

## TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u>   | <u>TEST NAME</u>   | <u>MANUFACTURER</u> | <u>USE</u>   |
|--|--|---------------------|--|
| 81002  | Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen | Various             | Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections |
| 81025  | Urine pregnancy tests by visual color comparison   | Various             | Diagnosis of pregnancy   |
| 82270<br>82272<br>G0107 (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                         |

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|---|---|---|---|
| 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Phamatech At Home Drug Test (Model 9063)                         | Phamatech                               | Screening test for the presence/detection of amphetamine in urine         |
|   | 2. Phamatech QuickScreen One Step Amphetamine Test                  | Phamatech                               |   |
| 80101QW (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. Phamatech At Home Drug Test (Model 9078)                         | Phamatech                               |   |
|   | 4. Phamatech At Home Drug Test (Model 9078T)                        | Phamatech                               |   |
|   | 5. Worldwide Medical Corporation, First Check® Home Drug Test (THC) | Worldwide Medical Corporation           |   |
| 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Phamatech At Home Drug Test (Model 9073)                         | Phamatech                               | Screening test for the presence/detection of cocaine metabolites in urine |
|   | 2. Phamatech At Home Drug Test (Model 9073T)                        | Phamatech                               |   |
|   | 3. Phamatech QuickScreen One Step Cocaine Screening Test            | Phamatech                               |   |

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|---|---|---------------------|--|
| 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Phamatech At Home Drug Test (Model 9068)             | Phamatech           | Screening test for the presence/detection of methamphetamines in urine   |
|   | 2. Phamatech QuickScreen One Step Methamphetamine Test  | Phamatech           |  |
| 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | DynaGen NicCheck I Test Strips                          | Dynagen, Inc.       | Detects nicotine and/or its metabolites in urine, which is used as an aid in indicating the smoking status of an individual and as an aid in the identification of a smoker as a low or high nicotine consumer |
| 80101QW (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           |  |
| 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Phamatech At Home Drug Test (Model 9133)             | Phamatech           | Screening test for the presence/detection of phencyclidine in urine  |
|   | 2. Phamatech QuickScreen One Step PCP Screening Test    | Phamatech           |  |

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|---|---|-----------------------------------|---|
| 80101QW (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     |   |
| 80101QW (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 phencyclidine (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 |   |
| 80101QW (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, cannabinoids (THC), cocaine metabolites, methamphetamines, and opiates in urine        |

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| 80101QW (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 cannabinoids (THC), cocaine metabolites, opiates and methamphetamines in urine  |
| 80101QW (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, cannabinoids (THC), cocaine metabolites, methamphetamines, opiates, and phencyclidine 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. Biotechnostix Rapid Response One Step Multi-Drug, Multi-Line Screen Test Device*                                    | Acon Laboratories, Inc.       |  |
|   | 5. iCassette Multi-Drug, Multi-Line Screen Test Device   | Acon Laboratories, Inc.       |  |
|   | 6. RediScreen Multi-Drug, Multi-Line Screen Test Device  | Acon Laboratories, Inc.       |  |
| 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Biotechnostix Rapid Response Multi-Drug, Multi-Line Screen Test Card with Integrated Cup*                           | Acon Laboratories, Inc        | Screening test for the presence/detection of amphetamines, cannabinoids (THC), cocaine metabolites, methamphetamines, methylenedioxymethamphetamine, opiates, and phencyclidine in urine |
|   | 2. First Check Diagnostics First Check Multi Drug Cup*   | First Check Diagnostics LLC   |  |

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|---|--|-----------------------------|--|
| 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Branan Medical Corporation ToxCup Drug Screen Cup  | Branan Medical Corporation  | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, cannabinoids (THC), cocaine metabolites, methadone, methamphetamines, methylenedioxyamphetamine, opiates, oxycodone, and phencyclidine in urine  |
| 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Branan Medical Corporation Fastect II Drug Screen Dipstick Test   | Branan Medical Corporation  | Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, cannabinoids (THC), cocaine metabolites, methadone, methamphetamines, methylenedioxyamphetamine, opiates, oxycodone, phencyclidine and tricyclic antidepressants in urine                      |
|   | 2. First Check Diagnostics First Check 12 Drug Test*   | First Check Diagnostics LLC |  |
| 80178QW   | ReliaLAB Inc. InstaRead Lithium System {fingerstick or venipuncture whole blood}   | Akers Laboratories, Inc.    | Measures lithium blood levels in whole blood   |
| 81002, 82570QW  | 1. Bayer Multistick Pro 7G Reagent Strips  | Bayer 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 and semi-quantitative measurement of creatinine in urine for the detection of patients at risk for developing kidney damage |
|   | 2. Bayer Multistick Pro 10LS Reagent Strips  | Bayer Diagnostics           |  |
|   | 3. Bayer Multistick Pro 11 Reagent Strips  | Bayer Diagnostics           |  |
| 81003QW   | 1. Bayer Clinitek 50 Urine Chemistry Analyzer – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated | Bayer                       | 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. Biosys Laboratories Optima Urine Analyzer   | Biosys Laboratories         |  |

