

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 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 |

This list includes updates through 6/17/2004

TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|---|---|---|---|
| 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. ADC CLIA Waived Marijuana (THC) Test | Advantage Diagnostics Corporation (ADC) | Screening test for the presence/detection of cannabinoids (THC) in urine |
| | 2. Phamatech At Home Drug Test (Model 9078) | Phamatech | |
| | 3. Phamatech At Home Drug Test (Model 9078T) | Phamatech | |
| | 4. 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 | |

This list includes updates through 6/17/2004

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

This list includes updates through 6/17/2004

* 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> |
|---|---|--|---|
| 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 1. Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test | ADC | Screening test for the presence/detection of cannabinoids (THC) and cocaine metabolites in urine |
| | 2. ADC CLIA Waived Marijuana (THC) and Cocaine Test | ADC | |
| | 3. Forefront Diagnostics <u>Drugfree@Home</u> THC/COC Test Kit | Forefront Diagnostics, Inc. | |
| | 4. 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.) | 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 |
| | Advantage Diagnostics Corporation ADC Multiple Drug Test Card Alatex Scientific Peace of Mind Multiple Drugs of Abuse Test | Advantage Diagnostics Corporation 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 |
| 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 |

This list includes updates through 6/17/2004

* 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> |
|--------------------|--|---|--|
| 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 | |
| | 3. Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated | Boehringer Mannheim Corporation | |
| | 4. Hypoguard Diascreen® Urine Chemistry Analyzer | Hypoguard USA, Inc. | |
| | 5. Roche Diagnostics Urisys 1100 Urine Analyzer | Roche Diagnostics Corp. | |
| | 6. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer | Roche Diagnostics/Boehringer Mannheim Corporation | |
| | 7. Teco Diagnostics URITEK TC-101 Urine Strip Reader | Teco Diagnostics | |
| | 8. ThermoBiostar™ PocketChem™ UA | ThermoBiostar™ | |

This list includes updates through 6/17/2004

* 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> |
|---|--|--|---|
| 81007QW | Diatech Diagnostics Uriscreeen (for OTC use) | Savyon/USA | Detects catalase in urine which is associated with urinary tract infections (UTIs). White blood cells and some bacteria associated with UTIs are positive for catalase. |
| 82010QW | PTS Bioscanner (for OTC use) - for blood ketones | Polymer Technology Systems, Inc. | Measures ketones in whole blood |
| 82010QW, 82962 | Abbott Laboratories, Medisense Products Precision™ Xtra™ Advanced Diabetes Management System (K983504) Abbott Medisense Precision Xtra Advanced Diabetes Management System (K040814)* | Abbott Laboratories, Inc. Abbott Laboratories, Inc | Monitoring of blood glucose levels and measures ketones in whole blood |
| 82044QW, 82570QW | 1. Bayer Clinitek 50 Urine Chemistry Analyzer - for microalbumin, creatinine 2. Bayer Diagnostics/MICROALBUSTIX™ Reagent Strip | Bayer Corp. Bayer Inc. | Semi-quantitative measurement of microalbumin and creatinine in urine for the detection of patients at risk for developing kidney damage |
| 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 2. OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test 3. STC Diagnostics Q.E.D. A150 Saliva Alcohol Test 4. STC Diagnostics Q.E.D. A350 Saliva Alcohol Test | OraSure Technologies, Inc. OraSure Technologies, Inc. STC Technologies Inc. STC Technologies Inc. | Quantitative determination of alcohol (ethanol) in saliva |
| 82120QW, 83986QW | 1. Litmus Concepts FemExam TestCard (from vaginal swab) | Litmus Concepts, Inc. | Qualitative test of a vaginal fluid sample for elevated pH (pH greater than or equal to 4.7) and the presence of volatile amines |

