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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 2155 | Date: February 11, 2011 |
| | Change Request 7266 |

SUBJECT: New Waived Tests

I. SUMMARY OF CHANGES: This instruction informs contractors of new waived tests approved by the Food and Drug Administration under Clinical Laboratory Improvement Amendments of 1988. Since these tests are marketed immediately after approval, the Centers for Medicare and Medicaid Services must notify its contractors of the new tests so that the contractors can accurately process claims. This Recurring Update Notification (RUN) can be found in Chapter 16, Section 70.8.

EFFECTIVE DATE: April 1, 2011

IMPLEMENTATION DATE: April 4, 2011

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

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|--------------|---|
| N/A | |

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

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

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

Attachment – Recurring Update Notification

| | | | |
|--------------------|--------------------------|--------------------------------|-----------------------------|
| Pub. 100-04 | Transmittal: 2155 | Date: February 11, 2011 | Change Request: 7266 |
|--------------------|--------------------------|--------------------------------|-----------------------------|

SUBJECT: New Waived Tests

Effective Date: April 1, 2011

Implementation Date: April 4, 2011

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 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.

| CPT Code | Effective Date | Description |
|--------------------|-----------------------|---|
| 87880QW | October 4, 2010 | BTNX, Inc. Strep A Rapid Test |
| 86308QW | October 4, 2010 | Consult Diagnostics Mononucleosis Cassette {Whole Blood} |
| 82274QW G0328QW | October 4, 2010 | BTNX Inc. Rapid Response Fecal Immunochemical Test (FIT) |
| 82274QW G0328QW | October 4, 2010 | American IVD Biotechnology Services Inc. FOB/CRC Advanced+ |
| G0434QW | January 1, 2011 | Amedica Biotech AmediCheck Instant Test Cup |
| G0434QW | January 1, 2011 | Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test |
| G0434QW | January 1, 2011 | Insight Medical Multi-Drug of Abuse Urine Test |
| G0434QW | January 1, 2011 | Jant Pharmacal Corporation Accutest Drug Test Cup |
| G0434QW | January 1, 2011 | Micro Distributing II, Ltd Multi-Drug of Abuse Urine Test |
| G0434QW | January 1, 2011 | Millenium Laboratories Multi-Drug of Abuse Urine Test |
| G0434QW | January 1, 2011 | NexScreen LLC, NexScreen Cup |
| G0434QW | January 1, 2011 | On the Spot Drug Testing Multi-Drug of Abuse Urine Test |
| G0434QW | January 1, 2011 | Physicians' Test Multi-Drug of Abuse Urine Test |
| G0434QW | January 1, 2011 | Total Diagnostic Solutions Multi-Drug of Abuse Urine Test |

| CPT Code | Effective Date | Description |
|-----------------|-----------------------|---|
| G0434QW | January 1, 2011 | UCP Biosciences, Inc. Drug Screening Test Cards |
| G0434QW | January 1, 2011 | UCP Biosciences, Inc. Multiple Drug Screen Cups |

For 2011, the code G0430 has been deleted and G0434 is its replacement. Therefore, the code G0434QW replaces G0430QW in the attached list.

In 2011, the description for code G0431 was changed from “Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class” to “Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter.” Hence, the following CLIA waived complexity test systems mentioned in the attached list had their code changed from G0431QW to G0434QW:

- Phamatech QuickScreen One Step Amphetamine Test,
- Accu-Stat Drugs of Abuse Home Test for Marijuana (THC),
- ADC CLIA Waived Marijuana (THC) Test,
- First Check Diagnostics LLC, First Check Home Drug Test Marijuana,
- Phamatech QuickScreen One Step THC Screening Test,
- Phamatech At Home Drug Test (Model 9078),
- Phamatech At Home Drug Test (Model 9078T),
- Worldwide Medical Corporation, First Check® Home Drug Test (THC),
- Phamatech At Home Drug Test (Model 9073),
- Phamatech At Home Drug Test (Model 9073T),
- Phamatech QuickScreen One Step Cocaine Screening Test,
- Phamatech At Home Drug Test (Model 9068),
- Phamatech QuickScreen One Step Methamphetamine Test,
- DyanGen NicCheck II Test Strips,
- Mossman Associates, Inc. NicCheck I Test Strips,
- Phamatech At Home Drug Test (Model 9083),
- Phamatech QuickScreen One Step Opiate Screening Test, and
- Phamatech At Home Drug Test (Model 9133).

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 categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

II. BUSINESS REQUIREMENTS TABLE

| Number | Requirement | Responsibility (place an “X” in each applicable column) | | | | | | | | | |
|--------|---|---|-------------|--------|---------------------------------|-------------|------------------------------|-------------|-------------|-------------|-------|
| | | A / B | D M E | F I | C A R R I E R | R H I | Shared-System Maintainers | | | | OTHER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| 7266.1 | The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier. | X | | | X | | | | | | |
| 7266.2 | The Medicare contractor shall permit the use of code G0434QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after January 1, 2011. | X | | | X | | | | | X | |
| 7266.3 | The Medicare contractor shall deny the use of the code G0431QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after April 1, 2011. | X | | | X | | | | | X | |
| 7266.4 | 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 | | | X | | | | | | |
| 7266.5 | Contractors shall not use the explanatory information under the “Use” column in the attachment as the reason for rejecting a claim. | X | | | X | | | | | | |

III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility (place an “X” in each applicable column) | | | | | | | | | |
|--------|---|---|-------------|--------|---------------------------------|-------------|------------------------------|-------------|-------------|-------------|-------|
| | | A / B | D M E | F I | C A R R I E R | R H I | Shared-System Maintainers | | | | OTHER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| 7266.6 | A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ 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 site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your 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 | | | X | | | | | | |

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

Use "Should" to denote a recommendation.

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

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Kathy Todd (410) 786-3385

Post-Implementation Contact(s): Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs) and Carriers*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: 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.