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|---------------------|---|---|--|
| 81003QW (cont.)     | 3. Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated | Boehringer Mannheim Corporation                   | Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections   |
|                     | 4. Hypoguard Diascreen® Urine Chemistry Analyzer  | Hypoguard USA, Inc.                               |  |
|                     | 5. Physician Sales & Service, Inc. PSS Select Urine Analyzer  | Biosys Laboratories, Inc.                         |  |
|                     | 6. Roche Diagnostics Urisys 1100 Urine Analyzer   | Roche Diagnostics Corp.                           |  |
|                     | 7. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer   | Roche Diagnostics/Boehringer Mannheim Corporation |  |
|                     | 8. Teco Diagnostics URITEK TC-101 Urine Strip Reader  | Teco Diagnostics                                  |  |
|                     | 9. ThermoBiostar™ PocketChem™ UA  | ThermoBiostar™                                    |  |
| 81003QW,<br>82570QW | Bayer Clinitek Status Urine Chemistry Analyzer*   | Bayer Healthcare, Llc                             | 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 semi-quantitative measurement of creatinine in urine for the detection of patients at risk for developing kidney damage |
| 81007QW             | Diatech Diagnostics Uriscreen (for OTC use)   | Savyon/USA  | Detects catalase in urine which is associated with urinary tract infections (UTIs). White blood cells and some bacteria associated with UTIs are positive for catalase.  |
| 82010QW             | PTS Bioscanner (for OTC use) - for blood ketones  | Polymer Technology Systems, Inc.                  | Measures ketones in whole blood  |
| 82010QW,<br>82962   | 1. Abbott Laboratories, Medisense Products Precision™ Xtra™ Advanced Diabetes Management System (K983504)   | Abbott Laboratories, Inc.                         | Monitoring of blood glucose levels and measures ketones in whole blood   |

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| 82010QW,<br>82962 (cont.)   | 2. Abbott Medisense Precision Xtra Advanced Diabetes Management System (K040814) | Abbott Laboratories, Inc   | Monitoring of blood glucose levels and measures ketones in whole blood   |
| 82044QW,<br>82570QW   | 1. Bayer Clinitek 50 Urine Chemistry Analyzer - for microalbumin, creatinine     | Bayer Corp.                | Semi-quantitative measurement of microalbumin and creatinine in urine for the detection of patients at risk for developing kidney damage |
|   | 2. Bayer Diagnostics/<br>MICROALBUSTIX™<br>Reagent Strip                         | Bayer Inc.                 |  |
| 82055QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test                         | OraSure Technologies, Inc. | Quantitative determination of alcohol (ethanol) in saliva  |
|   | 2. OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test                         | OraSure Technologies, Inc. |  |
|   | 3. STC Diagnostics Q.E.D. A150 Saliva Alcohol Test                               | STC Technologies Inc.      |  |
|   | 4. STC Diagnostics Q.E.D. A350 Saliva Alcohol Test                               | STC Technologies Inc.      |  |
| 82120QW,<br>83986QW   | 1. Litmus Concepts FemExam TestCard (from vaginal swab)                          | Litmus Concepts, Inc.      | Qualitative test of a vaginal fluid sample for elevated pH (pH greater than or equal to 4.7) and the presence of volatile amines         |
|   | 2. Quidel QuickVue Advance pH and Amines Test                                    | Quidel Corporation         |  |
| 82271QW   | 1. Aerscher Hemaprompt FG  | Aerscher Diagnostics       | Rapid screening test to detect the presence of gastric occult blood  |
|   | 2. SmithKline Gastrocult   | SmithKline                 |  |
| 82271QW,<br>83986QW   | Beckman Coulter Primary Care Diagnostics Gastrocult®                             | Beckman Coulter, Inc.      | Rapid screening test to detect the presence of gastric occult blood and determine the pH (acid-base balance) of gastric aspirates        |
| 82274QW<br>G0328QW  | 1. Beckman Coulter Hemocult ICT  | Beckman Coulter, Inc.      | Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay                        |

