951QW, 82952QW (cont.)   | 2. HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer                       | HemoCue, Inc.       | Measures glucose levels in whole blood  |
|  | 3. Abbott i-STAT G Cartridge {Whole Blood}   | i-Stat Corporation  |   |
| 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 85014QW  | Abbott i-STAT EC4+ Cartridge {Whole Blood}   | i-Stat Corporation  | Measures glucose, potassium, sodium, and hematocrit in whole blood  |
| 82962, 82465QW (Contact your Medicare carrier for claims instructions.)  | Roche Diagnostics Accutrend Plus System {fingerstick whole blood}                    | Roche Diagnostics   | Monitoring of blood glucose levels and cholesterol  |
| 82962, 82985QW   | 1. LXN Duet Glucose Control Monitoring System  | LXN Corporation     | Monitoring of blood glucose levels and measures fructosamine, which is used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period      |

**This list includes updates from Change Request FFS10198**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

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|---------------------------|--|--|--|
| 82962,<br>82985QW (cont.) | 2. LXN IN CHARGE Diabetes Control System   | LXN Corporation  | Monitoring of blood glucose levels and measures fructosamine, which is used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period |
| 82985QW                   | LXN Fructosamine Test System   | LXN Corporation  | Used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period (Not a useful test for screening diabetes mellitus)                    |
| 82947QW                   | 1. Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Glucose test strips)<br>2. Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home eGLU test strips)<br>3. Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels Glucose test strips)<br>4. Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels eGLU test strips) | Polymer Technology Systems, Inc.<br>Polymer Technology Systems, Inc.<br>Polymer Technology Systems, Inc.<br>Polymer Technology Systems, Inc. | Measures glucose in whole blood  |
| 83001QW                   | 1. Acon Laboratories, Inc. FSH Menopause Predictor Test<br>2. Acon Laboratories, Inc. FSH One Step Menopause Test Device {Professional Use}<br>3. Acon Laboratories, Inc. FSH One Step Menopause Test Strip {Professional Use}<br>4. Applied Biotech, Inc. RU25 Plus FSH Menopause Test<br>5. Biotechnostix, Inc. Rapid Response FSH One Step Menopause Test Device  | ACON Laboratories, Inc.<br>ACON Laboratories, Inc.<br>ACON Laboratories, Inc.<br>Applied Biotech, Inc.<br>ACON Laboratories, Inc.            | Detects follicle stimulating hormone in urine  |

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|--------------------|--|--------------------------------------|---|
| 83001QW (cont.)    | 6. Genosis Fertell Female Fertility Test                         | Genosis, Inc.                        | Detects follicle stimulating hormone in urine   |
|                    | 7. Genua Menopause Monitor Test                                  | Genua 1944 Inc                       |   |
|                    | 8. Synova Healthcare MenocheckPro (Professional Use)             | Applied Biotech, Inc.                |   |
| 83036QW            | 1. Axis-Shield Afinion AS100 Analyzer                            | Axis-Shield Poc                      | Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes   |
|                    | 2. Alere Technologies AS, Alere Afinion AS101 Analyzer           | Axis-Shield Poc                      |   |
|                    | 3. Bayer A1CNow+ Professional Use                                | Bayer Healthcare, LLC                |   |
|                    | 4. Siemens Medical Diagnostics DCA Vantage Analyzer              | Siemens Healthcare Diagnostics, Inc. |   |
|                    | 5. PTS Diagnostics A1CNow + Professional Use                     | Polymer Technology Systems, Inc.     |   |
|                    | 6. Siemens DCA 2000 Analyzer                                     | Siemens Healthcare Diagnostics, Inc. |   |
|                    | 7. Siemens DCA 2000+ Analyzer                                    | Siemens Healthcare Diagnostics, Inc  |   |
| 83037QW            | 1. Bayer A1CNow+ {For professional use}                          | Bayer Corp.                          | Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes using devices cleared by the FDA for home use |
|                    | 2. Bayer A1C Now SelfCheck                                       | Bayer Healthcare, Llc.               |   |
|                    | 3. BIO-RAD in2it (II) System Analyzer Prescription Home Use      | Bio-Rad Laboratories, Inc.           |   |
|                    | 4. Bio-Rad Micromat II Hemoglobin A1c Prescription Home Use Test | Bio-Rad Laboratories, Inc.           |   |
|                    | 5. Cholestech GDX A1C Test (Prescription Home Use)               | Cholestech Corporation               |   |
|                    | 6. Provalis Diagnostics Glycosal™ HbA1c Test                     | Provalis Diagnostics Ltd.            |   |