ATTACHMENT – TESTS GRANTED WAIVED STATUS UNDER CLIA

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 82272 (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 7266

* 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> |
|---|--|---------------------|--|
| 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. | |

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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 (Contact your Medicare carrier for claims instructions.), 83718QW, 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. Piccolo Point of Care Chemistry Analyzer (Lipid Panel Reagent Disc) (Whole Blood) | Abaxis, Incorporated | |
| | 4. Polymer Technology Systems CardioChek PA Analyzer {PTS Panels Lipid Panel Test Strips} | Polymer Technology Systems, Inc. | |
| 80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84460QW, 84478QW | Cholestech LDX (Lipid Profile – ALT (GPT)){Whole Blood} | Cholestech Corp. | Measures alanine aminotransferase, total cholesterol, HDL cholesterol, and triglycerides in whole blood |
| 80069QW | 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> |
|---|--|---|--|
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Phamatech QuickScreen One Step Amphetamine Test | Phamatech | Screening test for the presence/detection of amphetamine in urine |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Accu-Stat Drugs of Abuse Home Test for Marijuana (THC) | Accu-Stat Diagnostics, Inc. | Screening test for the presence/detection of cannabinoids (THC) in urine |
| | 2. ADC CLIA Waived Marijuana (THC) Test | Advantage Diagnostics Corporation (ADC) | |
| | 3. First Check Diagnostics LLC, First Check Home Drug Test Marijuana | ACON Laboratories, Inc. | |
| | 4. Phamatech QuickScreen One Step THC Screening Test | Phamatech | |
| | 5. Phamatech At Home Drug Test (Model 9078) | Phamatech | |
| | 6. Phamatech At Home Drug Test (Model 9078T) | Phamatech | |
| | 7. Worldwide Medical Corporation, First Check® Home Drug Test (THC) | Worldwide Medical Corporation | |

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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> |
|---|--|--------------------------|--|
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Phamatech At Home Drug Test (Model 9073) | Phamatech | Screening test for the presence/detection of cocaine metabolites in urine |
| | 2. Phamatech At Home Drug Test (Model 9073T) | Phamatech | Screening test for the presence/detection of cocaine metabolites in urine |
| | 3. Phamatech QuickScreen One Step Cocaine Screening Test | Phamatech | |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Phamatech At Home Drug Test (Model 9068) | Phamatech | Screening test for the presence/detection of methamphetamines in urine |
| | 2. Phamatech QuickScreen One Step Methamphetamine Test | Phamatech | |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. DyanGen NicCheck II Test Strips | DynaGen, Inc. | Detects nicotine and/or its metabolites in urine, which is used as an aid in indicating the smoking status of an individual and as an aid in the identification of a smoker as a low or high nicotine consumer |
| | 2. Mossman Associates, Inc. NicCheck I Test Strips | Mossman Associates, Inc. | |

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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> |
|---|---|-----------------------------|--|
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Phamatech At Home Drug Test (Model 9083) | Phamatech | Screening test for the presence/detection of opiates in urine |
| | 2. Phamatech QuickScreen One Step Opiate Screening Test | Phamatech | |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Phamatech At Home Drug Test (Model 9133) | Phamatech | Screening test for the presence/detection of phencyclidine (PCP) in urine |
| | 2. Phamatech QuickScreen One Step PCP Screening Test | Phamatech | |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Accu-Stat Drugs of Abuse Home Test for Marijuana (THC) and Cocaine (COC) | Accu-Stat Diagnostics, Inc. | Screening test for the presence/detection of cannabinoids (THC) and cocaine metabolites in urine |
| | 2. Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test | ADC | |
| | 3. ADC CLIA Waived Marijuana (THC) and Cocaine Test | ADC | |

This list includes updates from Change Request 7266

* 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> |
|--|---|--------------------------------------|--|
| | 4. Forefront Diagnostics Drugfree@Home THC/COC Test Kit | Forefront Diagnostics, Inc. | |
| | 5. Worldwide Medical Corporation, First Check® Home Drug Test (THC-COC) | Worldwide Medical Corporation | |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Alfa Scientific Designs, Inc. Instant-View Drug of Abuse Urine Cassette Test | Alfa Scientific Designs, Inc. | Screening test for the presence/detection of morphine and oxycodone in urine |
| G0434QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 2. Alfa Scientific Designs, Inc. Instant-View Drug of Abuse Urine Cup Test | Alfa Scientific Designs, Inc. | Screening test for the presence/detection of morphine and oxycodone in urine |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. ADC CLIA Waived Multiple Drug Test Card | ADC | Screening test for the presence/detection of cannabinoids (THC), cocaine metabolites, methamphetamines, opiates, and PCP in urine |
| | 2. Advantage Diagnostics Corporation ADC Multiple Drug Test Card | Advantage Diagnostics Corporation | |
| | 3. Alatex Scientific Peace of Mind Multiple Drugs of Abuse Test | Advantage Diagnostics Corporation | |

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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> |
|---|--|-------------------------------|--|
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Phamatech At Home Drug Test (Model 9150T) | Phamatech | Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, and opiates in urine |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Worldwide Medical Corporation, First Check® Home Drug Test Panel 4 (THC-COC-OPI-MET) | Worldwide Medical Corporation | Screening test for the presence/detection of THC, cocaine metabolites, opiates and methamphetamines in urine |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Accu-Stat Drugs of Abuse Home Test for Marijuana, Cocaine, Amphetamine, Methamphetamines, Opiates and Phencyclidine | Accu-Stat Diagnostics, Inc. | Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, opiates, and PCP in urine |
| | 2. accutest Multi-Drug, Multi-Line Screen Test Device | ACON Laboratories, Inc. | |
| | 3. Acon One Step Multi-Drug, Multi-Line Screen Test Device (Professional Use) | ACON Laboratories, Inc. | Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, opiates, and PCP in urine |
| | 4. Biotechnostix Rapid Response One Step Multi-Drug, Multi-Line Screen Test Device | ACON Laboratories, Inc. | |
| | 5. iCassette Multi-Drug, Multi-Line Screen Test Device | ACON Laboratories, Inc. | |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|--|--|-----------------------------|--|
| | 6. RediScreen Multi-Drug, Multi-Line Screen Test Device | ACON Laboratories, Inc. | |
| | 7. Redwood Toxicology Laboratory Reditest 6 Cassette substance abuse screening device {Professional Use} | Innovacon, Inc. | |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Biotechnostix Rapid Response Multi-Drug, Multi-Line Screen Test Card with Integrated Cup | ACON Laboratories, Inc. | Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, methylenedioxymethamphetamine (MDMA), opiates, and PCP in urine |
| G0434QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 2. Drug Detection Devices Ltd. Multi-Drug Multi-Line Screeners Dip Drug Test With the Integrated Screeners AutoSplit KO Test Cup | Innovacon, Inc. | Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, MDMA , opiates, and PCP in urine |
| | 3. First Check Diagnostics First Check Multi Drug Cup | First Check Diagnostics LLC | |
| | 4. Innovacon Integrated E-Z Split Key Cup II {Professional Use} | Innovacon, Inc. | |
| | 5. Noble Medical Inc. Split-Specimen Cup | ACON Laboratories, Inc. | |
| | 6. 1 Step Detect Associates DTX Drug Test Cup Integrated E-Z Split Key Cup II | Biosite Inc. | |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|---|--|-------------------------------|---|
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 7. Quest Diagnostics Incorporated, Express Results Integrated Multi-Drug Screen Cup {professional use} | Innovacon, Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, and PCP in urine |
| | 8. Wolfe Drug Testing RealityCheck Integrated Specimen Cup | Innovacon, Inc. | |
| | Branan Medical Corporation ToxCup Drug Screen Cup | Branan Medical Corporation | |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Innovacon Multi-Clin Drug Screen Test Device | Innovacon, Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, opiates, oxycodone, PCP, propoxyphene and tricyclic antidepressants in urine |
| | 2. Inverness Medical Innovations Signify ER Drug Screen | Biosite Inc. | |
| | 3. Jant Pharmacal Accutest MultiDrug ER11 Drug Screen Test Device | Innovacon, Inc. | |
| | 4. Abbott Diagnostics Signify ER Drug Screen Test | Innovacon, Inc. | |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Test | Alfa Scientific Designs, Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, MDMA, morphine, PCP and tricyclic antidepressants in urine |