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|--|---|----------------------------------|---|
| 82274QW<br>G0328QW (cont.)                                       | 2. Clarity Hemosure One-Step Immunological Fecal Occult Blood Test                    | Wampole Laboratories             | Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay |
|  | 3. Clearview Ultra FOB Test   | RAC Medical Group, Inc.          |   |
|  | 4. Enterix InSure™ Fecal Occult Blood Test  | Enterix, Inc.                    |   |
|  | 5. Enterix InSure Fecal Immunochemical Test   | Enterix, Inc.                    |   |
|  | 1. Advanced Care  | Johnson & Johnson                |   |
| 82465QW (Contact your Medicare carrier for claims instructions.) | 2. Boehringer Mannheim Accu-Chek InstantPlus Cholesterol                              | Boehringer Mannheim              | Cholesterol monitoring  |
|  | 3. ChemTrak AccuMeter   | ChemTrak                         |   |
|  | 4. ENA.C.T Total Cholesterol Test   | ActiMed Laboratories, Inc.       |   |
|  | 5. ActiMed Laboratories ENA.C.T. Total Cholesterol Test (PDU)                         | ActiMed Laboratories, Inc.       |   |
|  | 6. Lifestream Technologies Cholesterol Monitor  | Lifestream Technologies, Inc.    |   |
|  | 7. Lifestream Technologies Personal Cholesterol Monitor                               | Lifestream Technologies, Inc.    |   |
|  | 8. Polymer Technology Systems (PTS) MTM Bioscanner 1000 (for OTC use) for cholesterol | Polymer Technology Systems, Inc. |   |
|  | 9. PTS Bioscanner Test Strips Cholesterol   | Polymer Technology Systems, Inc. |   |

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|--|--|----------------------------------|---|
| 82465QW (Contact your Medicare carrier for claims instructions.),<br>83718QW,<br>84478QW,<br>80061QW   | 1. Piccolo Point of Care Chemistry Analyzer (Lipid Panel Reagent Disc) (Whole Blood)           | Abaxis, Incorporated             | Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood                 |
|  | 2. Polymer Technology Systems CardioChek PA Analyzer {PTS Panels Lipid Panel Test Strips}      | Polymer Technology Systems, Inc. |   |
| 82465QW (Contact your Medicare carrier for claims instructions.),<br>82962   | 1. Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels Chol + Glu Test Panel)        | Polymer Technology Systems, Inc. | Measures total cholesterol and monitors blood glucose levels                                  |
|  | 2. Roche Diagnostics AccuChek Instant Plus Dual Testing System                                 |                                  |   |
| 82465QW(Contact your Medicare carrier for claims instructions.),<br>83718QW  | Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels CHOL+HDL Test Panel Test Strips) | Polymer Technology Systems, Inc. | Measures total cholesterol and HDL cholesterol in whole blood                                 |
| 82465QW (Contact your Medicare carrier for claims instructions.),<br>83718QW,<br>84478QW,<br>82947QW,<br>82950QW,<br>82951QW,<br>82952QW,<br>80061QW | Cholestech LDX   | Cholestech                       | Measures total cholesterol, HDL cholesterol, triglycerides, and glucose levels in whole blood |
| 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                   |

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| 82679QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.),<br>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,<br>82950QW,<br>82951QW,<br>82952QW   | 1. HemoCue B-Glucose Photometer<br><br>2. HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer   | HemoCue<br><br>HemoCue, Inc.   | Measures glucose levels in whole blood   |
| 82985QW   | LXN Fructosamine Test System  | LXN Corporation  | Used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period (Not a useful test for screening diabetes mellitus)                    |
| 82962,<br>82985QW   | 1. LXN Duet Glucose Control Monitoring System<br><br>2. LXN IN CHARGE Diabetes Control System   | LXN Corporation<br><br>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 |
| 83001QW   | 1. Acon Laboratories, Inc. FSH Menopause Predictor Test<br>2. Acon Laboratories, Inc. FSH One Step Menopause Test Device {Professional Use}<br>3. Acon Laboratories, Inc. FSH One Step Menopause Test Strip {Professional Use}<br>4. Applied Biotech, Inc. RU25 Plus FSH Menopause Test | Acon Laboratories, Inc.<br><br>Acon Laboratories, Inc<br><br>Acon Laboratories, Inc<br><br>Applied Biotech, Inc. | Detects follicle stimulating hormone in urine  |