**This list includes updates from Change Request FFS10198**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

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|---|--|------------------------------------|---|
| 83037QW (cont.)   | 7. Provalis Diagnostics In2it In-Office Analyzer (II) Prescription Home Use Test System              | Provalis Diagnostics Ltd           | Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes using devices cleared by the FDA for home use |
| 83516QW   | Rapid Pathogen Screening, Inc. InflammDry  | Rapid Pathogen Screening, Inc.     | Detection of elevated levels of the MMP-9 protein in human tears, from patients suspected of having dry eye.  |
| 82044QW   | 1. Beckman Coulter ICON Microalb   | Beckman Coulter, Inc.              | Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease                       |
|   | 2. Boehringer Mannheim Chemstrip Micral  | Boehringer Mannheim                |   |
|   | 3. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Test  | Diagnostic Chemicals Limited       |   |
|   | 4. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick)                           | Diagnostic Chemicals Limited (USA) |   |
|   | 5. Genzyme Diagnostics OSOM ImmunoDip Urinary Albumin Test   | Genzyme Diagnostics                |   |
|   | 6. Roche Diagnostics Chemstrip Micral (urine dipstick)   | Roche Diagnostics Corporation      |   |
| 83605QW   | KDK Corporation Lactate Pro System   | KDK Corporation                    | Quantitative measurement of lactate in whole blood  |
| 83655QW   | ESA Biosciences LeadCare II Blood Lead Testing System (whole blood)                                  | ESA Biosciences, Inc.              | Quantitative measurement of blood lead in whole blood   |
| 83718QW,<br>84478QW,<br>82947QW, 82950QW,<br>82951QW, 82952QW | Polymer Technology Systems CardioChek PA Analyzer (PTS Panels Metabolic Chemistry Panel Test Strips) | Polymer Technology Systems, Inc.   | Measures HDL cholesterol, triglycerides, and glucose in whole blood   |
| 83721QW   | Polymer Technology Systems Cardiochek PA Analyzer  | Polymer Technology Systems, Inc.   | Measures LDL cholesterol in whole blood   |
| 83861QW   | TearLab Corporation TearLab Osmolarity System  | TearLab Corporation                | Impedance measurement of tear fluid to provide an indirect assessment of osmolarity.  |

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|---------------------------|--|--|--|
| 83880QW                   | <ol style="list-style-type: none"> <li>1. Biosite Triage Meter {Whole Blood}</li> <li>2. Biosite Triage Meter Plus {Whole Blood}</li> </ol>  | Biosite Incorporated   | Quantitative measurement of B-type natriuretic peptide (BNP)   |
| 83986QW                   | All qualitative color comparison pH testing - body fluids (other than blood)   | Various  | pH detection (acid-base balance) in body fluids such as semen, amniotic fluid, and gastric aspirates   |
| 83986QW                   | <ol style="list-style-type: none"> <li>1. Dale Medical Products, Inc. RightLevel pH</li> <li>2. Dale Medical Products, Inc. RightSpot pH</li> <li>3. RightBio Metrics, RightSpot Infant pH Indicator</li> <li>4. RightBio Metrics, RightSpot pH Detector</li> <li>5. RightBio Metrics, RightSpot pH Indicator</li> </ol>   | EZ-NG, LLC.<br>EZ-NG, LLC.<br>Right BioMetrics<br>Right BioMetrics<br>Right BioMetrics   | Gastric pH detection (acid-base balance)   |
| 83986QW                   | <ol style="list-style-type: none"> <li>1. FemTek pHEM-ALERT®</li> <li>2. Common Sense Ltd. Norma-Sense Vaginal Discharge pH Test</li> <li>3. Common Sense Ltd. VA-Sense Kit</li> <li>4. Common Sense Ltd. VS-Sense Test {qualitative}</li> <li>5. Lil' Drug Store Products Inc. Vagi-Screen Vaginal Health Test</li> <li>6. Teco Diagnostics OBGYN-VpH Vaginal pH Screening Kit</li> </ol> | FemTek, LLC<br>Common Sense Ltd.<br>Common Sense, Ltd.<br>Common Sense, Ltd<br>Lil' Drug Store Products Inc.<br>Teco Diagnostics | Vaginal pH detection (acid-base balance)   |
| 84295QW, 84132QW, 85014QW | Abbott i-STAT E3+ Cartridge {Whole Blood}  | i-Stat Corporation   | Measures potassium, sodium, and hematocrit in whole blood  |
| 84443QW                   | <ol style="list-style-type: none"> <li>1. Aventir Biotech LLC, Forsure TSH Test {Whole Blood}</li> </ol>   | Screening Devices Canada Inc.  | Qualitative determination of human thyroid stimulating hormone (TSH) in whole blood, which is a rapid TSH assay for hypothyroidism screening in adults |