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* Newly added waived test system

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|---|---|-------------------------------|---|
| G0434QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 2. Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Cup Test | Alfa Scientific Designs, Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, MDMA, morphine, PCP and tricyclic antidepressants in urine |
| | 3. BTNX Inc. Know Multi-Drug One Step Screen Test Panel (Urine) | Alfa Scientific Designs, Inc. | |
| | 4. BTNX Inc. Rapid Response Multi-Drug One Step Screen Test Panel (Urine) | Alfa Scientific Designs, Inc. | |
| | 5. Confrim Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test* | Alfa Scientific Designs, Inc. | |
| | 6. Insight Medical Multi-Drug of Abuse Urine Test* | Alfa Scientific Designs, Inc. | |
| | 7. Micro Distributing II, Ltd Multi-Drug of Abuse Urine Test* | Alfa Scientific Designs, Inc. | |
| | 8. Millenium Laboratories Multi-Drug of Abuse Urine Test* | Alfa Scientific Designs, Inc | |
| | 9. Physicians' Test Multi-Drug of Abuse Urine Test* | Alfa Scientific Designs, Inc. | |
| | 10. On the Spot Drug Testing Multi-Drug of Abuse Urine Test * | Alfa Scientific Designs, Inc. | |
| | 11. Quik Test USA, Inc. Multi-Drug of Abuse Urine Test | Alfa Scientific Designs, Inc. | |
| | 12. Screen Tox Multi-Drug of Abuse Urine Test | Alfa Scientific Designs, Inc. | |
| | 13. Total Diagnostic Solutions Multi-Drug of Abuse Urine Test* | Alfa Scientific Designs, Inc | |

This list includes updates from Change Request 7266

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TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|---|---|--------------------------------------|---|
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Aventir Biotech LLC Home Check Multiple Drug Test Cup | Tianjin New Bay Bioresearch Co. Ltd. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, morphine, oxycodone, PCP and tricyclic antidepressants in urine |
| | 2. Aventir Biotech LLC Home Check Multiple Drug Cup Test {Professional version} | Tianjin New Bay Bioresearch Co. Ltd | |
| | 3. Syntron Bioresearch Quikscreen Multiple Drug Cup Test {Professional version} | Tianjin New Bay Bioresearch Co. Ltd | |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Amedica Biotech Amedica Drug Screen Test Cup | Amedica Biotech, Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine |
| | 2. Amedica Biotech AmediCheck Instant Test Cup* | Amedica Biotech, Inc.` | |
| | 3. Ameditech, Inc ImmuTest Drug Screen Cup | Biosite Inc. | |
| | 4. Branam Medical Corporation Fastest II Drug Screen Dipstick Test | Branan Medical Corporation | |
| | 5. Branam Medical Corporation, FasTox Multiple Drug Dipcard | Branan Medical Corporation | |
| | 6. Branam Medical Corporation, QuickTox Drug Screen Dipcard | Branan Medical Corporation | |
| | 7. CLIAwaived, Inc. Rapid Drug Test | Biosite Inc. | |
| | 8. Express Diagnostics, DrugCheck Waive Cup | Biosite Inc. | |

This list includes updates from Change Request 7266

* 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> |
|---|---|-----------------------------|--|
| | 9. First Check Diagnostics First Check 12 Drug Test | First Check Diagnostics LLC | |
| | 10. Jant Pharmacal Corporation ACCUTEST Drug Test Cup* | Amedica Biotech, Inc | |
| | 11. Millennium Laboratories Clinical Supply, Inc Multi-Drug Pain Med Screen Cup | Biosite Inc. | |
| | 12. NexScreen LLC, NexScreen Cup* | Amedica Biotech, Inc. | |
| | 13. Noble Medical Inc. NOBLE 1 Step Cup {OTC} | Biosite Inc. | |
| G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 14. Redwood Toxicology Laboratory, Inc Reditest Freedom Cup | Biosite Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine |
| | 15. Twin Spirit, Inc. DrugSmart Cup | Biosite Inc. | |
| | 16. US Diagnostics ProScreen Drugs of Abuse Cup {OTC} | Biosite Inc. | |
| | 1. American Screening Corporation OneScreen Drug Test Cards | UCP Biosciences, Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, and tricyclic antidepressants in urine |
| | 2. American Screening Corporation OneScreen Drug Test Cups | UCP Biosciences, Inc. | |
| | 3. American Screening Corporation Reveal Multi-Drug Testing Cups | UCP Biosciences, Inc | |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 4. Express Diagnostics International Inc. DrugCheck Waive Drug Test Cards | UCP Biosciences, Inc. | |

This list includes updates from Change Request 7266

* 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> |
|---|---|---------------------------------|---|
| | 5. Express Diagnostics International Inc. DrugCheck Waive Multiple Drug Screen Cups | UCP Biosciences, Inc. | |
| | 6. UCP Biosciences, Inc. Drug Screening Test Cards* | UCP Biosciences | |
| | 7. UCP Biosciences, Inc. Multiple Drug Screen Cups* | UCP Biosciences | |
| | 8. UCP Biosciences, Inc., UCP Home Drug Screening Test Cards | UCP Biosciences, Inc. | |
| G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | American Bio Medica Rapid TOX | American Bio Medica Corp. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, opiates, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine |
| 80178QW | ReliaLAB Inc. InstaRead Lithium System {fingerstick or venipuncture whole blood} | Akers Laboratories, Inc. | Measures lithium blood levels in whole blood |
| 81003QW | 1. Biosys Laboratories Optima Urine Analyzer | BioSys Laboratories, 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 |
| | 2. Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated | Boehringer Mannheim Corporation | |
| | 3. Cole-Talyor Marketing Inc. CTI-120 Urine Strip Analyzer | Acon Laboratories, Inc. | |
| | 4. Consult diagnostics Urine Analyzer | BioSys Laboratories, Inc. | |