This list includes updates through 6/17/2004

* 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> |
|--|--|--|---|
| 82120QW, 83986QW (cont.) | 2. Quidel QuickVue Advance pH and Amines Test | Quidel Corporation | Qualitative test of a vaginal fluid sample for elevated pH (pH greater than or equal to 4.7) and the presence of volatile amines |
| 82273QW | 1. Aerscher Hemaprompt FG 2. SmithKline Gastrocult | Aerscher Diagnostics SmithKline | Rapid screening test to detect the presence of gastric occult blood |
| 82273QW, 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. Beckman Coulter Hemocult ICT* 2. Enterix InSure™ Fecal Occult Blood Test 3. Enterix InSure Fecal Immunochemical Test | Beckman Coulter, Inc. Enterix, Inc. Enterix, Inc. | Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay |
| 82465QW (Contact your Medicare carrier for claims instructions.) | 1. Advanced Care 2. Boehringer Mannheim Accu-Chek InstantPlus Cholesterol 3. ChemTrak AccuMeter 4. ENA.C.T Total Cholesterol Test 5. ActiMed Laboratories ENA.C.T. Total Cholesterol Test (PDU) 6. Lifestream Technologies Cholesterol Monitor 7. Lifestream Technologies Personal Cholesterol Monitor | Johnson & Johnson Boehringer Mannheim ChemTrak ActiMed Laboratories, Inc. ActiMed Laboratories, Inc. Lifestream Technologies Lifestream Technologies, Inc. | Cholesterol monitoring |

This list includes updates through 6/17/2004

* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|--|--|----------------------------------|---|
| 82465QW (cont.) (Contact your Medicare carrier for claims instructions.) | 8. Polymer Technology Systems (PTS) MTM Bioscanner 1000 (for OTC use) for cholesterol | Polymer Technology Systems, Inc. | Cholesterol monitoring |
| | 9. PTS Bioscanner Test Strips Cholesterol | Polymer Technology Systems, Inc. | |
| 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW | Polymer Technology Systems CardioChek PA Analyzer {PTS Panels Lipid Panel Test Strips} | Polymer Technology Systems, Inc. | Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood |
| 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW, 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 |
| 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 |

This list includes updates through 6/17/2004

* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|---|--|------------------------|--|
| 82947QW, 82950QW, 82951QW, 82952QW | 1. HemoCue B-Glucose Photometer | HemoCue | Measures glucose levels in whole blood |
| | 2. HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer | HemoCue, Inc. | |
| 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, 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. Applied Biotech, Inc. RU25 Plus FSH Menopause Test | Applied Biotech, Inc. | Detects follicle stimulating hormone in urine |
| | 2. Genua Menopause Monitor Test | Genua 1944 Inc | |
| | 3. Synova Healthcare MenocheckPro (Professional Use)* | Applied Biotech, Inc. | |
| 83036QW | 1. Bayer DCA 2000 – glycosylated hemoglobin (Hgb A1c) | Bayer | 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. Bio-Rad Micromat II Hemoglobin A1c Prescription Home Use Test | Bio-Rad Laboratories | |
| | 4. Cholestech GDX A1C Test (Prescription Home Use) | Cholestech Corporation | |
| | 5. Metrika A1c Now™ - Professional Use (K000887) | Metrika, Inc. | |
| | 6. Metrika A1c Now for Prescription Home Use (K020234) | Metrika, Inc. | |
| | 7. Metrika A1c Now for Professional Use (K020235) | Metrika, Inc. | |

This list includes updates through 6/17/2004

* 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> |
|--------------------|--|---------------------------------------|---|
| 83036QW (cont.) | 8. Metrika DRx® HbA1c (Professional Use Test System) | Metrika, Inc. | Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes |
| | 9. Provalis Diagnostics Glycosal™ HbA1c Test | Provalis Diagnostics Ltd. | |
| 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 |
| 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) |
| 84460QW | Cholestech LDX® Alanine Aminotransferase (ALT) Test | CHOLESTECH Corporation | Quantitative determination of alanine aminotransferase in whole blood |
| 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 |