**This list includes updates from Change Request FFS10198**

\* Newly added waived test system

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|--------------------|---|--|--|
| 84443QW (cont.)    | 2. BTNX, Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette     | Screening Devices Canada Inc.                      | Qualitative determination of human thyroid stimulating hormone (TSH) in whole blood, which is a rapid TSH assay for hypothyroidism screening in adults |
|                    | 3. BTNX, Inc Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette | Screening Devices Canada Inc.                      |  |
|                    | 4. CLIAwaived Inc. Thyroid Test Rapid TSH Cassette {Whole Blood}            | Screening Devices Canada Inc.                      |  |
|                    | 5. Germaine Laboratories, Inc. AimStep Thyroid Screen {whole blood}         | Screening Devices Canada Inc.                      |  |
|                    | 6. ThyroTec, Inc. ThyroTest Whole Blood TSH Test                            | ThyroTec, Inc.                                     |  |
|                    | 7. Jant Pharmacal Accutest TSH {Whole Blood}                                | Screening Devices Canada Inc.                      |  |
|                    | 8. Qualigen, Inc. FastChek TSH {Whole blood}                                | Screening Devices Canada Inc.                      |  |
|                    | 84450QW, 84520QW  | Arkray SPOTCHEM EZ Chemistry Analyzer{whole blood} |  |
| 84450QW            | Cholestech LDX Aspartate Aminotransferase (AST)(SGOT)                       | Cholestech Corporation                             | Quantitative determination of aspartate aminotransferase in whole blood  |
| 84460QW            | Cholestech LDX® Alanine Aminotransferase (ALT) Test                         | Cholestech Corporation                             | Quantitative determination of alanine aminotransferase in whole blood  |
| 84703QW            | Bayer Clinitek 50 Urine Chemistry Analyzer - for HCG, urine                 | Bayer Corp.  | Diagnosis of pregnancy   |
| 85014QW            | Wampole STAT-CRIT Hct   | Wampole Laboratories                               | Screen for anemia  |
| 85018QW            | 1. AimStrip Hb Hemoglobin (Hb) Testing System                               | Acon Laboratories, Inc.                            | Measures hemoglobin level in whole blood   |
|                    | 2. Alere HemoPoint H2 System  | Stanbio Laboratory                                 |  |
|                    | 3. Biosafe Laboratories, Inc., Anemiapro Self Screener                      | Biosafe Laboratories, Inc.                         |  |

**This list includes updates from Change Request FFS10198**

\* Newly added waived test system

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|--|--|---|--|-----------------------|--|
| 85018QW (cont.)  | 4. Clarity HbCheck Hemoglobin Testing System                         | Acon Laboratories, Inc.   | Measures hemoglobin level in whole blood |                       |  |
|  | 5. HemoCue Donor Hemoglobin Checker System HemoCue                   | HemoCue, Inc.   |  |                       |  |
|  | 6. HemoCue Hemoglobin System   | HemoCue, Inc.   |  |                       |  |
|  | 7. HemoCue Hemoglobin 201+ (Capillary, Venous, Arterial Whole Blood) | HemoCue, Inc.   |  |                       |  |
|  | 8. HemoCue Hemoglobin 201+/HemoCue Hemoglobin Microcuvette System    | HemoCue, Inc.   |  |                       |  |
|  | 9. HemoCue Hb 301 System   | HemoCue, Inc.   |  |                       |  |
|  | 10. GDS Diagnostics HemoSite Meter - for hemoglobin                  | GDS Technology, Inc.  |  |                       |  |
|  | 11. GDS Technology STAT-Site MHgb Test System                        | GDS Technology  |  |                       |  |
|  | 85576QW  | Accumetrics VerifyNow Aspirin Assay                                     |  | Accumetrics Inc.      | Qualitative assay to measure platelet aggregation  |
|  | 85610QW (Contact your Medicare carrier for claims instructions.)     | 1. AlereINRatio®2 PT/INR Home Monitoring System {Prescription Home Use} |  | Alere San Diego, Inc. | Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumadin or warfarin effect; screen for Vitamin K deficiency |
|  |  | 2. AvoSure PT System (prescription home use)                            |  | Avocet Medical, Inc.  |  |
| 3. AvoSure Pro (professional use)  |  | Avocet Medical, Inc.  |  |                       |  |
| 4. CoaguChek PST for Prothrombin Time  |  | Boehringer Mannheim Corporation   |  |                       |  |
| 5. Coag-Sense Prothrombin Time (PT/INR) Monitoring system (Professional use) |  | CoaguSense, Inc.  |  |                       |  |