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| 83001QW (cont.)    | 5. Biotechnostix, Inc. Rapid Response FSH One Step Menopause Test Device*                   | Acon Laboratories, Inc    | Detects follicle stimulating hormone in urine   |
|                    | 6. Genua Menopause Monitor Test   | Genua 1944 Inc            |   |
|                    | 7. Synova Healthcare MenocheckPro (Professional Use)  | Applied Biotech, Inc.     |   |
| 83036QW            | 1. Axis-Shield Afinion AS100 Analyzer*  | Axis-Sheild Poc As        | Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes   |
|                    | 2. Bayer DCA 2000 – glycosylated hemoglobin (Hgb A1c)                                       | Bayer Corp.               |   |
|                    | 3. Bayer DCA 2000+ - glycosylated hemoglobin (Hgb A1c)                                      | Bayer Corp.               |   |
|                    | 4. Metrika A1c Now™ - Professional Use (K000887)  | Metrika, Inc.             |   |
|                    | 5. Metrika A1c Now for Professional Use (K020235)   | Metrika, Inc.             |   |
|                    | 6. Metrika DRx® HbA1c (Professional Use Test System)  | Metrika, Inc.             |   |
| 83037QW            | 1. Bio-Rad Micromat II Hemoglobin A1c Prescription Home Use Test                            | Bio-Rad Laboratories      | Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes using devices cleared by the FDA for home use |
|                    | 2. Cholestech GDX A1C Test (Prescription Home Use)  | Cholestech Corporation    |   |
|                    | 3. Metrika A1c Now for Prescription Home Use (K020234)                                      | Metrika, Inc.             |   |
|                    | 4. Provalis Diagnostics Glycosal™ HbA1c Test  | Provalis Diagnostics Ltd. |   |
|                    | 5. Provalis Diagnostics In2it In-Office Analyzer (II) A1C Prescription Home Use Test System | Provalis Diagnostics Ltd  |   |

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| 83518QW            | 1. Beckman Coulter ICON Microalb  | Beckman Coulter                    | Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease |
|                    | 2. Boehringer Mannheim Chemstrip Micral   | Boehringer Mannheim                |   |
|                    | 3. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Test                             | Diagnostic Chemicals Limited       |   |
|                    | 4. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick)          | Diagnostic Chemicals Limited (USA) |   |
|                    | 5. Roche Diagnostics Chemstrip Micral (urine dipstick)                              | Roche Diagnostics Corporation      |   |
| 83605QW            | KDK Corporation Lactate Pro System  | KDK Corporation                    | Quantitative measurement of lactate in whole blood  |
| 83718QW            | PTS Bioscanner (for OTC use) - for HDL cholesterol                                  | Polymer Technology Systems, Inc.   | Measures HDL cholesterol in whole blood   |
| 83721QW            | Polymer Technology Systems Cardiochek PA Analyzer                                   | Polymer Technology Systems, Inc.   | Measures LDL cholesterol in whole blood   |
| 83880QW            | 1. Biosite Triage Meter {Whole Blood}<br>2. Biosite Triage Meter Plus {Whole Blood} | Biosite Incorporated               | Quantitative measurement of b-type natuiretic 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            | FemTek pHEM-ALERT®  | FemTek, LLC                        | Vaginal pH detection (acid-base balance)  |
| 84443QW            | ThyroTec, Inc. ThyroTest Whole Blood TSH Test                                       | ThyroTes, Inc.                     | Qualitative determination of human thyroid stimulating hormone (TSH) in whole blood, which is a rapid TSH assay for hypothyroidism screening in adults        |
| 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   |