This list includes updates from Change Request 7266

* 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> |
|------------------------------------|--|---|--|
| | 5. Henry Schein OneStepPlus Urine Analyzer | Macherey-Nagel GmbH & Co., Kg. | |
| | 6. Hypoguard Diascreen® Urine Chemistry Analyzer | Hypoguard USA, Inc. | |
| | 7. Jant Pharmacal Corporation Accustrip URS Reader | | |
| | 8. Physician Sales & Service, Inc. PSS Select Urine Analyzer | BioSys Laboratories, Inc. | |
| | 9. Roche Diagnostics Urisys 1100 Urine Analyzer | Roche Diagnostics Corp. | |
| | 10. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer | Roche Diagnostics/Boehringer Mannheim Corporation | |
| 81003QW (cont.) | 11. Teco Diagnostics URITEK TC-101 Urine Strip Reader | Teco 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 |
| | 12. ThermoBiostar™ PocketChem™ UA | ThermoBiostar™ | |
| 81003QW, 82044QW, 82570QW | 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 | |

This list includes updates from Change Request 7266

* 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> |
|---|---|----------------------------------|---|
| | 3. Siemens, Clinitek Status Connect System | Siemens Healthcare Diagnostics | |
| 81007QW | 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. |
| 82010QW | PTS Bioscanner (for OTC use) - for blood ketones | Polymer Technology Systems, Inc. | Measures ketones in whole blood |
| 82010QW, 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, 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 | |

This list includes updates from Change Request 7266

* 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, 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 | 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 Dagnostics OSOM ImmunoDip Urinary Albumin Test | Genzyme Dignositcs | |
| 82044QW(cont.) | 6. Roche Diagnostics Chemstrip Micral (urine dipstick) | Roche Diagnostics Corporation | Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease |
| 82247QW, 84075QW, 84155QW, 84450QW, 84460QW | Arkay SPOTCHEM EZ Chemistry Analyer (Spotchem II Basicpanel 2) { Whole Blood } | Polymedco, Inc. | Measures alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, total bilirubin and urea levels in whole blood |

This list includes updates from Change Request 7266

* 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> |
|---|--|-------------------------------|---|
| 82055QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test | OraSure Technologies, Inc. | Quantitative determination of alcohol (ethanol) in saliva |
| | 2. OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test | OraSure Technologies, Inc. | |
| | 3. STC Diagnostics Q.E.D. A150 Saliva Alcohol Test | STC Technologies Inc. | |
| | 4. STC Diagnostics Q.E.D. A350 Saliva Alcohol Test | STC Technologies Inc. | |
| 82120QW, 83986QW | 1. 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 |
| | 2. Quidel QuickVue Advance pH and Amines Test | Quidel Corporation | |
| 82271QW | 1. Aerscher Hemaprompt FG | Aerscher Diagnostics | Rapid screening test to detect the presence of gastric occult blood |
| | 2. SmithKline Gastrocult | SmithKline | Rapid screening test to detect the presence of gastric occult blood |
| 82271QW, 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 G0328QW | 1. American IVD Biotechnology Services Inc. FOB/CRC Advanced+* | Ind Diagnostic Inc. | Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay |
| 82274QW G0328QW(cont.) | 2. Beckman Coulter Hemocult ICT (K961062) & (K080812) | Beckman Coulter, Inc. | Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay |
| | 3. BTNX Inc. Know Fecal Occult Blood (FOB) Self Test | Alfa Scientific Designs, Inc. | |
| | 4. BTNX Inc. Rapid Response Fecal Immunochemical Test (FIT)* | Ind Diagnostic Inc. | |

This list includes updates from Change Request 7266

* 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> |
|---------------------------|--|------------------------------|---|
| | 5. BTNX Inc. Rapid Response Immunological Fecal Occult Blood Test (iFOBT) | Teco Diagnostics | |
| | 6. BTNX Inc. Rapid Response Fecal Occult Blood (FOB) Self Test | Alfa Scientific Designs, Inc | |
| | 7. Care Diagnostics Clarity iFOB Test | Care Diagnostics, Inc. | |
| | 8. Clarity Hemosure One-Step Immunological Fecal Occult Blood Test | Wampole Laboratories | |
| | 9. Clearview Ultra FOB Test | RAC Medical Group, Inc. | |
| | 10. Consult Diagnostics Immunochemical Fecal Occult Blood Test (iFOBT) | Immunostics, Inc. | |
| | 11. Enterix InSure™ Fecal Occult Blood Test | Enterix, Inc. | |
| | 12. Enterix InSure Fecal Immunochemical Test | Enterix, Inc. | |
| | 13. Enterix Insure II Fecal Immunochemical Test | Enterix, Inc. | |
| | 14. Germaine Laboratories AimStep Immunological Fecal Occult Blood Test (iFOBT) | New Bay Bioresearch Co. Ltd. | |
| | 15. Germaine Laboratories Compliance Gold iFOB (immunological fecal occult blood) Test | New Bay Bioresearch Co. Ltd. | |
| | 16. Henry Schein One Step+ iFOBT | Immunostics, Inc. | |
| | 17. immoCare Fecal Occult Blood Test | Care Diagnostic, Inc. | |
| 82274QW G0328QW(cont.) | 18. Immunostics, Inc., hema-screen Specific Immunochemical Fecal Occult Blood Test | Immunostics, In | Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay |

This list includes updates from Change Request 7266

* 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> |
|---|--|------------------------------|---|
| | 19. InSure Quik Fecal Immunochemical Test (F.I.T.) | Enterix, Inc. | |
| | 20. Inverness Medical Clearview iFOBT Complete Fecal Occult Blood Test | New Bay Research Co. Ltd. | |
| | 21. Jant Pharmacal Accutest Immunological Fecal Occult Blood Test (iFOBT) | New Bay Bioresearch Co. Ltd. | |
| | 22. OcculTech Fecal Occult Blood Rapid Test | YD Diagnosites Corp. | |
| | 23. Teco Rapid Fecal Occult Blood (FOB) Card Test | Teco Diagnostics | |
| 82374QW, 82435QW, 82550QW, 82565QW, 82947QW, 84132QW, 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, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW, 85014QW | Abbott i-STAT 6+ Cartridge { Whole Blood } | i-Stat Corporation | Measures chloride, glucose, potassium, sodium, urea nitrogen, and hematocrit in whole blood |

This list includes updates from Change Request 7266

* 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.) | 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. | |
| | 6. Lifestream Technologies Cholesterol Monitor | Lifestream Technologies, Inc. | |
| | 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.), 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 CardioChek PA Analyzer (PTS Panels CHOL+HDL Panel Test Strips) | Polymer Technology Systems, Inc. | |

This list includes updates from Change Request 7266

* 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.), 82962 | 3. Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels CHOL+HDL Test Panel Test Strips) | Polymer Technology Systems, Inc. | |
| | 1. Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels Chol + Glu Test Panel) | Polymer Technology Systems, Inc. | Measures total cholesterol and monitors blood glucose levels |
| | 2. Roche Diagnostics AccuChek Instant Plus Dual Testing System | | |
| 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 CardioChek PA Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips) | Polymer Technology Systems, Inc. | |