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| <b><u>CPT CODE(S)</u></b>   | <b><u>TEST NAME</u></b>   | <b><u>MANUFACTURER</u></b>                               | <b><u>USE</u></b>  |                                |  |
|---|---|--|--|--------------------------------|--|
| 85610QW (cont.)<br>(Contact your Medicare carrier for claims instructions.) | 6. CoaguSense Self-Test Prothrombin Time/INR Monitoring System (Prescription Home Use)                | CoaguSense, Inc.   | Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumadin or warfarin effect; screen for Vitamin K deficiency |                                |  |
|   | 7. HemoSense INRatio System   | HemoSense, Inc.  |  |                                |  |
|   | 8. ITC Protime Microcoagulation System for Prothrombin Time   | International Technidyne Corporation (ITC)               |  |                                |  |
|   | 9. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Prescription Home Use | International Technidyne Corporation                     |  |                                |  |
|   | 10. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Professional Use     | International Technidyne Corporation                     |  |                                |  |
|   | 11. Lifescan Harmony™ INR Monitoring System -- Prescription Home Use and Professional Use             | Lifescan, Inc.   |  |                                |  |
|   | 12. Roche/Boehringer Mannheim CoaguChek System for Professional Use                                   | Roche Diagnostics/<br>Boehringer Mannheim Corporation    |  |                                |  |
|   | 13. Roche Diagnostics Coaguchek PST   | Roche Diagnostics  |  |                                |  |
|   | 14. Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time)                                | Roche Diagnostics  |  |                                |  |
|   | 15. Roche Diagnostics CoaguChek XS  | Roche Diagnostics  |  |                                |  |
|   | 16. Roche Diagnostics CoaguChek XS Plus System  | Roche Diagnostics  |  |                                |  |
|   | 86294QW   | 1. Bion Diagnostic Sciences BTA stat Test (for home use) |  | Bion Diagnostic Sciences, Inc. | Immunoassay for the qualitative detection of bladder tumor associated antigen in urine of persons diagnosed with bladder cancer, and used as an aid in the management of bladder cancer patients |
|   |   | 2. LifeSign Status BTA                                   |  | Polymedco, Inc.                |  |

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 \* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

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|--------------------|--|---|--|
| 86308QW            | Screening test for mononucleosis (mono) categorized as waived complexity. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the currently waived test systems.                                    | Various   | Qualitative screening test for the presence of heterophile antibodies in human whole blood, which is used as an aid in the diagnosis of infectious mononucleosis |
| 86318QW            | Immunoassay for <i>Helicobacter pylori</i> antibodies, single step method, categorized as waived complexity. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the currently waived test systems. | Various   | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood   |
| 86386QW            | <ol style="list-style-type: none"> <li>Alere NMP22 BladderChek Test (Prescription Home Use) and (Professional Use)</li> <li>Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use</li> </ol>  | Alere<br><br>Maritech, Inc.   | Immunoassay for the qualitative detection of nuclear matrix protein NMP22 in urine for use as an aid in monitoring bladder cancer patients                       |
| 86618QW            | Wampole PreVue™ <i>B. burgdorferi</i> Antibody Detection Assay   | Wampole Laboratories  | Qualitative detection of IgG/IgM antibodies to <i>Borrelia burgdorferi</i> (causative agent of Lyme disease) in whole blood                                      |
| 86701QW            | <ol style="list-style-type: none"> <li>bioLytical INSTI HIV-1 Antibody Test {Fingerstick Whole Blood}</li> <li>OraSure Technologies OraQuick Rapid HIV-1 Antibody Test</li> <li>OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood</li> </ol>   | BioLytical Laboratories, Inc.<br><br>OraSure Technologies, Inc.<br><br>OraSure Technologies, Inc. | Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1)  |