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| 84478QW  | PTS, Inc. Bioscanner 2000 for Triglycerides   | Polymer Technology Systems, Inc.  | Measures triglycerides in whole blood  |
| 84703QW  | Bayer Clinitek 50 Urine Chemistry Analyzer - for HCG, urine   | Bayer Corp  | Diagnosis of pregnancy   |
| 85014QW  | Wampole STAT-CRIT Hct   | Wampole Laboratories  | Screen for anemia  |
| 85018QW  | <ol style="list-style-type: none"> <li>1. Biosafe Laboratories, Inc., Anemiapro Self Screener</li> <li>2. HemoCue Donor Hemoglobin Checker System HemoCue</li> <li>3. HemoCue Hemoglobin System</li> <li>4. HemoCue Hemoglobin 201+ (Capillary, Venous, Arterial Whole Blood)</li> <li>5. HemoCue Hemoglobin 201+/HemoCue Hemoglobin Microcuvette System</li> <li>6. GDS Diagnostics HemoSite Meter - for hemoglobin</li> <li>7. GDS Technology STAT-Site MHgb Test System</li> </ol> | <p>Biosafe Laboratories, Inc.</p> <p>HemoCue</p> <p>HemoCue</p> <p>HemoCue</p> <p>HemoCue</p> <p>GDS Technology, Inc.</p> <p>GDS Technology</p>                         | Measures hemoglobin level in whole blood   |
| 85576QW  | Accumetrics VerifyNow Aspirin Assay   | Accumetrics Inc.  | Qualitative assay to measure platelet aggregation  |
| 85610QW (Contact your Medicare carrier for claims instructions.) | <ol style="list-style-type: none"> <li>1. AvoSure PT System (prescription home use)</li> <li>2. AvoSure Pro (professional use)</li> <li>3. CoaguChek PST for Prothrombin Time</li> <li>4. HemoSense INRatio System</li> <li>5. ITC Protime Microcoagulation System for Prothrombin Time</li> </ol>  | <p>Avocet Medical, Inc.</p> <p>Avocet Medical, Inc.</p> <p>Boehringer Mannheim Corporation</p> <p>HemoSense, Inc.</p> <p>International Technidyne Corporation (ITC)</p> | 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 |

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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>   |
|--|---|---|--|
| 85610QW (Contact your Medicare carrier for claims instructions.) (cont.) | 6. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Prescription Home Use | International Technidyne 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 |
|  | 7. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Professional Use      | International Technidyne Corporation                  |  |
|  | 8. Lifescan Harmony™ INR Monitoring System -- Prescription Home Use and Professional Use              | Lifescan, Inc.  |  |
|  | 9. Roche/Boehringer Mannheim CoaguChek System for Professional Use                                    | Roche Diagnostics/<br>Boehringer Mannheim Corporation |  |
|  | 10. Roche Diagnostics CoaguChek PST   | Roche Diagnostics                                     |  |
|  | 11. Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time)                                | Roche Diagnostics Corporation                         |  |
| 86294QW  | 1. Bion Diagnostic Sciences BTA stat Test (for home use)  | Bion Diagnostic Sciences, Inc.                        | Immunoassay for the qualitative detection of bladder tumor associated antigen in urine of persons diagnosed with bladder cancer, and used as an aid in the management of bladder cancer patients   |
|  | 2. Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use               | Maritech, Inc.  |  |
| 86308QW  | 1. Acon Mononucleosis Rapid Test Device {Whole Blood}   |   | 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. Acon Mononucleosis Rapid Test Strip {Whole Blood}  |   |  |
|  | 3. Applied Biotech SureStep Mono Test (whole blood)   | Applied Biotech, Inc.                                 |  |

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| <u>CPT CODE(S)</u> | <u>TEST NAME</u>  | <u>MANUFACTURER</u>         | <u>USE</u>   |
|--------------------|---|-----------------------------|--|
| 86308QW (cont.)    | 4. BioStar Aceava Mono Test<br>(whole blood)                                  | Wyntek Diagnostics, 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 |
|                    | 5. Clearview Mono-plus II   | Applied Biotech, Inc.       |  |
|                    | 6. Genzyme Contrast Mono (whole blood)  | Genzyme Diagnostics         |  |
|                    | 7. Genzyme OSOM Mono Test   | Wyntek Diagnostics, Inc.    |  |
|                    | 8. Icon Mono*   | Beckman Coulter, Inc.       |  |
|                    | 9. Instant Technologies iScreen Mononucleosis Rapid Test Device {Whole Blood} | Acon Laboratories, Inc.     |  |
|                    | 10. Instant Technologies iScreen Mononucleosis Rapid Test Strip {Whole Blood} | Acon Laboratories, Inc.     |  |
|                    | 11. Jant Accutest Infectious Mononucleosis Test (whole blood)                 | Applied Biotech, Inc.       |  |
|                    | 12. LifeSign UniStep Mono Test (whole blood)                                  | Princeton BioMeditech Corp. |  |
|                    | 13. McKesson Medi-lab Performance Infectious Mononucleosis Test               | Applied Biotech, Inc.       |  |
|                    | 14. Meridian ImmunoCard STAT Mono (for whole blood)                           | Applied Biotech, Inc.       |  |
|                    | 15. Polymedco, Inc. Poly stat Mono  | Applied Biotech, Inc.       |  |
|                    | 16. Quidel Cards O.S. Mono (for whole blood)                                  | Quidel Corporation          |  |
|                    | 17. Quidel QuickVue+ Infectious Mononucleosis (Whole Blood)                   | Quidel Corporation          |  |
|                    | 18. RAC Medical Clarity MONO Mononucleosis Rapid Test Device {Whole Blood}*   | Acon Laboratories, Inc.     |  |
|                    | 19. Remel RIM® A.R.C. Mono Test   | Applied Biotech, Inc.       |  |

