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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 3479 | Date: March 18, 2016 |
| | Change Request 9563 |

SUBJECT: New Waived Test

I. SUMMARY OF CHANGES: This change will inform contractors of new CLIA waived tests approved by the Food and Drug Administration. Since these tests are marketed immediately after approval, Centers for Medicare & Medicaid Services (CMS) must notify its contractors of the new tests so that the contractors can accurately process claims. There are 12 newly added waived complexity tests. This Recurring Update Notification applies to Chapter 16, section 70.8 of the IOM.

EFFECTIVE DATE: July 1, 2016

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

IMPLEMENTATION DATE: July 5, 2016

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.*

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|--------------|---|
| D | 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: 3479 | Date: March 18, 2016 | Change Request: 9563 |
|-------------|-------------------|----------------------|----------------------|

SUBJECT: New Waived Test

EFFECTIVE DATE: July 1, 2016

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

IMPLEMENTATION DATE: July 5, 2016

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:

- 81007QW, September 25, 2015, Jant Pharmacal Corporation Accutest Uriscreeen (Bacteriuria);
- G0434QW [from November 3, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test Marijuana (THC) Cassette;
- G0434QW [from November 3, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test Marijuana (THC) Cup;
- G0434QW [from November 3, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test Marijuana (THC) DipCard;
- G0434QW [from November 3, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test MDMA Cup;
- G0434QW [from November 3, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test MDMA DipCard;
- 87631QW, December 3, 2015, Cepheid Gene Xpert Xpress System (Xpert Flu+RSV Xpress);
- G0434QW [from December 17, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Premier BIOTECH Premier Bio-cup & Bio-Dip;

| Number | Requirement | Responsibility | | | | | | | | | |
|--------|---|----------------|---|----------------------------|----------------------------------|------------------|-------------|-------------|-------|-------------|--|
| | | A/B MAC | | D M E M A C | Shared- System Maintainers | | | | Other | | |
| | | A | B | | H H H | F I S S | M C S | V M S | | C W F | |
| 9563.3 | 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 | | | | | | | | |
| 9563.4 | 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 M E M A C | C E D I | | |
| | | A | B | H H H | | | | |
| 9563.5 | MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/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 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:

"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 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 FFS9563

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 FFS9563
 * 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. 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 (Contact your Medicare carrier for claims instructions.), 82962, 83718QW, 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 (Contact your Medicare carrier for claims instructions.), 82962, 83718QW, 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 (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 |
| 80061QW, 82465QW 82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84450QW, 84460QW, 84478QW | Alere Cholestech LDX {Whole Blood} | Alere, Inc. | Measures alanine aminotransferase, aspartate aminotransferase, total cholesterol, HDL cholesterol, glucose, 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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TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|---|---|------------------------------------|--|
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Phamatech QuickScreen One Step Amphetamine Test | Phamatech | Screening test for the presence/detection of amphetamine in urine |
| | 2. BTNX Inc Rapid Response X-Press Drug Test Cassette Amp/Amphetamine | BTNX Inc. | |
| | 3. BTNX Inc Rapid Response X-Press Drug Test Strip Amp/Amphetamine | BTNX Inc. | |
| | 4. Healgen Amphetamine Test Cassette | LSI International Inc. | |
| | 5. Healgen Amphetamine Test Cup | LSI International Inc. | |
| | 6. Healgen Amphetamine Test Dip Card | | |
| | 7. Healgen Amphetamine Test Strip | LSI International Inc. | |
| | 8. Wondfo Amphetamine Urine Test {Cup Format} | Guangzhou Wondfo Biotech Co., Ltd. | |
| | 9. Wondfo Amphetamine Urine Test {Dip card Format} | Guangzhou Wondfo Biotech Co., Ltd. | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. AssureTech Co. Ltd, AssureTech Secobarbital Strip {OTC} | LSI International | Screening test for the presence/detection of barbiturates in urine |
| | 2. W.H.P.M., Inc. First Sign® Drug of Abuse Butalbital Cup Test | LSI International | |
| | 3. W.H.P.M., Inc. First Sign® Drug of Abuse Butalbital Dip Card Test | LSI International | |
| | 4. Wondfo Secobarbital Urine Test {Cup Format} | Guangzhou Wondfo Biotech Co., Ltd. | |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|--|--|---|--|
| G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 5. Wondfo Secobarbital Urine Test {Dip card Format} | Guangzhou Wondfo Biotech Co., Ltd. | Screening test for the presence/detection of barbiturates in urine |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Wondfo Oxazepam Urine Test {Cup Format} | Guangzhou Wondfo Biotech Co., Ltd. | Screening test for the presence/detection of benzodiazepines in urine |
| | 2. Wondfo Oxazepam Urine Test {Dip card Format} | Guangzhou Wondfo Biotech Co., Ltd. | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Assure Tech Co., Ltd AssureTech Buprenorphine Strip | LSI International | Screening test for the presence/detection of buprenorphine in urine |
| G0477QW (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. BTNX Inc Rapid Response X-Press Drug Test Cassette | BTNX Inc. | |
| | 4. BTNX Inc Rapid Response X-Press Drug Test Strip | BTNX Inc. | |
| | 5. Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test Marijuana (THC) Cassette* | LSI International Inc. | |
| | 6. Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test Marijuana (THC) Cup* | LSI International Inc. | |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|---|---|----------------------------|--|
| G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 7. Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test Marijuana (THC) DipCard* | LSI International Inc. | Screening test for the presence/detection of cannabinoids (THC) in urine |
| | 8. Healgen THC One Step Marijuana Test Cassette | Healgen Scientific, LLC | |
| | 9. Healgen THC One Step Marijuana Test Cup | Healgen Scientific, LLC | |
| | 10. Healgen THC One Step Marijuana Test Dip Card | Healgen Scientific, LLC | |
| | 11. Healgen THC One Step Marijuana Test Strip | Healgen Scientific, LLC | |
| | 12. First Check Diagnostics LLC, First Check Home Drug Test Marijuana | ACON Laboratories, Inc. | |
| | 13. Phamatech QuickScreen One Step THC Screening Test | Phamatech | |
| | 14. Phamatech At Home Drug Test (Model 9078) | Phamatech | |
| | 15. Phamatech At Home Drug Test (Model 9078T) | Phamatech | |
| | 16. Polymed Therapeutics FaStep Marijuana Panel Dip | PolyMed Therapeutics, Inc. | |
| | 17. Polymed Therapeutics FaStep Marijuana Quick Cup | PolyMed Therapeutics, Inc. | |
| | 18. Polymed Therapeutics FaStep Marijuana Strip | PolyMed Therapeutics, Inc. | |
| | 19. Polymed Therapeutics FaStep Marijuana Turn-Key Split Cup | PolyMed Therapeutics, Inc. | |
| | 20. SCI International Inc. New Choice At Home Drug Test: Marijuana (Strip Format) | Ind Diagnostic Inc. | |