**This list includes updates from Change Request FFS10198**

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|---------------------|--|-----------------------------------|--|
|                     | 4. Trinity Biotech Uni-Gold Recombigen HIV Test (Fingerstick, Venipuncture Whole Blood)                                    | Trinity Biotech                   |  |
| 86780QW             | Diagnostics Direct LLC Syphilis Health Check {FingerStick Whole Blood}   | Diagnostics Direct LLC            | Immunochromatographic assay for the detection of <i>Treponema pallidum</i> (syphilis) antibodies in whole blood  |
| G0433QW             | 1. OraSure OraQuick Advance Rapid HIV-1/2 Antibody Test {oral fluid, fingerstick whole blood and venipuncture whole blood} | OraSure Technologies, Inc.        | Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood , venipuncture whole blood and/or oral fluid specimens |
|                     | 2. OraSure Technologies OraQuick In-Home HIV Test {Oral Fluid}   | OraSure Technologies, Inc.        |  |
|                     | 3. Chembio Diagnostic Systems, Inc, DPP HIV 1/2 Assay {Oral Fluid}   | Chembio Diagnostic Systems, Inc.  |  |
|                     | 4. Clearview Complete HIV 1/2 {Fingerstick Venipuncture, whole blood}  | Chembio Diagnostic Systems, Inc.  |  |
| 86803QW,<br>G0472QW | OraQuick HCV Rapid Antibody Test and OraQuick Visual Reference Panel   | Orasure Technologies Inc.         | Qualitative immunoassay to detect antibodies to hepatitis C virus in fingerstick whole blood and venipuncture whole blood specimens  |
| 87077QW             | 1. Ballard Medical Products CLOtest  | Ballard Medical Products          | Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)   |
|                     | 2. Delta West CLOtest  | Delta West<br>Tri-Med Specialties |  |
|                     | 3. GI Supply HP-FAST   | Mycoscience Labs, Inc.            |  |
|                     | 4. GI Supply, Div. Chek-Med Systems HP One   | GI Supply                         |  |
|                     | 5. Jant Accutest Rapid Urease test (H. pylori detection)   | ARJ Medical, Inc.                 |  |
|                     | 6. Medical Instruments Corporation Pronto Dry H. pylori  | Medical Instruments Corporation   |  |
|                     | 7. Serim Pyloritek Test Kit  | Serim                             |  |

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|--|--|--|---|
| 87210QW  | 1. Stesans Maybe?Mom Mini Ovulation Microscope<br>2. O2 Unlimited Donna Ovulation Tester   | LEC Associates<br>O2 Unlimited Corp.   | Detects ferning pattern in saliva which is used in the determination of ovulation (optimal for conception)  |
| 87338QW  | Meridian Bioscience Immunocard STAT! HpSA (Stool)  | Meridian Bioscience, Inc.              | Immunoassay for rapid, qualitative detection of <i>Helicobacter pylori</i> antigens in stool  |
| 87389QW [from December 5, 2014 to December 31, 2014],<br>87806QW [on and after January 1, 2015],<br>G0475QW [on and after January 1, 2017] | Orgenics, Alere Determine HIV-1/2 Ag/Ab Combo {fingerstick Whole Blood}  |  | Detects antigen to HIV-1, and antibodies to HIV-1 and HIV-2 in whole blood  |
| 87449QW  | ZymeTx Zstatflu® Test  | Zymetx, Inc.                           | Qualitative determination of influenza types A and B from throat swab specimens that does not differentiate between types A and B   |
| 87502QW  | 1. Alere i Influenza A & B Test {Direct Nasal swab only}<br>2. RocheMolecular, cobas Liat System (cobas Liat Influenza A/B Assay)        | Alere Scarborough, Inc.<br>IQuum, Inc. | Differential and qualitative detection of Influenza A and Influenza B viral nucleic acids using isothermal nucleic acid amplification technology<br>Real-time RT-PCR assay for detection and discrimination of Influenza A and Influenza B in nasopharyngeal swab specimens   |
| 87631QW  | 1. Cepheid Gene Xpert Xpress System (Xpert Flu+RSV Xpress)<br>2. Roche Molecular, cobas Liat System cobas Liat Influenza A/B & RSV Assay | Cepheid<br>IQUUM, INC.                 | Detection of influenza A, influenza B and respiratory syncytial virus (RSV) viral RNA by reverse transcriptase polymerase chain reaction assay  |
| 87633QW  | BioFire Diagnostics, FilmArray 2.0 EZ Configuration Instrument (Viral and Bacterial Nucleic Acids){Nasopharyngeal Swabs}                 | BioFire Diagnostics, LLC               | Multiplexed nucleic acid test for detection and identification of multiple respiratory pathogen nucleic acids in nasopharyngeal swabs   |
| 87651QW  | 1. Alere i Instrument<br>2. Roche Molecular, cobas Liat System   | Alere Scarborough, Inc.<br>IQuum, Inc. | Detection of Group A Strep bacterial nucleic acids utilizing isothermal nucleic acid amplification technology<br>Detection of Streptococcus group A utilizing nucleic acid purification and polymerase chain reaction (PCR) technology (automation and integration of sample purification, nucleic acid amplification, and detection of the target sequence using real-time PCR) to detect Streptococcus pyogenes |