This list includes updates from Change Request 7266

* 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.), 83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW, 80061QW | 1. Cholestech LDX | Cholestech Corp. | Measures total cholesterol, HDL cholesterol, triglycerides, and glucose in whole blood |
| | 2. Infopia USA LipidPro lipid profile and glucose measuring system | Infopia CO., Ltd. | |
| 82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83036QW, 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.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84478QW, 84450QW, 84460QW | 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 |

This list includes updates from Change Request 7266

* 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> |
|--|---|--------------------------|--|
| 82523QW | 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 | Abbott i-STAT Crea Cartridge {Whole Blood} | i-Stat Corporation | Quantitative measurement of creatinine in whole blood |
| 82565QW, 84520QW | Abaxis Piccolo xpress Chemistry Analyzer (Kidney Check Panel){Whole Blood} | Abaxis, Inc. | Quantitative measurement of creatinine and urea nitrogen in whole blood |
| 82040QW, 82150QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84075QW, 84155 QW, 84450QW, 84460QW, 84520QW, 84550QW | 1. 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 |
| | 2. Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood} | Abaxis, Inc. | |

This list includes updates from Change Request 7266

* 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 |
| | 2. HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer | HemoCue, Inc. | |
| | 3. Abbott i-STAT G Cartridge { Whole Blood} | i-Stat Corporation | |

This list includes updates from Change Request 7266

* 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> |
|---|--|-------------------------|--|
| 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 |
| 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) |
| 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 |
| | 2. LXN IN CHARGE Diabetes Control System | LXN Corporation | |
| 83001QW | 1. Acon Laboratories, Inc. FSH Menopause Predictor Test | ACON Laboratories, Inc. | Detects follicle stimulating hormone in urine |
| | 2. Acon Laboratories, Inc. FSH One Step Menopause Test Device {Professional Use} | ACON Laboratories, Inc. | |
| | 3. Acon Laboratories, Inc. FSH One Step Menopause Test Strip {Professional Use} | ACON Laboratories, Inc. | |
| | 4. Applied Biotech, Inc. RU25 Plus FSH Menopause Test | Applied Biotech, Inc. | |
| | 5. Biotechnostix, Inc. Rapid Response FSH One Step Menopause Test Device | ACON Laboratories, Inc. | |

This list includes updates from Change Request 7266

* 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> |
|--------------------|---|--------------------------------------|---|
| | 6. Genosis Fertell Female Fertility Test | Genosis, Inc. | |
| | 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-Sheild Poc As | Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes |
| | 2. Siemens Medical Diagnostics DCA Vantage Analyzer | Siemens Healthcare Diagnostics, Inc. | |
| | 3. Siemens DCA 2000 Analyzer | Siemens Healthcare Diagnostics, Inc. | |
| | 4. 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. Bio-Rad Micromat II Hemoglobin A1c Prescription Home Use Test | Bio-Rad Laboratories | |
| | 3. Cholestech GDX A1C Test (Prescription Home Use) | Cholestech Corporation | |
| | 4. Provalis Diagnostics Glycosal™ HbA1c Test | Provalis Diagnostics Ltd. | |
| | 5. Provalis Diagnostics In2it In-Office Analyzer (II) A1C Prescription Home Use Test System | Provalis Diagnostics Ltd | |
| 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 | PTS Bioscanner (for OTC use) - for HDL cholesterol | Polymer Technology Systems, Inc. | Measures HDL cholesterol in whole blood |

This list includes updates from Change Request 7266

* 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> |
|---|--|--|--|
| 83718QW, 84478QW, 82947QW, 82950QW, 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 |
| 83880QW | 1. Biosite Triage Meter {Whole Blood} 2. Biosite Triage Meter Plus {Whole Blood} | 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 | 1. FemTek pHEM-ALERT® 2. Common Sense Ltd. Norma-Sense Vaginal Discharge pH Test 3. Common Sense Ltd. VA-Sense Kit 4. Common Sense Ltd. VS-Sense Test {qualitative} 5. Lil' Drug Store Products Inc. Vagi- Screen Vaginal Health Test | FemTek, LLC Common Sense Ltd. Common Sense, Ltd. Common Sense, Ltd Lil' Drug Store Products Inc. | 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 | 1. Aventir Biotech LLC, Forsure TSH Test {Whole Blood} 2. BTNX, Inc Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette | Screening Devices Canada Inc. 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 7266

* 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> |
|---------------------|--|-------------------------------|---|
| | 3. CLIAwaived Inc. Thyroid Test Rapid TSH Cassette { Whole Blood } | Screening Devices Canada Inc. | |
| | 4. ThyroTec, Inc. ThyroTest Whole Blood TSH Test | ThyroTes, Inc. | |
| | 5. Jant Pharmacal Accutest TSH { Whole Blood } | Screening Devices Canada Inc. | |
| | 6. Qualigen, Inc. FastChek TSH { Whole blood } | Screening Devices Canada Inc. | |
| 84520QW, 84450QW | Arkray SPOTCHEM EZ Chemistry Analyzer{ whole blood } | Arkray, Inc. | Quantitative determination of blood urea nitrogen (BUN) and aspartate aminotransferase in 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. Biosafe Laboratories, Inc., Anemiapro Self Screener | Biosafe Laboratories, Inc. | Measures hemoglobin level in whole blood |
| | 2. HemoCue Donor Hemoglobin Checker System HemoCue | HemoCue, Inc. | |
| | 3. HemoCue Hemoglobin System | HemoCue, Inc. | |
| | 4. HemoCue Hemoglobin 201+ (Capillary, Venous, Arterial Whole Blood) | HemoCue, Inc. | |
| | 5. HemoCue Hemoglobin 201+/HemoCue Hemoglobin Microcuvette System | HemoCue, Inc. | |
| | 6. HemoCue Hb 301 System | HemoCue, Inc. | |

This list includes updates from Change Request 7266

* 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> |
|---|---|--|--|
| 85018QW(cont.) | 7. GDS Diagnostics HemoSite Meter - for hemoglobin | GDS Technology, Inc. | Measures hemoglobin level in whole blood |
| | 8. 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. AvoSure PT System (prescription home use) | Avocet Medical, 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 Pro (professional use) | Avocet Medical, Inc. | |
| | 3. CoaguChek PST for Prothrombin Time | Boehringer Mannheim Corporation | |
| | 4. CoaguSense Self-Test Prothrombin Time/INR Monitoring System (Prescription Home Use) | Coagusense, Inc. | |
| 85610QW(cont.) (Contact your Medicare carrier for claims instructions.) | 5. HemoSense INRatio System | HemoSense, 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 |
| | 6. ITC Prottime Microcoagulation System for Prothrombin Time | International Technidyne Corporation (ITC) | |
| | 7. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Prescription Home Use | International Technidyne Corporation | |
| | 8. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Professional Use | International Technidyne Corporation | |
| | 9. Lifescan Harmony™ INR Monitoring System -- Prescription Home Use and Professional Use | Lifescan, Inc. | |