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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> |
|--|---|------------------------------------|---|
| G0477QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 21. Wondfo Cannabinoids Urine Test {Cup Format} | Guangzhou Wondfu Biotech Co., Ltd. | Screening test for the presence/detection of cannabinoids (THC) in urine |
| | 22. Wondfo Cannabinoids Urine Test {Dip card Format} | Guangzhou Wondfu Biotech Co., Ltd. | |
| | 23. Worldwide Medical Corporation, First Check® Home Drug Test (THC) | Worldwide Medical Corporation | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. BTNX Inc Rapid Response X-Press Drug Test (COC/Cocaine){Cup format} | BTNX Inc. | Screening test for the presence/detection of cocaine metabolites in urine |
| | 2. BTNX Inc Rapid Response X-Press Drug Test (COC/Cocaine){Dip card format} | BTNX Inc. | |
| | 3. Healgen COC One Step Cocaine Test Cassette | Healgen Scientific LLC | |
| | 4. Healgen COC One Step Cocaine Test Cup | Healgen Scientific LLC | |
| | 5. Healgen COC One Step Cocaine Test Dip Card | Healgen Scientific LLC | |
| | 6. Healgen COC One Step Cocaine Test Strip | Healgen Scientific LLC | |
| | 7. Phamatech At Home Drug Test (Model 9073) | Phamatech | |
| | 8. Phamatech At Home Drug Test (Model 9073T) | Phamatech | |
| | 9. Phamatech QuickScreen One Step Cocaine Screening Test | Phamatech | |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|---|---|----------------------------|--|
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Assure Tech Co., Ltd AssureTech Methadone Strip | LSI International | Screening test for the presence/detection of methadone in urine |
| | 2. BTNX Inc Rapid Response X-Press Drug Test (MTD/Methadone){Cup format} | BTNX Inc. | |
| | 3. BTNX Inc Rapid Response X-Press Drug Test (MTD/Methadone){Dip card format} | BTNX Inc. | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. BTNX Inc Rapid Response X-Press Drug Test (MET/Methamphetamine) {Cup format} | BTNX Inc. | Screening test for the presence/detection of methamphetamines in urine |
| | 2. BTNX Inc Rapid Response X-Press Drug Test (MET/Methamphetamine){Dip card format} | BTNX Inc. | |
| | 3. Healgen mAMP One Step Methamphetamine Test Cassette | Healgen Scientific, LLC | |
| | 4. Healgen mAMP One Step Methamphetamine Test Cup | Healgen Scientific, LLC | |
| | 5. Healgen mAMP One Step Methamphetamine Test Dip Card | Healgen Scientific, LLC | |
| | 6. Healgen mAMP One Step Methamphetamine Test Strip | Healgen Scientific, LLC | |
| | 7. Phamatech At Home Drug Test (Model 9068) | Phamatech | |
| | 8. Phamatech QuickScreen One Step Methamphetamine Test | Phamatech | |
| | 9. Polymed Therapeutics FaStep Methamphetamine Panel Dip | Polymed Therapeutics, Inc. | |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|---|--|----------------------------|--|
| G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 10. Polymed Therapeutics FaStep Methamphetamine Quick Cup | Polymed Therapeutics, Inc. | Screening test for the presence/detection of methamphetamines in urine |
| | 11. Polymed Therapeutics FaStep Methamphetamine Strip | Polymed Therapeutics, Inc. | |
| | 12. Polymed Therapeutics FaStep Methamphetamine Turn-Key Split Cup | Polymed Therapeutics, Inc. | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. BTNX Inc Rapid Response X-Press Drug Test (MDMA/Methylenedioxymethamphetamine){Cup format} | BTNX Inc. | Screening test for the presence/detection of 3,4-methylenedioxymethamphetamine HCl (MDMA) in urine |
| | 2. BTNX Inc Rapid Response X-Press Drug Test (MDMA/Methylenedioxymethamphetamine){Dip card format} | BTNX Inc. | |
| | 3. Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test MDMA Cup* | LSI International Inc. | |
| | 4. Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test MDMA DipCard* | LSI International Inc. | |
| | 5. Healgen Scientific LLC Healgen MDMA (Ecstasy) Test Cassette | LSI International Inc. | |
| | 6. Healgen Scientific LLC Healgen MDMA (Ecstasy)Test Cup | LSI International Inc. | |
| | 7. Healgen Scientific LLC Healgen MDMA (Ecstasy) Test Dip Card | LSI International Inc. | |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|---|--|------------------------|--|
| G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 8. Healgen Scientific LLC Healgen MDMA (Ecstasy) Test Strip | LSI International Inc. | Screening test for the presence/detection of 3,4-methylenedioxyamphetamine HCl (MDMA) in urine |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. BTNX Inc Rapid Response X-Press Drug Test (MOP/Morphine){Cup format} | BTNX Inc. | Screening test for the presence/detection of morphine in urine |
| | 2. BTNX Inc Rapid Response X-Press Drug Test (MOP/Morphine){Dip card format} | BTNX Inc. | |
| | 3. Healgen Morphine Test Cassette | Healgen Scientific LLC | |
| | 4. Healgen Morphine Test Cup | Healgen Scientific LLC | |
| | 5. Healgen Morphine Test Dip Card | Healgen Scientific LLC | |
| | 6. Healgen Morphine Test Strip | Healgen Scientific LLC | |
| | 7. Healgen MOP One Step Morphine Test Cassette | Healgen Scientific LLC | |
| | 8. Healgen MOP One Step Morphine Test Cup | Healgen Scientific LLC | |
| | 9. Healgen MOP One Step Morphine Test Dip Card | Healgen Scientific LLC | |
| | 10. Healgen MOP One Step Morphine Test Strip | Healgen Scientific LLC | |
| | 11. W.H.P.M., Inc. First Sign® Drug of Abuse Morphine Dip Card Test | LSI International | |

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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> |
|---|---|--------------------------|--|
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. BTNX Inc Rapid Response X-Press Drug Test Morphine (2000){Cup format} | BTNX Inc. | Screening test for the presence/detection of morphine in urine at a cutoff concentration of 2000ng/ml |
| | 2. BTNX Inc Rapid Response X-Press Drug Test Morphine (2000){Dip card format} | BTNX Inc. | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. CLIAwaived Inc. Instant Nicotine Detection Test | Mossman Associates, 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. DyanGen NicCheck II Test Strips | DynaGen, Inc. | |
| | 3. Mossman Associates, Inc. NicCheck I Test Strips | Mossman Associates, Inc. | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. BTNX Inc Rapid Response X-Press Drug Test Natriptyline{Cup format} | BTNX Inc. | Screening test for the presence/detection of natriptyline (major metabolite of tricyclic antidepressants) in urine |
| | 2. BTNX Inc Rapid Response X-Press Drug Test Natriptyline{Dip card format} | BTNX Inc. | |
| G0477QW (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 | |
| | 3. Quest Products, Inc. DrugHAWK Buprenorphine Drug Test Cup | S.D. biotek, LLC | |

This list includes updates from Change Request FFS9563

* 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> |
|---|---|------------------------------------|--|
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. BTNX Inc Rapid Response X-Press Drug Test Oxazepam Cassette | BTNX Inc. | Screening test for the presence/detection of oxazepam (major metabolite of benzodiazepines) in urine |
| | 2. BTNX Inc Rapid Response X-Press Drug Test Oxazepam Strip | BTNX Inc. | |
| | 3. Healgen Oxazepam Test Cassette | Healgen Scientific LLC | |
| | 4. Healgen Oxazepam Test Cup | Healgen Scientific LLC | |
| | 5. Healgen Oxazepam Test Dip Card | Healgen Scientific LLC | |
| | 6. Healgen Oxazepam Test Strip | Healgen Scientific LLC | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. AssureTech Co. LTD, AssureTech Oxycodone Strip {OTC} | LSI International Inc | Screening test for the presence/detection of oxycodone in urine |
| | 2. Healgen Oxycodone Test Cassette | LSI International Inc | |
| | 3. Healgen Oxycodone Test Cup | LSI International Inc. | |
| | 4. Healgen Oxycodone Test Dip Card | LSI International Inc. | |
| | 5. Healgen Oxycodone Test Strip | LSI International Inc. | |
| | 6. Wondfo Oxycodone Urine Test {Dip card format} | Guangzhou Wondfo Biotech Co., Ltd. | |
| | 7. Wondfo Oxycodone Urine Test {Cup format} | Guangzhou Wondfo Biotech Co., Ltd. | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. BTNX Inc Rapid Response X-Press Drug Test (PCP/Phencyclidine){Cup format} | BTNX Inc. | Screening test for the presence/detection of phencyclidine (PCP) in urine |
| | 2. BTNX Inc Rapid Response X-Press Drug Test (PCP/Phencyclidine){Dip card format} | BTNX Inc. | |

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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> | | |
|--|---|--|---|-----------|---|
| G0477QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 3. Healgen Scientific LLC Healgen Phencyclidine Test Cassette | LSI International Inc. | Screening test for the presence/detection of phencyclidine (PCP) in urine | | |
| | 4. Healgen Scientific LLC Healgen Phencyclidine Test Cup | LSI International Inc. | | | |
| | 5. Healgen Scientific LLC Healgen Phencyclidine Test Dip Card | LSI International Inc. | | | |
| | 6. Healgen Scientific LLC Healgen Phencyclidine Test Strip | LSI International Inc. | | | |
| | 7. Phamatech At Home Drug Test (Model 9133) | Phamatech | | | |
| | 8. Phamatech QuickScreen One Step PCP Screening Test | Phamatech | | | |
| | G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. BTNX Inc Rapid Response X-Press Drug Test Secobarbital Cassette | | BTNX Inc. | Screening test for the presence/detection of secobarbital (major metabolite of barbiturates) in urine |
| | | 2. BTNX Inc Rapid Response X-Press Drug Test Secobarbital Strip | | BTNX Inc. | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. AssureTech Co. Ltd, AssureTech Secobarbital/Oxycodone Panel Dip {OTC} | LSI International | Screening test for the presence/detection of barbiturates and oxycodone | | |
| | 2. AssureTech Co. Ltd, AssureTech Secobarbital/Oxycodone Quick Cup {OTC} | LSI International | | | |
| | 3. AssureTech Co. Ltd, AssureTech Secobarbital/Oxycodone Turn Key-Split Cup {OTC} | LSI International | | | |

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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> |
|---|--|-------------------------------|--|
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Assure Tech Co., Ltd AssureTech Buprenorphine/Methadone Panel Dip | LSI International | Screening test for the presence/detection of buprenorphine and methadone |
| | 2. Assure Tech Co., Ltd AssureTech Buprenorphine/Methadone Quick Cup | LSI International | |
| | 3. Assure Tech Co., Ltd AssureTech Buprenorphine/Methadone Turn Key-Split Cup | LSI International | |
| G0477QW (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 | |
| | 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 | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Dip Card Tests | Chemtron Biotech, Inc. | Screening test for the presence/detection of buprenorphine and tricyclic antidepressants |
| | 2. Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Cassette Tests | Chemtron Biotech, Inc. | |