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|--------------------|---|--|---|
| 87801QW            | Alere i System Respiratory Syncytial Virus  | Alere Scarborough, Inc.  | Qualitative detection of RSV viral RNA in direct nasopharyngeal swabs and nasopharyngeal swabs eluted in viral transport media utilizing isothermal nucleic acid amplification technology                             |
| 87804QW            | Quidel QuickVue® Influenza Test   | Quidel Corporation   | Qualitative detection of influenza type A and type B antigens from nasal swab, nasal wash or nasal aspirate specimens that does not differentiate between influenza types A and B                                     |
| 87804QW            | <ol style="list-style-type: none"> <li>1. Alere Influenza A &amp; B Test (For use with nasal Swabs only.)</li> <li>2. Alere BinaxNow Influenza A &amp; B Card {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens }</li> <li>3. BD Veritor System for Rapid Detection of Flu A+B (For use with nasal and nasopharyngeal swabs) {Includes a Reader }</li> <li>4. BinaxNow Influenza A &amp; B Test, K092223</li> <li>5. BinaxNOW® Influenza A &amp; B Test in nasopharyngeal (NP) swab and nasal wash/aspirate specimens, K041049</li> <li>6. BinaxNOW Influenza A &amp; B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}, K053126</li> <li>7. BinaxNOW Influenza A &amp; B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens and Nasal Specimens (NS)}</li> <li>8. BioSignFlu A+B {Nasal and nasopharyngeal swabs }</li> <li>9. Henry Schein OneStep+ Influenza A&amp;B Test</li> </ol> | <ol style="list-style-type: none"> <li>Alere Scarborough, Inc.</li> <li>Alere Scarborough, Inc.</li> <li>Becton, Dickinson and Company</li> <li>Binax, Inc</li> <li>Binax, Inc.</li> <li>Binax, Inc.</li> <li>Binax, Inc.</li> <li>Princeton Biomeditech Corporation</li> <li>Alere Scarborough, Inc.</li> </ol> | <p>Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that does differentiate between influenza types A and B</p> |