This list includes updates from Change Request 7266

* 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> |
|--------------------|--|--|--|
| | 10. Roche/Boehringer Mannheim CoaguChek System for Professional Use | Roche Diagnostics/ Boehringer Mannheim Corporation | |
| | 11. Roche Diagnostics Coaguchek PST | Roche Diagnostics | |
| | 12. Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time) | Roche Diagnostics | |
| | 13. Roche Diagnostics CoaguChek XS | 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. Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use | Maritech, Inc. | |
| 86308QW | 1. Acceava Mono II {Whole Blood} | Biosite Inc. | 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 |
| 86308QW (cont.) | 2. Acceava Mono Cassette {For whole Blood} | Princeton BioMeditech Corp. | 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 |
| | 3. Acon Mononucleosis Rapid Test Device {Whole Blood} | ACON Laboratories, Inc. | |
| | 4. Acon Mononucleosis Rapid Test Strip {Whole Blood} | ACON Laboratories, Inc. | |
| | 5. Applied Biotech SureStep Mono Test (whole blood) | Applied Biotech, Inc. | |
| | 6. BioStar Acceava Mono Test (whole blood) | Wyntek Diagnostics, Inc. | |
| | 7. Cardinal Health SP Brand Rapid Test Mono {Whole Blood} | Cardinal Health | |

This list includes updates from Change Request 7266

* 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> |
|--------------------|--|--|--|
| | 8. Clearview MONO Whole Blood, K042272/A013 | Inverness Medical Professional Diagnostics | |
| | 9. Clearview MONO Whole Blood, K042272/A016 | Innovacon, Inc. | |
| | 10. Clearview Mono-plus II | Applied Biotech, Inc. | |
| | 11. Consult Diagnostics Mononucleosis Cassette {Whole Blood}* | Princeton BioMeditech Corp. | |
| | 12. Genzyme Contrast Mono (whole blood) | Genzyme Diagnostics | |
| | 13. Genzyme OSOM Mono Test | Wyntek Diagnostics, Inc. | |
| | 14. Icon Mono | Beckman Coulter, Inc. | |
| | 15. Immuno Detector Mono {Whole Blood} | Princeton BioMeditech Corp. | |
| | 16. Instant Technologies iScreen Mononucleosis Rapid Test Device {Whole Blood} | ACON Laboratories, Inc. | |
| | 17. Instant Technologies iScreen Mononucleosis Rapid Test Strip {Whole Blood} | ACON Laboratories, Inc. | |
| 86308QW (cont.) | 18. Jant Accutest Infectious Mononucleosis Test (whole blood) | Applied Biotech, Inc. | 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 |
| | 19. Jant Pharmacal Accutest Value + Mononucleosis Rapid Test {Whole Blood} | Innovacon, Inc. | |
| | 20. LifeSign Status Mono {for whole blood} | Princeton BioMeditech Corp. | |
| | 21. LifeSign UniStep Mono Test (whole blood) | Princeton BioMeditech Corp. | |
| | 22. McKesson Medi-lab Performance Infectious Mononucleosis Test | Applied Biotech, Inc. | |
| | 23. Meridian ImmunoCard STAT Mono (for whole blood) | Applied Biotech, Inc. | |

This list includes updates from Change Request 7266

* 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> |
|--------------------|---|--|--|
| | 24. PerMaxim RediScreen Mononucleosis {Whole Blood} | ACON Laboratories, Inc. | |
| | 25. Polymedco, Inc. Poly stat Mono | Applied Biotech, Inc. | |
| | 26. Poly Stat Mono Test {Whole Blood} | Innovacon, Inc. | |
| | 27. ProAdvantage by NDC Infectious Mononucleosis Test Device (Whole Blood Only) | Biosite Inc. | |
| | 28. Quidel Cards O.S. Mono (for whole blood) | Quidel Corporation | |
| | 29. Quidel QuickVue+ Infectious Mononucleosis (Whole Blood) | Quidel Corporation | |
| | 30. RAC Medical Clarity MONO Mononucleosis Rapid Test Device {Whole Blood} | ACON Laboratories, Inc. | |
| | 31. Remel RIM® A.R.C. Mono Test | Applied Biotech, Inc. | |
| | 32. Seradyn Color Q Mono (whole blood) | Genzyme Diagnostics | |
| 86308QW (cont.) | 33. Signify Mono Cassette {Whole Blood} | Innovacon, Inc. | 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 |
| | 34. Signify Mono Whole Blood | Inverness Medical Professional Diagnostics | |
| | 35. Stanbio Rely Mono Rapid Test{Whole Blood} | Innovacon, Inc. | |
| | 36. Wampole Mono-Plus WB | Wampole Laboratories | |
| | 37. Wyntek Diagnostics OSOM Mono Test (whole blood) | Wyntek Diagnostics, Inc. | |
| | 38. Wyntek Signify Mono Test | Wyntek Diagnostics, Inc. | |
| 86318QW | 1. Abbott FlexPak HP Test for whole blood | SmithKline Diagnostics, Inc. | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood |

This list includes updates from Change Request 7266

* 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> |
|--------------------|---|--------------------------------|--|
| | 2. Abbott Laboratories Signify H. Pylori Cassette {Whole Blood} | Innovacon, Inc. | |
| | 3. Abbott TestPack Plus H. pylori (for whole blood) | Abbott Laboratories | |
| | 4. Acon® H. pylori Test Device | ACON Laboratories, Inc. | |
| | 5. Alfa Scientific Designs Instant View H. Pylori Whole Blood Rapid Test | Alfa Scientific Designs, Inc. | |
| | 6. Applied Biotech SureStep H. pylori WB Test (whole blood) | Applied Biotech, Inc. | |
| | 7. Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to H. Pylori in Whole Blood | Beckman Coulter, Inc. | |
| | 8. Becton Dickinson Link 2 H. pylori Rapid Test (for whole blood) | Cortecs Diagnostics Limited | |
| | 9. Cardinal Health SP Brand Rapid Test H. pylori (K990892) | Applied Biotech Inc. | |
| 86318QW (cont.) | 10. Cardinal Health SP Brand Rapid Test H. pylori {Whole Blood}(K024350/A15) | Innovacon, Inc. | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood |
| | 11. Diagnostic Test Group Clarity H. pylori Rapid Test Device {Whole Blood} | Princeton BioMeditech Corp. | |
| | 12. EarlyDetect H. Pylori Whole Blood Rapid Test | Alpha Scientific Designs, Inc. | |
| | 13. Fisher Healthcare Sure-View H. pylori Test {Whole Blood} | Innovacon, Inc. | |
| | 14. Germaine Laboratories, Aimstep H. pylori {whole blood} | ACON Laboratories, Inc. | |
| | 15. Henry Schein One Step+ H. Pylori Rapid Test Device (Whole Blood) | Innovacon, Inc. | |