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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> |
|---|---|-------------------------------|--|
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Quest Products, Inc. DrugHAWK MDMA and OPI Drug Test Cup (Urine){Cup format} | S.D.biotek, LLC | Screening test for the presence/detection of MDMA and opiates in urine |
| G0477QW (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 |
| | 2. Alfa Scientific Designs, Inc. Instant-View Drug of Abuse Urine Cup Test | Alfa Scientific Designs, Inc. | |
| | 3. Insight Medical Drug of Abuse Urine Cassette Test | Alfa Scientific Designs, Inc. | |
| | 4. Insight Medical Drug of Abuse Urine Cup Test | Alfa Scientific Designs, Inc. | |
| | 5. Instant Technologies, Inc. iScreen Drug of Abuse Urine (Cassette) Test | Alfa Scientific Designs, Inc. | |
| | 6. Instant Technologies, Inc. iScreen Drug of Abuse Urine (Cup) Test | Alfa Scientific Designs, Inc. | |
| | 7. Jant Pharmacal Accutest Drug of Abuse Urine (Cassette) Test | Alfa Scientific Designs, Inc. | |
| | 8. Jant Pharmacal Accutest Drug of Abuse Urine (Cup) Test | Alfa Scientific Designs, Inc. | |
| | 9. Total Diagnostic Solutions Drug of Abuse Urine (Cassette) Test | Alfa Scientific Designs, Inc. | |
| | 10. Total Diagnostic Solutions Drug of Abuse Urine (Cup) Test | Alfa Scientific Designs, Inc. | |

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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> |
|---|--|-----------------------------------|---|
| G0477QW (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. Alatech Scientific Peace of Mind Multiple Drugs of Abuse Test | Advantage Diagnostics Corporation | |
| G0477QW (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 |
| G0477QW (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 |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Alfa Scientific Designs, Inc. Confidential Drug Test – Multi Drugs of Abuse Urine Test (OTC) | Alfa Scientific Designs, Inc. | Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, MDMA and morphine in urine |
| G0477QW (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. | |
| | 4. Alere iCassette Drug Screen | Alere | |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|--|--|-------------------------|--|
| G0477QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 5. Biotechnostix Rapid Response One Step Multi-Drug, Multi-Line Screen Test Device | ACON Laboratories, Inc. | Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, opiates, and PCP in urine |
| | 6. iCassette Multi-Drug, Multi-Line Screen Test Device | ACON Laboratories, Inc. | |
| | 7. RediScreen Multi-Drug, Multi-Line Screen Test Device | ACON Laboratories, Inc. | |
| | 8. Redwood Toxicology Laboratory Reditest 6 Cassette substance abuse screening device {Professional Use} | Innovacon, Inc. | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Cassette Tests | Chemtron Biotech, Inc | Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, morphine, and PCP in urine |
| | 2. Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Dip | Chemtron Biotech, Inc | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Cassette Tests | Chemtron Biotech, Inc | Screening test for the presence/detection of benzodiazepines, barbiturates, MDMA, methadone, opiates, and oxycodone in urine |
| | 2. Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Dip Card Tests | Chemtron Biotech, Inc | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Alere Toxicology Service, Inc. Tox Screen Drugs of Abuse Test Cup | Alere | Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, methylenedioxyamphetamine (MDMA), opiates, and PCP in urine |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|--|--|--|--|
| G0477QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 2. 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, methylenedioxyamphetamine (MDMA), opiates, and PCP in urine |
| | 3. Drug Detection Devices Ltd. Multi-Drug Multi-Line Screeners Dip Drug Test With the Integrated Screeners AutoSplit KO Test Cup | Innovacon, Inc. | |
| | 4. First Check Diagnostics First Check Multi Drug Cup | First Check Diagnostics LLC | |
| | 5. Innovacon Integrated E-Z Split Key Cup II {Professional Use} | Innovacon, Inc. | |
| | 6. Noble Medical Inc. Split-Specimen Cup | ACON Laboratories, Inc. | |
| | 7. 1 Step Detect Associates DTX Drug Test Cup Integrated E-Z Split Key Cup II | Biosite Inc. | |
| | 8. Quest Diagnostics Incorporated, Express Results Integrated Multi-Drug Screen Cup {professional use} | Innovacon, Inc. | |
| | 9. Wolfe Drug Testing RealityCheck Integrated Specimen Cup | Innovacon, Inc. | |
| | G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Wondfo Multi-Drug Urine Test Panel {Dip Card Format} | Guangzhou Wondfo Biotech Co., Ltd. |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Nobel Medical Inc. INSTA-SCREEN Multi-Drug Urine Test Cup | Guangzhou Wondfo Biotech Co., Ltd. | Screening test for the presence/detection of cocaine metabolites, methamphetamines, MDMA, morphine, methadone, opiates, PCP and tricyclic antidepressants in urine |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|---|--|-------------------------------|---|
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Branan Medical Corporation ToxCup Drug Screen Cup | Branan Medical Corporation | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, morphine, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine |
| | 2. Express Diagnostic Int'l Inc DrugCheck Waive RT (Model 9308z) | Phamatech, Inc. | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Alere Toxicology Services Alere iCassette DX Drug Screen | Alere | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, and PCP in urine |
| | 2. Phamatech At Home 12 Drug Test (Model 9308T) | Phamatech, Inc. | |
| | 3. Phamatech At Home 12 Drug Test (Model 9308Z) | Phamatech, Inc. | |
| G0477QW (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. Instant Technologies, Inc. iCassette DX Drug Screen Test | Alere | |
| | 3. Inverness Medical Innovations Signify ER Drug Screen | Biosite Inc. | |
| | 4. Jant Pharmacal Accutest MultiDrug ER11 Drug Screen Test Device | Innovacon, Inc. | |
| | 5. Abbott Diagnostics Signify ER Drug Screen Test | Innovacon, Inc. | |
| G0477QW (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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|--|--|--------------------------------------|---|
| G0477QW (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. Confirm 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. | |
| | 14. Aventir Biotech LLC Home Check Multiple Drug Test Cup | Tianjin New Bay Bioresearch Co. Ltd. | |

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|--|--|-------------------------------------|---|
| G0477QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 15. Aventir Biotech LLC Home Check Multiple Drug Cup Test {Professional version} | Tianjin New Bay Bioresearch Co. Ltd | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, MDMA, morphine, PCP and tricyclic antidepressants in urine |
| | 16. Medimpex United Inc. MedimpexQ Test Multi X Drug Cup Test | Tianjin New Bay Bioresearch Co. Ltd | |
| | 17. Quest Products, Inc. DrugHAWK Drug Test Cup | S.D.biotek, LLC. | |
| | 18. Syntron Bioresearch Quikscreen Multiple Drug Cup Test {Professional version} | Tianjin New Bay Bioresearch Co. Ltd | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Chemtron Biotech, Inc. Chemtrue Multi-Panel DOA Dip Card Tests | . Chemtron Biotech, Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, morphine, opiates, oxycodone and PCP in urine |
| | 2. Chemtron Biotech, Inc. Chemtrue Multi-Panel DOA Dip Card with OPI 2000 Tests | Chemtron Biotech, Inc. | |
| | 3. Native Diagnostics International, DrugSmart Dip Single/Multi-Panel Drug Screen Dip Card Tests | Chemtron Biotech, Inc. | |
| G0477QW (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. Amedica Biotech Instant Test Cup | Amedica Biotech, Inc. | |
| | 4. Ameditech, Inc ImmuTest Drug Screen Cup | Biosite Inc. | |

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|--|---|-----------------------------|---|
| G0477QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 5. Branan Medical Corporation, FasTox Multiple Drug Dipcard | Branan Medical Corporation | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine |
| | 6. CLIAwaived, Inc. Rapid Drug Test | Biosite Inc. | |
| | 7. CLIAwaived, Inc. Rapid Drug Test Cup | Alere | |
| | 8. CLIAwaived, Inc. Rapid Drug Test Cup {OTC} | Biosite Inc. | |
| | 9. CLIAwaived Inc. Rapid Dip Drug Test | Branan Medical Corporation | |
| | 10. CLIAwaived Inc. Single Drug Dipstick Test | Branan Medical Corporation | |
| | 11. Clinical Reference Laboratory, Inc. Intelligent Transport Cup | Alere | |
| | 12. Express Diagnostics, DrugCheck Waive Cup | Biosite Inc. | |
| | 13. First Check Diagnostics First Check 12 Drug Test | First Check Diagnostics LLC | |
| | 14. Instant Technologies, iCup DX Drug Screen Cup | Biosite Inc. | |
| | 15. Jant Pharmacal Corporation ACCUTEST Drug Test Cup | Amedica Biotech, Inc | |
| | 16. Millennium Laboratories Clinical Supply, Inc Multi-Drug Pain Med Screen Cup | Biosite Inc. | |
| | 17. NexScreen LLC, NexScreen Cup | Amedica Biotech, Inc. | |
| | 18. Noble Medical Inc. NOBLE 1 Step Cup {OTC} | Alere | |
| | 19. Noble Medical Inc. NOBLE 1 Step Cup {OTC} | Biosite Inc. | |