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|--------------------|---|-----------------------------------|--|
| 87804QW (cont.)    | 10. LifeSign LLC, Status Flu A+B {Nasal and Nasopharyngeal Swabs}                             | Princeton Biomeditech Corporation | Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that does differentiate between influenza types A and B |
|                    | 11. OraSure QuickFlu Rapid A+B Test {Nasal and Nasopharyngeal Swabs}                          | Princeton Biomeditech Corporation |  |
|                    | 12. Quidel Quickvue Influenza A+B Test  | Quidel Corporation                |  |
|                    | 13. Quidel Sofia 2 {Sofia Influenza A+B FIA}*   | Quidel Corporation                |  |
|                    | 14. Sekisui Diagnostics LLC, OSOM Ultra Flu A&B Test {Nasal and Nasopharyngeal Swabs}         | Princeton Biomeditech Corporation |  |
|                    | 15. Sofia Analyzer and Influenza A+B FIA  | Quidel Corporation                |  |
| 87804QW            | 16. Sofia Analyzer and Influenza A+B FIA (for user with nasal swabs and nasopharyngeal swabs) | Quidel Corporation                | Qualitative detection of influenza type A antigen in nasopharyngeal specimens  |
|                    | 1. Binax Now® Flu A Test  | Binax, Inc.                       |  |
|                    | 2. BTNX, Inc. Rapid Response Influenza A Test Cassette  | SA Scientific, Inc.               |  |
|                    | 3. EarlyDetect Pro Influenza A Test   | SA Scientific, Inc.               |  |
| 87804QW            | 4. SA Scientific SAS Influenza A Test   | SA Scientific, Inc.               | Qualitative detection of influenza type B antigen in nasopharyngeal specimens  |
|                    | 1. Binax Now® Flu B Test  | Binax, Inc.                       |  |
|                    | 2. BTNX, Inc. Rapid Response Influenza B Test Cassette  | SA Scientific, Inc.               |  |
|                    | 3. EarlyDetect Pro Influenza B Test   | SA Scientific, Inc.               |  |
|                    | 4. SA Scientific SAS Influenza B Test   | SA Scientific, Inc.               |  |

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|--------------------|--|--------------------------------|---|
| 87807QW            | 1. Alere BinaxNOW RSV Card   | Alere Scarborough, Inc.        | Rapid immunoassay for the qualitative detection of RSV antigen  |
| 87807QW (cont.)    | 2. BD Veritor System for Rapid Detection of RSV (For use with nasopharyngeal specimens){Includes a reader}   | Becton, Dickinson and Company  | Rapid immunoassay for the qualitative detection of RSV antigen  |
|                    | 3. Binax NOW RSV Test (K021687)  | Binax, Inc.                    |   |
|                    | 4. Binax NOW RSV Test (K032166/A005)   | Binax, Inc.                    |   |
|                    | 5. Fisher Scientific Sure-View RSV Test  | SA Scientific, Inc.            |   |
|                    | 6. Integrated Biotechnology Quick Lab RSV Test   | Integrated Biotechnology Corp. |   |
|                    | 7. Quidel Quick View RSV Test  | Quidel Corporation             |   |
|                    | 8. SA Scientific SAS RSV Alert   | SA Scientific, Inc.            |   |
|                    | 9. Sofia RSV   | Quidel Corp.                   |   |
| 87808QW            | 1. Genzyme OSOM Trichomonas Rapid Test   | Genzyme Corp.                  | Immunoassay for the qualitative detection of <i>Trichomonas vaginalis</i> antigens from vaginal swabs   |
|                    | 2. Sekisui Diagnostics, LLC OSOM Trichomonas Rapid Test  | Genzyme Corp.                  |   |
| 87809QW            | 1. Rapid Pathogen Screening RPS Adeno Detector   | Rapid Pathogen Screening       | Immunochromatographic test for the qualitative detection of adenoviral antigens from eye fluid  |
|                    | 2. AdenoPlus (human eye fluid)   | Rapid Pathogen Screening, Inc. |   |
| 87880QW            | Streptococcus group A antigen detection by immunoassay with direct optical observation categorized as waived complexity. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the currently waived test systems. | Various                        | Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever |

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|---|--|-------------------------------|---|
| 87899QW   | Meridian Bioscience Immunocard STAT! HpSA {Stool}  | Meridian Bioscience, Inc.     | Immunoassay for the qualitative detection of <i>Helicobacter pylori antigens</i> in stool specimens   |
| 87905QW   | Gryphus Diagnostics BVBlue   | Gryphus Diagnostics, LLC      | Enzyme activity test for the detection of sialidase activity in vaginal fluid specimens, an enzyme produced by bacterial pathogens such as <i>Gardnerella vaginalis</i> , <i>Bacteroides</i> spp., <i>Prevotella</i> spp., and <i>Mobiluncus</i> spp. |
| 89300 QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | 1. Embryotech Laboratories FertilMARQ™ Home Diagnostic Screening Test for Male Infertility | Embryotech Laboratories, Inc. | Screening test to measure sperm concentration   |
|   | 2. SpermCheck Vasectomy  | Princeton BioMeditech Corp.   | Detects sperm in semen following a vasectomy  |
| 89321QW   | Fertell Male Fertility Test  | Genosis Ltd.                  | Determines whether the concentration of motile sperm is above a cut-off level of 10 million motile sperm cells per ml   |