This list includes updates from Change Request 7266

* 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> |
|--------------------|--|------------------------------|--|
| | 16. Immunostics Detector H. Pylori WB (H. pyloi Antibody Test) { Whole Blood } | Princeton BioMeditech Corp. | |
| | 17. Instant Technologies iScreen H.pylori Rapid Test Device | ACON Laboratories, Inc. | |
| | 18. Inverness Medical Clearview H. pylori Test { whole blood } | Innovacon, Inc. | |
| | 19. JANT Pharmacal Corp. H. pylori WBTest | Applied Biotech, Inc. | |
| | 20. Inverness Medical Signify H. Pylori Whole Blood | Innovacon, Inc. | |
| | 21. LifeSign Status H.pylori (for whole blood) | Princeton BioMeditech | |
| | 22. Meridian BioScience ImmunoCard STAT! H.pylori Whole Blood Test | Applied Biotech, Inc. | |
| | 23. Polymedco, Inc. Poly stat H.pylori | Applied Biotech, Inc. | |
| | 24. Polymedco Poly Stat H. Pylori Test (Whole Blood) | Innovacon, Inc. | |
| 86318QW (cont.) | 25. Pro-Advantage by NDC H. pylori Device (Whole Blood) | Innovacon, Inc. | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood |
| | 26. QuickVue One-Step H. Pylori Test for Whole Blood | Quidel Corporation | |
| | 27. Quidel QuickVue One-Step H.pylori II Test. | Quidel Corporation | |
| | 28. Remel RIM® A.R.C. H.pylori Test | Remel | |
| | 29. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood | SmithKline Diagnostics, Inc. | |
| | 30. Trinity Uni-Gold™ H.pylori | Trinity Biotech | |

This list includes updates from Change Request 7266

* 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> |
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| | 31. Wampole Laboratories Clearview H. pylori II {finger stick or whole blood} | Applied Biotech , Inc. | |
| 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 | 1. OraSure Technologies OraQuick Rapid HIV-1 Antibody Test | OraSure Technologies, Inc. | Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) |
| | 2. OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood | OraSure Technologies, Inc. | |
| | 3. Trinity Biotech Uni-Gold Recombigen HIV Test (Fingerstick, Venipuncture Whole Blood) | Trinity Biotech | |
| 86703QW | 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 oral fluid, fingerstick whole blood and venipuncture whole blood specimens |
| | 2. Clearview Complete HIV 1/2 {Fingerstick Venipuncture, whole blood} | Chembio Diagnostic Systems, Inc. | |
| 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 Tri-Med Specialties | |
| | 3. GI Supply HP-FAST | Mycoscience Labs, Inc. | |
| | 4. GI Supply, Div. Chek-Med Systems HP One | GI Supply | |
| | 5. Medical Instruments Corporation Pronto Dry H. pylori | Medical Instruments Corporation | |
| | 6. Serim Pyloritek Test Kit | Serim | |

This list includes updates from Change Request 7266

* 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> |
|--------------------|--|---------------------|--|
| 87210QW | 1. Stesans Maybe?Mom Mini Ovulation Microscope | LEC Associates | Detects ferning pattern in saliva which is used in the determination of ovulation (optimal for conception) |
| | 2. O2 Unlimited Donna Ovulation Tester | O2 Unlimited Corp. | |
| 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 |
| 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 | 1. Quidel Quickvue Influenza A+B Test | Quidel 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 |
| | 2. BinaxNow Influenza A & B Test, K092223 | Binax, Inc | |
| | 3. BinaxNOW® Influenza A & B Test in nasopharyngeal (NP) swab and nasal wash/aspirate specimens, K041049 | Binax, Inc. | |
| | 4. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}, K053126 | Binax, Inc. | |
| 87804QW (cont.) | 5. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens and Nasal Specimens (NS)} | Binax, Inc. | 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 |
| 87804QW | 1. Binax Now® Flu A Test | Binax, Inc. | Qualitative detection of influenza type A antigen in nasopharyngeal specimens |
| | 2. EarlyDetect Pro Influenza A Test | SA Scientific, Inc | |
| | 3. SA Scientific SAS Influenza A Test | SA Scientific, Inc. | |
| 87804QW | 1. Binax Now® Flu B Test | Binax, Inc. | Qualitative detection of influenza type B antigen in nasopharyngeal specimens |
| | 2. EarlyDetect Pro Influenza B Test | SA Scientific, Inc | |

This list includes updates from Change Request 7266

* 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> |
|--------------------|--|--------------------------------|---|
| 87807QW | 3. SA Scientific SAS Influenza B Test | SA Scientific, Inc. | Rapid immunoassay for the qualitative detection of respiratory syncytial virus antigen |
| | 1. Binax NOW RSV Test (K021687) | Binax, Inc. | |
| | 2. Binax NOW RSV Test (K032166/A005) | Binax, Inc. | |
| | 3. Fisher Scientific Sure-Vue RSV Test | SA Scientific, Inc. | |
| | 4. Integrated Biotechnology Quick Lab RSV Test | Integrated Biotechnology Corp. | |
| | 5. Quidel Quick Vue RSV Test | Quidel Corporation | |
| 87808QW | 6. SA Scientific SAS RSV Alert | SA Scientific, Inc. | Immunoassay for the qualitative detection of <i>Trichomonas vaginalis</i> antigens from vaginal swabs |
| | Genzyme OSOM Trichomonas Rapid Test | Genzyme Corp. | |
| 87809QW | Rapid Pathogen Screening RPS Adeno Detector | Rapid Pathogen Screening | Immunochromatographic test for the qualitative detection of adenoviral antigens from eye fluid |
| 87880QW | 1. Abbott Signify Strep A Test (from throat swab only) | Wyntek Diagnostics, Inc. | 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 |
| | 2. Abbott Laboratories Signify Strep A Dipstick | Innovacon, Inc. | |
| | 3. Acon® Strep A Rapid Strip Test | ACON Laboratories, Inc. | |
| 87880QW (cont.) | 4. Acon® Strep A Twist Rapid Test | ACON Laboratories, Inc. | 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 |
| | 5. Applied Biotech SureStep Strep A (II) (direct from throat swab) | Applied Biotech, Inc. | |
| | 6. Beckman Coulter ICON DS Strep A Test | Princeton BioMeditech Corp. | |
| | 7. Beckman Coulter ICON SC Strep A Test | ACON Laboratories, Inc. | |
| | 8. Beckman Coulter Primary Care Diagnostics ICON DS Strep A | ACON Laboratories, Inc. | |