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|--|---|----------------------------------|--|
| G0477QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 20. Premier Integrity Solutions P/Tox Drug Screen Cup {OTC} | Alere | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine |
| | 21. Premier Integrity Solutions P/Tox Drug Screen Cup {OTC} | Biosite Inc. | |
| | 22. Redwood Toxicology Laboratory, Inc Reditest Freedom Cup | Biosite Inc. | |
| | 23. Twin Spirit, Inc. DrugSmart Cup | Amedica Biotech, Inc. | |
| | 24. US Diagnostics ProScreen Drugs of Abuse Cup {OTC} | Alere | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 25. US Diagnostics ProScreen Drugs of Abuse Cup {OTC} | Biosite Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, morphine, oxycodone, PCP and tricyclic antidepressants in urine |
| | 1. American Institute of Toxicology, Inc., AIT Laboratories Drug of Abuse Cup | Guangzhou Wondfo Biotech Co. LTD | |
| | 2. BTNX Inc. Rapid Response Multi-Drug Urine Test Cup | Guangzhou Wondfo Biotech Co. LTD | |
| | 3. BTNX Inc. Rapid Response Multi-Drug Urine Test Panel | Guangzhou Wondfo Biotech Co. LTD | |
| | 4. uVera Diagnostics, Inc. CR2 Multi-Drug Urine Test Cup | Guangzhou Wondfo Biotech Co. LTD | |
| | 5. uVera Diagnostics, Inc. CR3 Multi-Drug Urine Test Cup | Guangzhou Wondfo Biotech Co. LTD | |
| | 6. uVera Diagnostics, Inc. SMARTOX U3 Multi-Drug Urine Test Cup | Guangzhou Wondfo Biotech Co. LTD | |
| | 7. Wal-Mart Stores, Inc. ReliOn Home Drug Urine Cup Test | Alfa Scientific Designs, Inc. | |

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|---|---|----------------------------------|--|
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Micro Distributing II, LTD One Step Multi-Drug Urine Test Panel | Guangzhou Wondfo Biotech Co. LTD | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, methamphetamines, MDMA, morphine, opiates, oxycodone and PCP in urine |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Clarity Diagnostics LLC, Clarity Multi-Drug Urine Test DipCard | LSI International Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, and PCP in urine |
| | 2. Clarity Diagnostics LLC, Clarity Multi-Drug Urine Test Cup | LSI International Inc. | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Alere iScreen DX Multi-Drugs of Abuse Dip Test | Branan Medical Corporation | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine |
| | 2. Alere iScreen DX Single Dip Card {The Alere iScreen DX Single Dip Card may include a maximum of four drugs in any combination of the 13 claimed drugs} | | |
| | 3. Branan Medical Corporation Fastect II Drug Screen Dipstick Test | Branan Medical Corporation | |
| | 4. Branan Medical Corporation, QuickTox Drug Screen Dipcard | Branan Medical Corporation | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Advin Multi-Drug Screen Test | Advin Biotech | 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 Discover Drug Test Cards | UCP Biosciences, Inc | |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|--|--|-----------------------|--|
| G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 3. American Screening Corporation Discover Multi-panel Drug Test Cups | 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 |
| | 4. American Screening Corporation, Inc., Multi-Drug Testing Cards | UCP Biosciences, Inc | |
| | 5. American Screening Corporation, Inc., Multi-Drug Testing Cups | UCP Biosciences, Inc | |
| | 6. American Screening Corporation OneScreen Drug Test Cards | UCP Biosciences, Inc. | |
| | 7. American Screening Corporation OneScreen Drug Test Cups | UCP Biosciences, Inc. | |
| | 8. Diagnostic Test Group Clarity Multi-Drug Test Cards | UCP Biosciences, Inc | |
| | 9. Diagnostic Test Group Clarity Multiple Drug Screen Cards | UCP Biosciences, Inc. | |
| | 10. Diagnostic Test Group Clarity Multiple Drug Screen Cups | UCP Biosciences, Inc. | |
| | 11. Diagnostic Test Group Clarity Simple Drug Screening Cups | UCP Biosciences, Inc. | |
| | 12. Express Diagnostics International Inc. DrugCheck Waive Drug Test Cards | UCP Biosciences, Inc. | |
| | 13. Express Diagnostics International Inc. DrugCheck Waive Multiple Drug Screen Cups | UCP Biosciences, Inc. | |
| | 14. UCP Biosciences, Inc. Drug Screening Test Cards | UCP Biosciences | |
| | 15. UCP Biosciences, Inc. Drug Screening Test Cups | UCP Biosciences, Inc. | |
| | 16. UCP Biosciences, Inc. U-Checker Drug Screening Test Cups | UCP Biosciences, Inc. | |

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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> |
|--|--|---|--|
| G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 17. Ultimate Analysis Cup UA Cups | 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 |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 18. American Bio Medica Rapid TOX 1. Chemtron Biotech, Inc. Chemtrue Drug Screen Cup Tests | American Bio Medica Corp. Chemtron Biotech, Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, oxycodone, PCP, and tricyclic antidepressants in urine |
| | 2. Chemtron Biotech, Inc. Chemtrue Drug Screen Cup Tests with OPI 2000 | Chemtron Biotech, Inc. | |
| | 3. Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Dip Card Tests | Chemtron Biotech, Inc. | |
| | 4. Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Dip Card with OPI 2000 Test | Chemtron Biotech, Inc. | |
| | 5. Clarity Diagnostics Multi-Panel Drug Screen Dip Card Tests | Chemtron Biotech, Inc. | |
| | 6. Clarity Diagnostics Multi-Panel Drug Screen Dip Card with OPI 2000 Tests | Chemtron Biotech, Inc. | |
| | 7. Native Diagnostics International DrugSmart Dip Multi-Panel Drug Screen Dip Card with OPI 2000 Tests | Chemtron Biotech, Inc. | |

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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> |
|--|--|------------------------|--|
| G0477QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 8. Native Diagnostics International; DrugSmart Drug Screen Cup Tests with OPI 2000 | Chemtron Biotech, Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, oxycodone, PCP, and tricyclic antidepressants in urine |
| | 9. Onsite Testing Specialists, Inc. On-site Testing Specialists Drug Screen Cup Tests | Chemtron Biotech, Inc. | |
| | 10. Onsite Testing Specialists, Inc. On-site Testing Specialists Drug Screen Cup Tests with OPI 2000 | Chemtron Biotech, Inc. | |
| | 11. On-Site Testing Specialists, Inc. On-Site Testing Specialist Single/Multi-Panel Drug Screen Dip Card Tests | Chemtron Biotech, Inc. | |
| | 12. On-Site Testing Specialists, Inc. On-Site Testing Specialist Single/Multi-Panel Drug Screen Dip Card with OPI 2000 Tests | Chemtron Biotech, Inc. | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Alere iCup DX 14 {Cassette Dip Card format} | Branan Medical Corp. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine |
| | 2. CLIAwaived Inc. Rapid Drug Test Cup {Cassette Dip Card format} | Branan Medical Corp. | |
| | 3. Coastline Medical Management Coastline Explorer Cup {Cassette Dip Card Format} | Branan Medical Corp. | |
| | 4. Noble Medical Inc. Noble 1 Step + Cup | Branan Medical Corp. | |
| | 5. PTox Drug Screen Cup {Cassette Dip Card format} | Branan Medical Corp. | |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|---|---|---------------------------------|---|
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. UCP Biosciences, Inc. UCP Multi-Drug Test Key Cups | UCP Biosciences, Inc. | 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 |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. American Screening Corporation, Inc. Discover Drug Test Cards | UCP Biosciences, Inc | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine |
| | 2. American Screening Corporation, Inc. Discover Multi-Panel Drug Test Cups | UCP Biosciences, Inc | |
| | 3. American Screening Corporation, Inc. Discover Plus Drug Test Cards* | UCP Biosciences, Inc | |
| | 4. American Screening Corporation, Inc. Discover Plus Multi-Panel Drug Test Cups* | UCP Biosciences, Inc | |
| | 5. American Screening Corporation One Screen Drug Test Cards | UCP Biosciences, Inc. | |
| | 6. American Screening Corporation, Reveal Mini Drug Test Cups | UCP Biosciences, Inc. | |
| | 7. American Screening Corporation Reveal Multi-Drug Testing Cups | UCP Biosciences, Inc. | |
| | 8. Medical Distribution Group Inc., Identify Diagnostics Drug Test Cards* | UCP Biosciences, Inc. | |
| | 9. Medical Distribution Group Inc., Identify Diagnostics Drug Test Cards* | UCP Biosciences, Inc. | |
| | 10. Medical Distribution Group Inc., Identify Home Drug Testing Device Test Cards | Medical Distribution Group Inc. | |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|--|--|---------------------------------|---|
| G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 11. Medical Distribution Group Inc., Identify Home Drug Testing Device Test Cups | Medical Distribution Group Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine |
| | 12. Tanner Scientific, Platinum Line® Multi-Panel Drug Test Cup | UCP Biosciences, Inc. | |
| | 13. Transmetron, Inc. Invitro Pro Drug Test Cards | UCP Biosciences, Inc. | |
| | 14. Transmetron Invitro Pro Drug Test Cups | UCP Biosciences, Inc. | |
| | 15. UCP Biosciences, Inc. UCP Compact Drug Test Cards | UCP Biosciences, Inc. | |
| | 16. UCP Biosciences, Inc. UCP Compact Drug Test Cups | UCP Biosciences, Inc. | |
| | 17. UCP Biosciences, Inc. UCP Drug Test Mini Cups | UCP Biosciences, Inc. | |
| | 18. UCP Biosciences, Inc. Multiple Drug Screen Cups | UCP Biosciences | |
| | 19. UCP Biosciences, Inc., UCP Home Drug Screening Test Cards | UCP Biosciences, Inc. | |
| | 20. UCP Biosciences, Inc., UCP Home Drug Screening Test Cups | UCP Biosciences, Inc. | |
| | 21. UCP Biosciences, Inc. U-Cup Drug Test Cards | UCP Biosciences, Inc. | |
| | 22. UCP Biosciences, Inc. U-Card Drug Test Cups | UCP Biosciences, Inc. | |