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|--|---|------------------------------|--|
| 86308QW (cont.)  | 20. Seradyn Color Q Mono (whole blood)  | Genzyme Diagnostics          | 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 |
|  | 21. Wampole Mono-Plus WB  | Wampole Laboratories         |  |
|  | 22. Wyntek Diagnostics OSOM Mono Test (whole blood)   | Wyntek Diagnostics, Inc.     |  |
| 86318QW  | 23. Wyntek Signify Mono Test  | Wyntek Diagnostics, Inc.     | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood   |
|  | 1. Abbott FlexPak HP Test for whole blood   | SmithKline Diagnostics, Inc. |  |
|  | 2. Abbott TestPack Plus H. pylori (for whole blood)   | Abbott Laboratories          |  |
|  | 3. Acon® H. pylori Test Device  | ACON Laboratories, Inc.      |  |
|  | 4. Applied Biotech SureStep H. pylori WB Test (whole blood)   | Applied Biotech, Inc.        |  |
|  | 5. Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to H. Pylori in Whole Blood | Beckman Coulter, Inc.        |  |
|  | 6. Becton Dickinson Link 2 H. pylori Rapid Test (for whole blood)   | Cortecs Diagnostics Limited  |  |
|  | 7. Cardinal Health SP Brand Rapid Test H. pylori  | Applied Biotech Inc.         |  |
|  | 8. Germaine Laboratories, Aimstep H. pylori {whole blood}   | Acon Laboratories, Inc.      |  |
|  | 9. Instant Technologies iScreen H.pylori Rapid Test Device  | Acon Laboratories, Inc.      |  |
|  | 10. JANT Pharmacal Corp. H. pylori WBTest   | Applied Biotech, Inc.        |  |
|  | 11. LifeSign Status H.pylori (for whole blood)  | Princeton BioMeditech        |  |
| 12. Meridian BioScience ImmunoCard STAT! H.pylori Whole Blood Test | Applied Biotech, Inc.   |                              |  |

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|---------------------------|---|------------------------------|--|
| 86318QW (cont.)           | 13. Polymedco, Inc. Poly stat H.pylori  | Applied Biotech, Inc.        | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood   |
|                           | 14. QuickVue One-Step H. Pylori Test for Whole Blood  | Quidel                       |  |
|                           | 15. Quidel QuickVue One-Step H.pylori II Test.  | Quidel Corporation           |  |
|                           | 16. Remel RIM® A.R.C. H.pylori Test   | Remel                        |  |
|                           | 17. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood                              | SmithKline Diagnostics, Inc. |  |
|                           | 18. Trinity Uni-Gold™ H.pylori  | Trinity BioTech              |  |
|                           | 19. Wampole Laboratories Clearview H. pylori II {finger stick or whole blood}   | Applied Biotech , Inc.       |  |
| 86618QW                   | Wampole PreVue™ <i>B. burgdorferi</i> Antibody Detection Assay  | Wampole Laboratories         | Qualitative detection of IgG/IgM antibodies to <i>Borrelia burgdorferi</i> (causative agent of Lyme disease) in whole blood  |
| 86701QW                   | 1. OraSure Technologies OraQuick Rapid HIV-1 Antibody Test  | OraSure Technologies, Inc.   | Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1)  |
|                           | 2. OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood                                | OraSure Technologies, Inc.   |  |
|                           | 3. Trinity Biotech Uni-Gold Recombigen HIV Test (Fingerstick, Venipuncture Whole Blood)                                 | Trinity Biotech              |  |
| 86703QW                   | OraSure OraQuick Advance Rapid HIV-1/2 Antibody Test {oral fluid, fingerstick whole blood and venipuncture whole blood} | OraSure Technologies, Inc.   | Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid, fingerstick whole blood and venipuncture whole blood specimens |