This list includes updates through 6/17/2004

* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>CPT CODE(S)</u> | <u>TEST NAME</u> | <u>MANUFACTURER</u> | <u>USE</u> |
|--|---|---|--|
| 85018QW | 1. HemoCue Donor Hemoglobin Checker System HemoCue | HemoCue | Measures hemoglobin level in whole blood |
| | 2. HemoCue Hemoglobin System | HemoCue | |
| | 3. HemoCue Hemoglobin 201+/HemoCue Hemoglobin Microcuvette System* | HemoCue | |
| | 4. GDS Diagnostics HemoSite Meter - for hemoglobin | GDS Technology, Inc. | |
| | 5. GDS Technology STAT-Site MHgb Test System | GDS Technology | |
| 85610QW (Contact your Medicare carrier for claims instructions.) | 1. AvoSure PT System (prescription home use) | Avocet Medical, Inc. | Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumadin or warfarin effect; screen for Vitamin K deficiency |
| | 2. AvoSure Pro (professional use) | Avocet Medical, Inc. | |
| | 3. CoaguChek PST for Prothrombin Time | Boehringer Mannheim Corporation | |
| | 4. HemoSense INRatio System | HemoSense, Inc. | |
| | 5. ITC Protime Microcoagulation System for Prothrombin Time | International Technidyne Corporation (ITC) | |
| | 6. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Prescription Home Use | International Technidyne Corporation | |
| | 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/ Boehringer Mannheim Corporation | |

This list includes updates through 6/17/2004

* 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.) | 10. Roche Diagnostics CoaguChek PST | Roche Diagnostics | 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 |
| | 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 | Matritech, Inc. | |
| 86308QW | 1. Applied Biotech SureStep Mono Test (whole blood) | Applied Biotech, Inc. | Qualitative screening test for the presence of heterophile antibodies in human whole blood, which is used as an aid in the diagnosis of infectious mononucleosis |
| | 2. BioStar Aceava Mono Test (whole blood) | Wyntek Diagnostics, Inc. | |
| | 3. Genzyme Contrast Mono (whole blood) | Genzyme Diagnostics | |
| | 4. Genzyme OSOM Mono Test | Wyntek Diagnostics, Inc. | |
| | 5. Jant Accutest Infectious Mononucleosis Test (whole blood) | Applied Biotech, Inc. | |
| | 6. LifeSign UniStep Mono Test (whole blood) | Princeton BioMeditech Corp. | |
| | 7. Meridian ImmunoCard STAT Mono (for whole blood) | Applied Biotech, Inc. | |
| | 8. Polymedco, Inc. Poly stat Mono | Applied Biotech, Inc. | |
| | 9. Quidel Cards O.S. Mono (for whole blood) | Quidel Corporation | |
| | 10. Quidel QuickVue+ Infectious Mononucleosis (Whole Blood) | Quidel Corporation | |

This list includes updates through 6/17/2004

* 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> |
|--------------------|---|------------------------------|--|
| 86308QW (cont.) | 11. Remel RIM® A.R.C. Mono Test | Applied Biotech, Inc. | Qualitative screening test for the presence of heterophile antibodies in human whole blood, which is used as an aid in the diagnosis of infectious mononucleosis |
| | 12. Seradyn Color Q Mono (whole blood) | Genzyme Diagnostics | |
| | 13. Wampole Mono-Plus WB | Wampole Laboratories | |
| | 14. Wyntek Diagnostics OSOM Mono Test (whole blood) | Wyntek Diagnostics, Inc. | |
| | 15. 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 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 <i>H. pylori</i> Rapid Test (for whole blood) | Cortecs Diagnostics Limited | |
| | 7. JANT Pharmacal Corp. H. pylori WBTest | Applied Biotech, Inc. | |
| | 8. LifeSign Status H.pylori (for whole blood) | Princeton BioMeditech | |
| | 9. Meridian BioScience ImmunoCard STAT! <i>H.pylori</i> Whole Blood Test | Applied Biotech, Inc. | |
| | 10. Polymedco, Inc. Poly stat H.pylori | Applied Biotech, Inc. | |
| | 11. QuickVue One-Step H. Pylori Test for Whole Blood | Quidel | |
| | 12. Quidel QuickVue One-Step H.pylori II Test. | Quidel Corporation | |