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|--|---|--|--|
| G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 23. Ultimate Analysis Cup Inc. UA Cups | UCP Biosciences, Inc. | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine |
| | 24. Ultimate Analysis Cup Inc. UA Cups Test Cards | UCP Biosciences, Inc. | |
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Premier BIOTECH Premier Bio-Cup & Bio-Dip* | Advin Biochemicals | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, EDDP (methadone metabolite), MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, and tricyclic antidepressants in urine |
| | 80178QW | ReliaLAB Inc. InstaRead Lithium System {fingerstick or venipuncture whole blood} | Akers Laboratories, Inc. |
| 81003QW | 1. Acon Laboratories, Inc. Foresight U120 Urine Analyzer | Acon 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. Acon Laboratories, Inc. Insight U120 Urine Analyzer | Acon Laboratories, Inc. | |
| | 3. Acon Mission U120 Urine Analyzer | Acon Laboratories, Inc. | |
| | 4. Biosys Laboratories Optima Urine Analyzer | BioSys Laboratories, Inc. | |
| | 5. BTNX Rapid Response U120 Urine Analyzer | Acon Laboratories, Inc. | |
| | 6. Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated | Boehringer Mannheim Corporation | |
| | 7. CLIAwaived Inc. Automated Urinalysis Test System | Acon Laboratories, Inc. | |

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|---------------------------|--|---|--|
| 81003QW(cont.) | 8. Cole-Talyor Marketing Inc. CTI-120 Urine Strip Analyzer | Acon 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 |
| | 9. Consult diagnostics Urine Analyzer | BioSys Laboratories, Inc. | |
| | 10. Germaine Laboratories Inc. AimStrip Urine Analyzer | Acon Laboratories, Inc. | |
| | 11. Henry Schein OneStepPlus Urine Analyzer | Macherey-Nagel GmbH & Co., Kg. | |
| | 12. Henry Schein Urispec Plus Urine Analyzer | Macherey-Nagel GmbH & Co., Kg. | |
| | 13. Hypoguard Diascreen® Urine Chemistry Analyzer | Hypoguard USA, Inc. | |
| | 14. Immunostics Inc., Detector Uristrip+ Analyzer | Acon Laboratories, Inc. | |
| | 15. Jant Pharmacal Corporation Accustrip URS Reader | Jant Pharmacal Corporation | |
| | 16. Medline 120 Urine Analyzer | Acon Laboratories, Inc. | |
| | 17. McKesson 120 Urine Analyzer | Acon Laboratories, Inc. | |
| | 18. Mediwatc urinewatch Urine Analyzer | Acon Laboratories, Inc. | |
| | 19. Moore Medical, mooremedical Urine Analyzer U120 | Acon Laboratories, Inc. | |
| | 20. Physician Sales & Service, Inc. PSS Select Urine Analyzer | BioSys Laboratories, Inc. | |
| | 21. Roche Diagnostics Urisys 1100 Urine Analyzer | Roche Diagnostics Corp. | |
| | 22. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer | Roche Diagnostics/Boehringer Mannheim Corporation | |
| | 23. Stanbio Uri-Trak 120 Urine Analyzer | Acon Laboratories, Inc. | |
| | 24. ThermoBiostar™ PocketChem™ UA | ThermoBiostar™ | |

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|------------------------------------|---|-------------------------------------|--|
| 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 | |
| | 3. Siemens, Clinitek Status Connect System | Siemens Healthcare Diagnostics | |
| 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, 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. | |

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|---|---|---------------------|---|
| 82040QW, 82150QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84075QW, 84155 QW, 84450QW, 84460QW, 84520QW, 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 |
| 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 |
| 82040QW, 82150QW, 82247QW, 82977QW, 84075QW, 84155QW, 84450QW, 84460QW | 2. Abaxis Piccolo xpress Chemistry Analyzer {Liver Panel Plus} (Whole Blood) | Abaxis, Inc | Measures alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, gamma glutamyltransferase, total bilirubin and total protein levels in whole blood |
| 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 |

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|--------------------|--|---|---|
| 82043QW | HemoCue Albumin 201 System | HemoCue, Inc. | Quantitative measurement of albumin in urine by immunoassay |
| 82044QW | <ol style="list-style-type: none"> 1. Beckman Coulter ICON Microalb 2. Boehringer Mannheim Chemstrip Micral 3. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Test 4. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick) 5. Genzyme Dagnostics OSOM ImmunoDip Urinary Albumin Test 6. Roche Diagnostics Chemstrip Micral (urine dipstick) | <ol style="list-style-type: none"> 1. Beckman Coulter, Inc. 2. Boehringer Mannheim 3. Diagnostic Chemicals Limited 4. Diagnostic Chemicals Limited (USA) 5. Genzyme Diagnostcs 6. 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 |
| 82947QW | <ol style="list-style-type: none"> 1. Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Glucose test strips) 2. Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home eGLU test strips) 3. Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels Glucose test strips) 4. Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels eGLU test strips) | <ol style="list-style-type: none"> 1. Polymer Technology Systems, Inc. 2. Polymer Technology Systems, Inc. 3. Polymer Technology Systems, Inc. 4. Polymer Technology Systems, Inc. | Measures glucose in whole blood |

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|---|--|----------------------------|---|
| G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Alere Toxicology services, iScreen Saliva Alcohol Test Strip | Acon Laboratories, Inc. | Quantitative determination of alcohol (ethanol) in saliva |
| | 2. Alfa Scientific Designs Inc. Oral-View Saliva Alcohol Test Strip | Acon Laboratories, Inc. | |
| | 3. American Screening Corporation, Reveal Saliva Alcohol Test Strip | Acon Laboratories, Inc. | |
| | 4. Acon Laboratories Inc. Mission Saliva Alcohol Test Strip | Acon Laboratories, Inc. | |
| | 5. Chematics Inc. Alco-Screen Saliva Alcohol Test | Chematics. Inc | |
| | 6. Chematics Inc. Alco-Screen 02 Saliva Alcohol Test | Chematics. Inc. | |
| | 7. CLIAwaived Inc. Rapid Saliva Alcohol Test | Acon Laboratories, Inc. | |
| | 8. Express Diagnostics International, Incorporated Saliva Alcohol Test | Teco Diagnostics | |
| | 9. Germaine Laboratories AimStrip Alcohol Saliva | Acon Laboratories, Inc. | |
| | 10. Jant Pharmacal Corporation Accustrip Saliva Alcohol Test Strip | Acon Laboratories, Inc. | |
| | 11. OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test | OraSure Technologies, Inc. | |
| | 12. OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test | OraSure Technologies, Inc. | |
| | 13. STC Diagnostics Q.E.D. A150 Saliva Alcohol Test | STC Technologies Inc. | |
| | 14. STC Diagnostics Q.E.D. A350 Saliva Alcohol Test | STC Technologies Inc. | |
| | 15. Teco Diagnostics Saliva Alcohol Test | Teco Diagnostics | |

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|---|---|-------------------------------|---|
| 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 Analyser (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 |
| | 2. SmithKline Gastrocult | SmithKline | |
| 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 |
| | 2. Beckman Coulter Hemocult ICT (K961062) & (K080812) | Beckman Coulter, Inc. | |
| | 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. | |
| | 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. | |

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|---------------------------|--|------------------------------|--|
| 82274QW G0328QW(cont.) | 10. Consult Diagnostics Immunochemical Fecal Occult Blood Test (iFOBT) | Immunostics, Inc. | Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay |
| | 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. Hemosure One-Step Fecal Occult Blood Test | Hemnosure, Inc. | |
| | 18. immoCare Fecal Occult Blood Test | Care Diagnostic, Inc. | |
| | 19. Immunostics, Inc., hema-screen Specific Immunochemical Fecal Occult Blood Test | Immunostics, In | |
| | 20. InSure Quik Fecal Immunochemical Test (F.I.T.) | Enterix, Inc. | |
| | 21. Inverness Medical Clearview iFOBT Complete Fecal Occult Blood Test | New Bay Research Co. Ltd. | |
| | 22. Jant Pharmacal Accutest Immunological Fecal Occult Blood Test (iFOBT) | New Bay Bioresearch Co. Ltd. | |
| | 23. Medline iFOB Test | Princeton BioMeditech Corp. | |
| | 24. Medline iFOB One-Step Immunological Fecal Occult Blood Test | Ind Diagnostics Inc. | |