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|--------------------|--|--|---|
| 87077QW            | <ol style="list-style-type: none"> <li>Ballard Medical Products CLOtest</li> <li>Delta West CLOtest</li> <li>GI Supply HP-FAST</li> <li>GI Supply, Div. Chek-Med Systems HP One</li> <li>Medical Instruments Corporation Pronto Dry H. pylori</li> <li>Serim Pyloritek Test Kit</li> </ol> | <p>Ballard Medical Products</p> <p>Delta West<br/>Tri-Med Specialties</p> <p>Mycoscience Labs, Inc.</p> <p>GI Supply</p> <p>Medical Instruments Corporation</p> <p>Serim</p> | Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)                                |
| 87210QW            | <ol style="list-style-type: none"> <li>Stesans Maybe?Mom Mini Ovulation Microscope</li> <li>O2 Unlimited Donna Ovulation Tester</li> </ol>   | <p>LEC Associates</p> <p>O2 Unlimited Corp.</p>  | Detects ferning pattern in saliva which is used in the determination of ovulation (optimal for conception)  |
| 87449QW            | ZymeTx Zstatflu® Test  | Zymetx, Inc.   | Qualitative determination of influenza types A and B from throat swab specimens that does not differentiate between types A and B   |
| 87804QW            | Quidel QuickVue® Influenza Test  | Quidel Corporation   | Qualitative detection of influenza type A and type B antigens from nasal swab, nasal wash or nasal aspirate specimens that does not differentiate between influenza types A and B |
| 87804QW            | <ol style="list-style-type: none"> <li>Quidel Quickvue Influenza A+B Test</li> <li>BinaxNOW® Influenza A &amp; B Test in nasopharyngeal (NP) swab and nasal wash/aspirate specimens</li> </ol>   | <p>Quidel Corporation</p> <p>Binax, Inc.</p>   | Qualitative detection of influenza type A and type B antigens from nasal swab, nasal wash or nasal aspirate specimens that does differentiate between influenza types A and B     |
| 87804QW            | <ol style="list-style-type: none"> <li>Binax Now® Flu A Test</li> <li>SA Scientific SAS Influenza A Test</li> </ol>  | <p>Binax, Inc.</p> <p>SA Scientific, Inc.</p>  | Qualitative detection of influenza type A antigen in nasopharyngeal specimens   |

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|--------------------|---|--------------------------------|---|
| 87804QW            | 1. Binax Now® Flu B Test  | Binax, Inc.                    | Qualitative detection of influenza type B antigen in nasopharyngeal specimens   |
|                    | 2. SA Scientific SAS Influenza B Test   | SA Scientific, Inc.            |   |
| 87807QW            | 1. Binax NOW RSV Test (K021687)   | Binax, Inc.                    | Rapid immunoassay for the qualitative detection of respiratory syncytial virus antigen  |
|                    | 2. Binax NOW RSV Test (K032166/A005)  | Binax, Inc.                    |   |
|                    | 3. Fisher Scientific Sure-Vue RSV Test  | SA Scientific, Inc.            |   |
|                    | 4. Integrated Biotechnology Quick Lab RSV Test  | Integrated Biotechnology Corp. |   |
|                    | 5. SA Scientific SAS RSV Alert  | SA Scientific, 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. Acon® Strep A Rapid Strip Test   | Acon Laboratories, Inc.        |   |
|                    | 3. Acon® Strep A Twist Rapid Test   | Acon Laboratories, Inc.        |   |
|                    | 4. Applied Biotech SureStep Strep A (II) (direct from throat swab)                      | Applied Biotech, Inc.          |   |
|                    | 5. Beckman Coulter ICON DS Strep A Test   | Princeton BioMeditech Corp.    |   |
|                    | 6. Beckman Coulter ICON SC Strep A Test   | Acon Laboratories, Inc         |   |
|                    | 7. Beckman Coulter Primary Care Diagnostics ICON DS Strep A                             | Acon Laboratories, Inc.        |   |
|                    | 8. Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test | Beckman Coulter                |   |
|                    | 9. Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab)                 | Applied Biotech, Inc.          |   |