This list includes updates from Change Request 7266

* 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> |
|--------------------|---|-----------------------------|---|
| | 9. Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test | Beckman Coulter, Inc. | |
| | 10. Becton Dickinson BD Chek Group A Strep A Test | Innovacon, Inc. | |
| | 11. Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab) | Applied Biotech, Inc. | |
| | 12. Binax NOW Strep A Test | Binax, Inc. | |
| | 13. BioStar Aceava Strep A Test (direct specimen only) | Wyntek Diagnostics, Inc. | |
| | 14. Biotechnostix Rapid Response Strep A Rapid Test Device | Acon Laboratories Co. | |
| | 15. Biotechnostix Rapid Response Strep A Rapid Test Strip | Acon Laboratories Co. | |
| | 16. BTNX, Inc. Strep A Rapid Test* | Sa Scientific, Inc. | |
| | 17. Cardinal Health SP Brand Rapid Test Strep A Dipstick(K033855) | Applied Biotech Inc. | |
| | 18. Cardinal Health SP Brand Rapid Test Strep A Dipstick (K010582/A028) | Innovacon, Inc. | |
| 87880QW (cont.) | 19. CLIA waived inc Rapid Strep A Test | Sa Scientific, Inc. | 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 |
| | 20. DE Healthcare Products, TruView Strep A Test | DE Healthcare Products | |
| | 21. DE Healthcare Products TruView Strep A Cassette Test | ACON Laboratories, Inc. | |
| | 22. Diagnostic Test Group Clarity Strep A Rapid Test Strips | Princeton BioMeditech Corp. | |
| | 23. Fisher HealthCare Sure-View Strep A (direct from throat swab) | Applied Biotech, Inc. | |

This list includes updates from Change Request 7266

* 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> |
|--------------------|--|-----------------------------|---|
| | 24. Genzyme Contrast Strep A (direct from throat swab) | Genzyme Diagnostics | |
| | 25. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size | Genzyme Corporation | |
| | 26. Genzyme OSOM Ultra Strep A Test | Genzyme General | |
| | 27. Germaine Laboratories StrepAim Rapid Dipstick Test | Germaine Laboratories, Inc. | |
| | 28. Germaine Laboratories Strep AIM Tower | Germaine Laboratories, Inc. | |
| | 29. Henry Schein Inc, One Step+ Strep A Test | Henry Schein | |
| | 30. Henry Schein Inc, One Step+ Strep A Dipstick Test | Henry Schein | |
| | 31. Immunostics Detector Strep A Direct | ACON Laboratories, Inc. | |
| | 32. Immunostics Immuno/Strep A Detector | ACON Laboratories, Inc. | |
| | 33. Instant Technologies iStrep Strep A | ACON Laboratories, Inc. | |
| | 34. Inverness Medical BioStar Acceava Strep A Test | Innovacon, Inc. | |
| 87880QW (cont.) | 35. Inverness Medical BioStar Acceava Strep A Twist | Innovacon, Inc. | 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 |
| | 36. Inverness Medical Signify Strep A Cassette (Inverness Medical Innovations) | Innovacon, Inc. | |
| | 37. Jant Pharmacal AccuStrip Strep A (II) (direct from throat swab) | Applied Biotech, Inc. | |
| | 38. Jant Pharmacal Accustrip Strep A Value+ Test Strip | Innovacon, Inc. | |

This list includes updates from Change Request 7266

* 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> |
|--------------------|---|-----------------------|---|
| | 39. Jant Pharmacal Accutest Integrated Strep A Rapid Test Device | Innovacon, Inc. | |
| | 40. Laboratory Supply Company (LSC) PEP Strep A Cassette Test | Acon Laboratories Co. | |
| | 41. LSC PEP Strep A Dipstick Test | Acon Laboratories Co. | |
| | 42. LifeSign LLC Status Strep A | Princeton BioMeditech | |
| | 43. Mainline Confirms Strep A Dots Test (direct from throat swab) | Applied Biotech, Inc. | |
| | 44. McKesson Medi-Lab Performance Strep A Test Dipstick | Applied Biotech, Inc. | |
| | 45. Meridian Diagnostics ImmunoCard STAT Strep A (direct from throat swab) | Applied Biotech, Inc. | |
| | 46. Moore Medical The Supply Experts Strep A Rapid Test – Dipstick | Innovacon, Inc. | |
| | 47. PSS Consult Diagnostics Strep A Dipstick | Innovacon, Inc. | |
| | 48. PSS World Medical Select Diagnostics Strep A Dipstick | Innovacon, Inc. | |
| | 49. PSS World Medical Select Diagnostics Strep A Twist | Innovacon, Inc. | |
| | 50. Polymedco, Inc. Poly stat A (II) | Applied Biotech, Inc. | |
| 87880QW (cont.) | 51. Polymedco Poly Stat Strep A Liquid Test | Applied Biotech, Inc. | 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 |
| | 52. QuickVue In-Line One-Step Strep A Test (K934484) | Quidel Corporation | |
| | 53. QuickVue® Dipstick Strep A | Quidel Corporation | |
| | 54. Quidel QuickVue® In-Line Strep A | Quidel Corporation | |
| | 55. Quidel QuickVue In-Line Strep A {direct from throat swab}(K934484/A013) | Quidel Corporation | |

This list includes updates from Change Request 7266

* 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> |
|---|--|-------------------------------|---|
| | 56. RAC Medical Clarity Strep A Rapid Test Strips | Acon Laboratories Co. | |
| | 57. Remel RIM® A.R.C. Strep A Test | Applied Biotech, Inc. | |
| | 58. SmithKline ICON Fx Strep A Test (from throat swab only) | Binax, Inc. | |
| | 59. Stanbio Laboratory E-Z Well Strep A Rapid Device Test | Acon Laboratories Co. | |
| | 60. Stanbio QuStick Strep A | Stanbio Laboratory | |
| | 61. Wyntek Diagnostics OSOM Strep A Test | Wyntek Diagnostics, Inc | |
| | 62. Wyntek OSOM® Ultra Strep A Test | Wyntek Diagnostics, Inc. | |
| 87905QW | 1. 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. |
| | 2. Genzyme Diagnostics OSOM BVBlue Test | Gryphus Diagnostics, LLC | |
| 87899QW | Meridian Bioscience Immunocard STAT! HpSA {Stool} | Meridian Bioscience, Inc. | Immunoassay for the qualitative detection of <i>Helicobacter pylori</i> antigens in stool specimens |
| 89300QW(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 |

This list includes updates from Change Request 7266

* Newly added waived test system