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|---|--|---------------------------------------|---|---|
| 82274QW G0328QW(cont.) | 25. OC-Light iFOB Test | Polymedco, Inc | Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay | |
| | 26. OSOM iFOB Test OSOM iFOBT Control Kit | Sekisui Diagnostics, Inc | | |
| | 27. OcculTech Fecal Occult Blood Rapid Test | YD Diagnostcs Corp. | | |
| | 28. Polymedco Poly Stat OC-light FOB Test | Polymedco, Inc. | | |
| | 29. Rapid Response(TM) FIT-Fecal Immunochemical Test | Orient Gene Biotech | | |
| | 30. Sekisui Diagnostics, LLC OSOM iFOB Test | Princeton BioMeditech Corp. | | |
| | 31. Tanner Scientific iFOB One Step Rapid Test | Zhejiang Orient Gene Biotech Co., Ltd | | |
| | 32. 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 | |
| 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 | | |

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|---|---|---|----------------------------------|---|
| 82465QW(cont.) (Contact your Medicare carrier for claims instructions.) | 4. ENA.C.T Total Cholesterol Test | ActiMed Laboratories, Inc. | Cholesterol monitoring | |
| | 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. | |
| | | 3. Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels CHOL+HDL Test Panel Test Strips) | Polymer Technology Systems, Inc. | |
| 4. Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels Chol + Glu Test Panel) | | Polymer Technology Systems, Inc. | | |
| 5. Roche Diagnostics AccuChek Instant Plus Dual Testing System | | | | |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
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| 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 82947QW, 82950QW, 82951QW, 82952QW | <ol style="list-style-type: none"> 1. Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips) 2. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips) | <p>Polymer Technology Systems, Inc.</p> <p>Polymer Technology Systems, Inc.</p> | Measures total cholesterol, HDL cholesterol, and glucose in whole blood |
| 82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84478QW, 80061QW | <ol style="list-style-type: none"> 1. Cholestech LDX | Cholestech Corp. | Measures total cholesterol, glucose, HDL cholesterol, and triglycerides in whole blood |
| 82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83036QW, 84478QW | <ol style="list-style-type: none"> 1. 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 | <ol style="list-style-type: none"> 1. 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 |

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|--|--|--------------------------|---|
| 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 |
| 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 | |
| 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 |

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|---|--|-------------------------|--|
| 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. | |
| | 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-Shield Poc | Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes |

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|---|---|---|---|
| 83036QW (cont.) | 2. Alere Technologies AS, Alere Afinion AS101 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 |
| | 3. Bayer AICNow+ Professional Use | Bayer Healthcare, LLC | |
| | 4. Siemens Medical Diagnostics DCA Vantage Analyzer | Siemens Healthcare Diagnostics, Inc. | |
| | 5. PTS Diagnostics AICNow + 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} | |
| 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. | |
| 7. Provalis Diagnostics In2it In-Office Analyzer (II) Prescription Home Use Test System | | Provalis Diagnostics Ltd | |
| 83516QW | Rapid Pathogen Screening, Inc. InflammADry | Rapid Pathogen Screening, Inc. | Detection of elevated levels of the MMP-9 protein in human tears, from patients suspected of having dry eye. |
| 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 |

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| 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 |
| 83861QW | TearLab Corporation TearLab Osmolarity System | TearLab Corporation | Impedance measurement of tear fluid to provide an indirect assessment of osmolarity. |
| 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. Dale Medical Products, Inc. RightLevel pH 2. Dale Medical Products, Inc. RightSpot pH 3. RightBio Metrics, RightSpot Infant pH Indicator 4. RightBio Metrics, RightSpot pH Detector 5. RightBio Metrics, RightSpot pH Indicator | EZ-NG, LLC. EZ-NG, LLC. Right BioMetrics Right BioMetrics Right BioMetrics | Gastric pH detection (acid-base balance) |
| 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} | FemTek, LLC Common Sense Ltd. Common Sense, Ltd. Common Sense, Ltd | Vaginal pH detection (acid-base balance) |

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| 83986QW (cont.) | 5. Lil' Drug Store Products Inc. Vagi-Screen Vaginal Health Test | 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} | 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 |
| | 2. BTNX, Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette | Screening Devices Canada Inc. | |
| | 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} | 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 |

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| 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. | |
| | 4. Clarity HbCheck Hemoglobin Testing System | Acon Laboratories, Inc. | |
| | 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. | |

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| 85610QW(cont.) (Contact your Medicare carrier for claims instructions.) | 4. CoaguChek PST for Prothrombin Time | Boehringer Mannheim Corporation | 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 |
| | 5. Coag-Sense Prothrombin Time (PT/INR) Monitoring system (Professional use) | CoaguSense, Inc. | |
| | 6. CoaguSense Self-Test Prothrombin Time/INR Monitoring System (Prescription Home Use) | CoaguSense, Inc. | |
| | 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/ 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 | |

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| 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. | |
| 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 |
| | 2. Acceava Mono Cassette {For whole Blood} | Princeton BioMeditech Corp. | |
| | 3. Acon Mononucleosis Rapid Test Device {Whole Blood} | ACON Laboratories, Inc. | |
| | 4. Acon Mononucleosis Rapid Test Strip {Whole Blood} | ACON Laboratories, Inc. | |
| | 5. AimStep Mono {Whole Blood} | Princeton BioMeditech Corp. | |
| | 6. Applied Biotech SureStep Mono Test (whole blood) | Applied Biotech, Inc. | |
| | 7. BioStar Acceava Mono Test (whole blood) | Wyntek Diagnostics, Inc. | |
| | 8. Cardinal Health SP Brand Rapid Test Mono {Whole Blood} | Cardinal Health | |
| | 9. Clearview MONO Whole Blood, K042272/A013 | Inverness Medical Professional Diagnostics | |
| | 10. Clearview MONO Whole Blood, K042272/A016 | Innovacon, Inc. | |
| | 11. Clearview Mono-plus II | Applied Biotech, Inc. | |
| | 12. Consult Diagnostics Mononucleosis Cassette {Whole Blood} | Princeton BioMeditech Corp. | |
| | 13. Genzyme Contrast Mono (whole blood) | Genzyme Diagnostics | |
| | 14. Genzyme OSOM Mono Test | Wyntek Diagnostics, Inc. | |
| | 15. Henry Schein OneStep Pro+ Mono {Whole Blood} | Princeton BioMeditech Corp. | |

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| 86308QW (cont.) | 16. Icon Mono | Beckman Coulter, 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 |
| | 17. Immuno Detector Mono { Whole Blood } | Princeton BioMeditech Corp. | |
| | 18. Instant Technologies iScreen Mononucleosis Rapid Test Device { Whole Blood } | ACON Laboratories, Inc. | |
| | 19. Instant Technologies iScreen Mononucleosis Rapid Test Strip { Whole Blood } | ACON Laboratories, Inc. | |
| | 20. Jant Accutest Infectious Mononucleosis Test (whole blood) | Applied Biotech, Inc. | |
| | 21. Jant Pharmacal Accutest Value + Mononucleosis Rapid Test { Whole Blood } | Innovacon, Inc. | |
| | 22. Jant Pharmacal Corp. Accutest Rapid Mono Test { Whole Blood } | Princeton BioMeditech Corp. | |
| | 23. LifeSign Status Mono {for whole blood } | Princeton BioMeditech Corp. | |
| | 24. LifeSign UniStep Mono Test (whole blood) | Princeton BioMeditech Corp. | |
| | 25. McKesson Medi-lab Performance Infectious Mononucleosis Test | Applied Biotech, Inc. | |
| | 26. Medline Mono Test Cassette { Whole Blood } | Princeton BioMeditech Corp. | |
| | 27. Meridian ImmunoCard STAT Mono (for whole blood) | Applied Biotech, Inc. | |
| | 28. PerMaxim RediScreen Mononucleosis { Whole Blood } | ACON Laboratories, Inc. | |
| | 29. Polymedco Polystat Mono { whole blood } | Princeton BioMeditech Corp. | |
| | 30. Polymedco, Inc. Poly stat Mono | Applied Biotech, Inc. | |