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|---------------------------|---|-----------------------------|---|
| 87880QW (cont.)           | 10. Binax NOW Strep A Test  | Binax                       | 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 |
|                           | 11. BioStar Aceava Strep A Test (direct specimen only)            | Wyntek Diagnostics, Inc.    |   |
|                           | 12. Biotechnostix Rapid Response Strep A Rapid Test Device        | Acon Laboratories Co.       |   |
|                           | 13. Biotechnostix Rapid Response Strep A Rapid Test Strip         | Acon Laboratories Co.       |   |
|                           | 14. Cardinal Health SP Brand Rapid Test Strep A Dipstick          | Applied Biotech Inc.        |   |
|                           | 15. DE Healthcare Products, TruView Strep A Test                  | DE Healthcare Products      |   |
|                           | 16. DE Healthcare Products TruView Strep A Cassette Test          | Acon Laboratories, Inc.     |   |
|                           | 17. Fisher HealthCare Sure-View Strep A (direct from throat swab) | Applied Biotech, Inc.       |   |
|                           | 18. Genzyme Contrast Strep A (direct from throat swab)            | Genzyme Diagnostics         |   |
|                           | 19. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size           | Genzyme Corporation         |   |
|                           | 20. Genzyme OSOM Ultra Strep A Test                               | Genzyme General             |   |
|                           | 21. Germaine Laboratories StrepAim Rapid Dipstick Test            | Germaine Laboratories, Inc. |   |
|                           | 22. Germaine Laboratories Strep AIM Tower                         | Germaine Laboratories, Inc. |   |
|                           | 23. Henry Schein Inc, One Step+ Strep A Test                      | Henry Schein                |   |
|                           | 24. Immunostics Detector Strep A Direct                           | Acon Laboratories, Inc      |   |

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|--------------------|--|------------------------|---|
| 87880QW (cont.)    | 25. Immunostics Immuno/Strep A Detector                                    | Acon Laboratories, Inc | Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever |
|                    | 26. Instant Technologies iStrep Strep A                                    | Acon Laboratories, Inc |   |
|                    | 27. Jant Pharmacal AccuStrip Strep A (II) (direct from throat swab)        | Applied Biotech, Inc.  |   |
|                    | 28. Laboratory Supply Company (LSC) PEP Strep A Cassette Test              | Acon Laboratories Co.  |   |
|                    | 29. LSC PEP Strep A Dipstick Test  | Acon Laboratories Co.  |   |
|                    | 30. LifeSign LLC Status Strep A  | Princeton BioMeditech  |   |
|                    | 31. Mainline Confirms Strep A Dots Test (direct from throat swab)          | Applied Biotech, Inc.  |   |
|                    | 32. McKesson Medi-Lab Performance Strep A Test Dipstick                    | Applied Biotech, Inc.  |   |
|                    | 33. Meridian Diagnostics ImmunoCard STAT Strep A (direct from throat swab) | Applied Biotech, Inc.  |   |
|                    | 34. Polymedco, Inc. Poly stat A (II)                                       | Applied Biotech, Inc.  |   |
|                    | 35. Polymedco Poly Stat Strep A Liquid Test                                | Applied Biotech, Inc   |   |
|                    | 36. QuickVue In-Line One-Step Strep A Test (K934484)                       | Quidel Corporation     |   |
|                    | 37. QuickVue® Dipstick Strep A   | Quidel Corporation     |   |
|                    | 38. Quidel QuickVue® In-Line Strep A                                       | Quidel Corporation     |   |
|                    | 39. RAC Medical Clarity Strep A Rapid Test Strips                          | Acon Laboratories Co.  |   |
|                    | 40. Remel RIM® A.R.C. Strep A Test   | Applied Biotech, Inc.  |   |
|                    | 41. SmithKline ICON Fx Strep A Test (from throat swab only)                | Binax                  |   |

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|---|---|-------------------------------|---|
| 87880QW (cont.)   | 42. Stanbio Laboratory E-Z Well Strep A Rapid Device Test                               | 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 |
|   | 43. Stanbio QuStick Strep A   | Stanbio Laboratory            |   |
|   | 44. Wyntek Diagnostics OSOM Strep A Test  | Wyntek Diagnostics, Inc       |   |
|   | 45. Wyntek OSOM® Ultra Strep A Test   | Wyntek Diagnostics, Inc.      |   |
| 87899QW   | Genzyme OSOM Trichomonas Rapid Test   | Genzyme Corp.                 | Qualitative detection of <i>Trichomonas vaginalis</i> from vaginal swabs  |
| 89300QW(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Embryotech Laboratories FertilMARQ™ Home Diagnostic Screening Test for Male Infertility | Embryotech Laboratories, Inc. | Screening test to measure sperm concentration   |

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