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|--------------------|---|--|--|
| 86308QW (cont.) | 31. Poly Stat Mono Test {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 |
| | 32. ProAdvantage by NDC Infectious Mononucleosis Test Device (Whole Blood Only) | Biosite Inc. | |
| | 33. Quidel Cards O.S. Mono (for whole blood) | Quidel Corporation | |
| | 34. Quidel QuickVue+ Infectious Mononucleosis (Whole Blood) | Quidel Corporation | |
| | 35. RAC Medical Clarity MONO Mononucleosis Rapid Test Device {Whole Blood} | ACON Laboratories, Inc. | |
| | 36. Remel RIM® A.R.C. Mono Test | Applied Biotech, Inc. | |
| | 37. Seradyn Color Q Mono (whole blood) | Genzyme Diagnostics | |
| | 38. Signify Mono Cassette {Whole Blood} | Innovacon, Inc. | |
| | 39. Signify Mono Whole Blood | Inverness Medical Professional Diagnostics | |
| | 40. Stanbio Rely Mono Rapid Test{Whole Blood} | Innovacon, Inc. | |
| | 41. Wampole Mono-Plus WB | Wampole Laboratories | |
| | 42. Wyntek Diagnostics OSOM Mono Test (whole blood) | Wyntek Diagnostics, Inc. | |
| | 43. 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 |
| | 2. Abbott Laboratories Signify H. Pylori Cassette {Whole Blood} | Innovacon, Inc. | |
| | 3. Abbott TestPack Plus H. pylori (for whole blood) | Abbott Laboratories | |

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| 86318QW (cont.) | 4. Acon® H. pylori Test Device | ACON Laboratories, Inc. | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood |
| | 5. Alere Clearview H. pylori Whole Blood Only {Whole Blood} | Alere San Diego, Inc. | |
| | 6. Alere Signify H. pylori Whole Blood Only {Whole Blood} | Alere San Diego, Inc. | |
| | 7. Alfa Scientific Designs Instant View H. Pylori Whole Blood Rapid Test | Alfa Scientific Designs, Inc. | |
| | 8. Applied Biotech SureStep H. pylori WB Test (whole blood) | Applied Biotech, Inc. | |
| | 9. Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to H. Pylori in Whole Blood | Beckman Coulter, Inc. | |
| | 10. Becton Dickinson Link 2 H. pylori Rapid Test (for whole blood) | Cortecs Diagnostics Limited | |
| | 11. Cardinal Health SP Brand Rapid Test H. pylori (K990892) | Applied Biotech Inc. | |
| | 12. Cardinal Health SP Brand Rapid Test H. pylori {Whole Blood}(K024350/A15) | Innovacon, Inc. | |
| | 13. Diagnostic Test Group Clarity H. pylori Rapid Test Device {Whole Blood} | Princeton BioMeditech Corp. | |
| | 14. EarlyDetect H. Pylori Whole Blood Rapid Test | Alpha Scientific Designs, Inc. | |
| | 15. Fisher Healthcare Sure-View H. pylori Test {Whole Blood} | Innovacon, Inc. | |
| | 16. Germaine Laboratories, Aimstep H. pylori {whole blood} | ACON Laboratories, Inc. | |
| | 17. Henry Schein One Step+ H. Pylori Rapid Test Device (Whole Blood) | Innovacon, Inc. | |

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| 86318QW (cont.) | 18. Immunostics Detector H. Pylori WB (H. pyloi Antibody Test) { Whole Blood } | Princeton BioMeditech Corp. | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood |
| | 19. Instant Technologies iScreen H.pylori Rapid Test Device | ACON Laboratories, Inc. | |
| | 20. Inverness Medical Clearview H. pylori Test { whole blood } | Innovacon, Inc. | |
| | 21. JANT Pharmacal Corp. H. pylori WBTest | Applied Biotech, Inc. | |
| | 22. Inverness Medical Signify H. Pylori Whole Blood | Innovacon, Inc. | |
| | 23. LifeSign Status H.pylori (for whole blood) | Princeton BioMeditech | |
| | 24. McKesson H. pylori Test (Whole Blood) | Alere | |
| | 25. Meridian BioScience ImmunoCard STAT! H.pylori Whole Blood Test | Applied Biotech, Inc. | |
| | 26. Polymedco, Inc. Poly stat H.pylori | Applied Biotech, Inc. | |
| | 27. Polymedco Poly Stat H. Pylori Test (Whole Blood) | Innovacon, Inc. | |
| | 28. Pro-Advantage by NDC H. pylori Device (Whole Blood) | Innovacon, Inc. | |
| | 29. QuickVue One-Step H. Pylori Test for Whole Blood | Quidel Corporation | |
| | 30. Quidel QuickVue H. pylori gII (For whole blood) | Quidel Corporation | |
| | 31. Remel RIM® A.R.C. H.pylori Test | Remel | |
| | 32. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood | SmithKline Diagnostics, Inc. | |
| | 33. Stanbio Rely H. plyori Rapid Test (Whole Blood) (Finger-stick only) | Alere | |

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| 86318QW (cont.) | 34. Trinity Uni-Gold™ H.pylori | Trinity Biotech | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood |
| | 35. Wampole Laboratories Clearview H. pylori II {finger stick or whole blood} | Applied Biotech , Inc. | |
| 86386QW | 1. Alere NMP22 BladderChek Test (Prescription Home Use) and (Professional Use) | Alere | Immunoassay for the qualitative detection of nuclear matrix protein NMP22 in urine for use as an aid in monitoring bladder cancer patients |
| | 2. Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use | Maritech, 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. bioLytical INSTI HIV-1 Antibody Test {Fingerstick Whole Blood} | BioLytical Laboratories, Inc. | Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) |
| | 2. OraSure Technologies OraQuick Rapid HIV-1 Antibody Test | OraSure Technologies, Inc | |
| | 3. OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood | OraSure Technologies, Inc. | |
| | 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. | |

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| G0433QW (cont.) | 3. Chembio Diagnostic Systems, Inc, DPP HIV 1/2 Assay {Oral Fluid} | Chembio Diagnostic Systems, 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 |
| | 4. Clearview Complete HIV 1/2 {Fingerstick Venipuncture, whole blood} | Chembio Diagnostic Systems, Inc. | |
| 86803QW, 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 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 | |
| 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. | |
| 87389QW[from December 5, 2014 to December 31, 2014], 87806QW [on and after January 1, 2015] | Oregenics, 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 |

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|--------------------|---|-------------------------------|--|
| 87502QW | 1. Alere i Influenza A & B Test {Direct Nasal swab only} | Alere Scarborough, Inc. | Differential and qualitative detection of Influenza A and Influenza B viral nucleic acids using isothermal nucleic acid amplification technology |
| | 2. RocheMolecular, cobas Liat System (cobas Liat Influenza A/B Assay) | IQuum, Inc. | Real-time RT-PCR assay for detection and discrimination of Influenza A and Influenza B in nasopharyngeal swab specimens |
| 87631QW | Cepheid Gene Xpert Xpress System (Xpert Flu+RSV Xpress)* | Cepheid | Detection of influenza A, influenza B and respiratory syncytial virus viral RNA by reverse transcriptase polymerase chain reaction assay |
| 87651QW | 1. Alere i Instrument | Alere Scarborough, Inc. | Detection of Group A Strep bacterial nucleic acids utilizing isothermal nucleic acid amplification technology |
| | 2. Roche Molecular, cobas Liat System | IQuum, Inc. | 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 |
| 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. Alere Influenza A & B Test (For use with nasal Swabs only.) | Alere Scarborough, 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 |
| | 2. Alere BinaxNow Influenza A & B Card {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens } | Alere Scarborough, Inc. | |
| | 3. BD Veritor System for Rapid Detection of Flu A+B (For use with nasal and nasopharyngeal swabs) {Includes a Reader} | Becton, Dickinson and Company | |
| | 4. BinaxNow Influenza A & B Test, K092223 | Binax, Inc | |
| | 5. BinaxNOW® Influenza A & B Test in nasopharyngeal (NP) swab and nasal wash/aspirate specimens, K041049 | Binax, Inc. | |

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|--------------------|--|-------------------------|--|
| 87804QW | 6. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}, K053126 | 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 |
| | 7. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens and Nasal Specimens (NS)} | Binax, Inc. | |
| | 8. Henry Schein OneStep+ Influenza A&B Test | Alere Scarborough, Inc. | |
| | 9. Quidel Quickvue Influenza A+B Test | Quidel Corporation | |
| | 10. Sofia Analyzer and Influenza A+B FIA | Quidel Corporation | |
| | 11. Sofia Analyzer and Influenza A+B FIA (for user with nasal swabs and nasopharyngeal swabs) | Quidel Corporation | |
| 87804QW | 1. Binax Now® Flu A Test | Binax, Inc. | Qualitative detection of influenza type A antigen in nasopharyngeal specimens |
| | 2. BTNX, Inc. Rapid Response Influenza A Test Cassette | SA Scientific, Inc. | |
| | 3. EarlyDetect Pro Influenza A Test | SA Scientific, Inc. | |
| | 4. 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. BTNX, Inc. Rapid Response Influenza BTest Cassette | SA Scientific, Inc. | |
| | 3. EarlyDetect Pro Influenza B Test | SA Scientific, Inc. | |
| | 4. SA Scientific SAS Influenza B Test | SA Scientific, Inc. | |
| 87807QW | 1. Alere BinaxNOW RSV Card | Alere Scarborough, Inc. | Rapid immunoassay for the qualitative detection of respiratory syncytial virus antigen |

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| 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 respiratory syncytial virus antigen |
| | 3. Binax NOW RSV Test (K021687) | Binax, Inc. | |
| | 4. Binax NOW RSV Test (K032166/A005) | Binax, Inc. | |
| | 5. Fisher Scientific Sure-Vue RSV Test | SA Scientific, Inc. | |
| | 6. Integrated Biotechnology Quick Lab RSV Test | Integrated Biotechnology Corp. | |
| | 7. Quidel Quick Vue 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 | |
| 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 | 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. Accustrip Strep A {Specimen type (Throat Swab)} | Princeton Biomeditech Corp. | |
| | 4. Acon® Strep A Rapid Strip Test | ACON Laboratories, Inc. | |
| | 5. Acon® Strep A Twist Rapid Test | ACON Laboratories, Inc. | |

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| 87880QW (cont.) | 6. Applied Biotech SureStep Strep A (II) (direct from throat swab) | 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 |
| | 7. Beckman Coulter ICON DS Strep A Test | Princeton BioMeditech Corp. | |
| | 8. Beckman Coulter ICON SC Strep A Test | ACON Laboratories, Inc. | |
| | 9. Beckman Coulter Primary Care Diagnostics ICON DS Strep A | ACON Laboratories, Inc. | |
| | 10. Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test | Beckman Coulter, Inc. | |
| | 11. Becton Dickinson BD Chek Group A Strep A Test | Innovacon, Inc. | |
| | 12. Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab) | Applied Biotech, Inc. | |
| | 13. BD Veritor System for Rapid Detection of Group A Strep (direct from throat swab) | Becton Dickinson and Company | |
| | 14. Binax NOW Strep A Test | Binax, Inc. | |
| | 15. BioStar Aceava Strep A Test (direct specimen only) | Wyntek Diagnostics, Inc. | |
| | 16. Biotechnostix Rapid Response Strep A Rapid Test Device | Acon Laboratories Co. | |
| | 17. Biotechnostix Rapid Response Strep A Rapid Test Strip | Acon Laboratories Co. | |
| | 18. BTNX Rapid Response Strep A Rapid Test Strips | Sa Scientific, Inc. | |
| | 19. BTNX, Inc. Strep A Rapid Test | Sa Scientific, Inc. | |

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| 87880QW (cont.) | 20. Cardinal Health Strep A Dipstick – Rapid Test (Throat Swab Specimen) | Alere SD | 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 |
| | 21. Cardinal Health SP Brand Rapid Test Strep A Dipstick(K033855) | Applied Biotech Inc. | |
| | 22. Cardinal Health SP Brand Rapid Test Strep A Dipstick (K010582/A028) | Innovacon, Inc. | |
| | 23. CLIA waived inc Rapid Strep A Test | Sa Scientific, Inc. | |
| | 24. DE Healthcare Products, TruView Strep A Test | DE Healthcare Products | |
| | 25. DE Healthcare Products TruView Strep A Cassette Test | ACON Laboratories, Inc. | |
| | 26. Diagnostic Test Group Clarity Strep A Rapid Test Strips | Princeton BioMeditech Corp. | |
| | 27. Fisher HealthCare Sure-Vue Strep A (direct from throat swab) | Applied Biotech, Inc. | |
| | 28. Genzyme Contrast Strep A (direct from throat swab) | Genzyme Diagnostics | |
| | 29. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size | Genzyme Corporation | |
| | 30. Genzyme OSOM Ultra Strep A Test | Genzyme General | |
| | 31. Germaine Laboratories StrepAim Rapid Dipstick Test | Germaine Laboratories, Inc. | |
| | 32. Germaine Laboratories Strep AIM Tower | Germaine Laboratories, Inc. | |
| | 33. Henry Schein Inc, One Step+ Strep A Test | Henry Schein | |
| 34. Henry Schein Inc, One Step+ Strep A Dipstick Test | Henry Schein | | |

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|--------------------|--|-----------------------------|---|
| 87880QW (cont.) | 35. Henry Schein OneStep Pro+ Strep A Cassette | Princeton Biomeditech Corp. | 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. Immunostics Detector Strep A Direct | ACON Laboratories, Inc. | |
| | 37. Immunostics Immuno/Strep A Detector | ACON Laboratories, Inc. | |
| | 38. Instant Technologies iStrep Strep A | ACON Laboratories, Inc. | |
| | 39. Inverness Medical BioStar Aceeva Strep A Test | Innovacon, Inc. | |
| | 40. Inverness Medical BioStar Aceeva Strep A Twist | Innovacon, Inc. | |
| | 41. Inverness Medical Signify Strep A Cassette (Inverness Medical Innovations) | Innovacon, Inc. | |
| | 42. Jant Pharmacal AccuStrip Strep A (II) (direct from throat swab) | Applied Biotech, Inc. | |
| | 43. Jant Pharmacal Accustrip Strep A Value+ Test Strip | Innovacon, Inc. | |
| | 44. Jant Pharmacal Accutest Integrated Strep A Rapid Test Device | Innovacon, Inc. | |
| | 45. Laboratory Supply Company (LSC) PEP Strep A Cassette Test | Acon Laboratories Co. | |
| | 46. LABSCO Advantage Strep A | Princeton BioMeditech Corp, | |
| | 47. LSC PEP Strep A Dipstick Test | Acon Laboratories Co. | |
| | 48. LifeSign LLC Status Strep A | Princeton BioMeditech | |
| | 49. Mainline Confirms Strep A Dots Test (direct from throat swab) | Applied Biotech, Inc. | |
| | 50. McKesson Medi-Lab Performance Strep A Test Dipstick | Applied Biotech, Inc. | |
| | 51. McKesson Strep A Test – Dipstick | Alere San Diego, Inc. | |
| | 52. McKesson Strep A Test – Twist | Alere San Diego, Inc. | |

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| 87880QW (cont.) | 53. Medline Strep A Test Strip {Throat Swab} | Alere, 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 |
| | 54. Meridian Diagnostics ImmunoCard STAT Strep A (direct from throat swab) | Applied Biotech, Inc. | |
| | 55. Mooremedical Strep A Rapid Test – Dipstick | Alere San Diego, Inc. | |
| | 56. Moore Medical The Supply Experts Strep A Rapid Test – Dipstick | Innovacon, Inc. | |
| | 57. Poly stat Strep A Strip Test {Specimen type (Throat Swab)} | Princeton Biomeditech Corp. | |
| | 58. Poly stat Strep A Flip Test | Princeton Biomeditech Corp. | |
| | 59. PSS Consult Diagnostics Strep A Dipstick | Innovacon, Inc. | |
| | 60. PSS World Medical Select Diagnostics Strep A Dipstick | Innovacon, Inc. | |
| | 61. PSS World Medical Select Diagnostics Strep A Twist | Innovacon, Inc. | |
| | 62. Polymedco, Inc. Poly stat A (II) | Applied Biotech, Inc. | |
| | 63. Polymedco Poly Stat Strep A Liquid Test | Applied Biotech, Inc | |
| | 64. QuickVue In-Line One-Step Strep A Test (K934484) | Quidel Corporation | |
| | 65. QuickVue® Dipstick Strep A | Quidel Corporation | |
| | 66. Quidel QuickVue® In-Line Strep A | Quidel Corporation | |
| | 67. Quidel QuickVue In-Line Strep A {direct from throat swab}(K934484/A013) | Quidel Corporation | |
| | 68. Quidel Sofia Strep A+FIA {from throat swab only} | Quidel Corporation | |

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|---|--|-------------------------------|---|
| 87880QW (cont.) | 69. RAC Medical Clarity Strep A Rapid Test Strips | Acon Laboratories Co. | 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 |
| | 70. Remel RIM® A.R.C. Strep A Test | Applied Biotech, Inc. | |
| | 71. Sekisui Diagnostics LLC, OSOM Strep A Test{direct from throat swab} | Sekisui Diagnostics LLC | |
| | 72. Sekisui Diagnostics LLC, OSOM Ultra Strep A Test | Sekisui Diagnostics LLC | |
| | 73. SmithKline ICON Fx Strep A Test (from throat swab only) | Binax, Inc. | |
| | 74. Stanbio Laboratory E-Z Well Strep A Rapid Device Test | Acon Laboratories Co. | |
| | 75. Stanbio QuStick Strep A | Stanbio Laboratory | |
| | 76. StrepAim {Specimen type (Throat Swab)} | Princeton Biomeditech Corp. | |
| | 77. Wyntek Diagnostics OSOM Strep A Test | Wyntek Diagnostics, Inc | |
| 78. Wyntek OSOM® Ultra Strep A Test | Wyntek Diagnostics, Inc. | | |
| 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. |
| 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 |

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|---------------------------|-----------------------------|----------------------------|---|
| 89321QW | Fertell Male Fertility Test | Genesis Ltd. | Determines whether the concentration of motile sperm is above a cut-off level of 10 million motile sperm cells per ml |

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