This list includes updates through 6/17/2004

* 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> |
|--------------------|--|-----------------------------------|--|
| 86318QW (cont.) | 13. Remel RIM® A.R.C. H.pylori Test | Remel | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood |
| | 14. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood | SmithKline Diagnostics, Inc. | |
| | 15. Trinity Uni-Gold™ H.pylori | Trinity BioTech | |
| 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) in fingerstick whole blood specimens |
| | 2. OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood | OraSure Technologies, Inc. | Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) in fingerstick 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. Medical Instruments Corporation Pronto Dry <i>H. pylori</i> | Medical Instruments Corporation | |
| | 6. 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. | |
| 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 |

This list includes updates through 6/17/2004

* 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> |
|--------------------|---|--------------------------|---|
| 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 | Binax Now® Flu A Test | Binax, Inc. | Qualitative detection of influenza type A antigen in nasal wash and nasopharyngeal swab specimens |
| 87804QW | Binax Now® Flu B Test | Binax, Inc. | Qualitative detection of influenza type B antigen in nasal wash and nasopharyngeal swab specimens |
| 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 Primary Care Diagnostics ICON DS Strep A | Acon Laboratories, Inc. | |
| | 6. Beckman Coulter ICON SC Strep A Test | Acon Laboratories, Inc | |
| | 7. Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test | Beckman Coulter | |
| | 8. Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab) | Applied Biotech, Inc. | |
| | 9. Binax NOW Strep A Test | Binax | |
| | 10. BioStar Aceeava Strep A Test (direct specimen only) | Wyntek Diagnostics, Inc. | |
| | 11. DE Healthcare Products, TruView Strep A Test | DE Healthcare Products | |
| | 12. Fisher HealthCare Sure-Vue Strep A (direct from throat swab) | Applied Biotech, Inc. | |
| | 13. Genzyme Contrast Strep A (direct from throat swab) | Genzyme Diagnostics | |

This list includes updates through 6/17/2004

* 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> |
|--------------------|--|-----------------------------|---|
| 87880QW (cont.) | 14. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size | Genzyme Corporation | 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 |
| | 15. Germaine Laboratories StrepAim Rapid Dipstick Test | Germaine Laboratories, Inc. | |
| | 16. Germaine Laboratories Strep AIM Tower | Germaine Laboratories, Inc. | |
| | 17. Henry Schein Inc, One Step+ Strep A Test | Henry Schein | |
| | 18. Immunostics Immuno/Strep A Detector | Acon Laboratories, Inc | |
| | 19. Instant Technologies iStrep Strep A | Acon Laboratories, Inc | |
| | 20. Jant Pharmacal AccuStrip Strep A (II) (direct from throat swab) | Applied Biotech, Inc. | |
| | 21. LifeSign LLC Status Strep A | Princeton BioMeditech | |
| | 22. Mainline Confirms Strep A Dots Test (direct from throat swab) | Applied Biotech, Inc. | |
| | 23. Meridian Diagnostics ImmunoCard STAT Strep A (direct from throat swab) | Applied Biotech, Inc. | |
| | 24. Polymedco, Inc. Poly stat A (II) | Applied Biotech, Inc. | |
| | 25. QuickVue In-Line One-Step Strep A Test (K934484) | Quidel Corporation | |
| | 26. QuickVue® Dipstick Strep A | Quidel Corporation | |
| | 27. Quidel QuickVue® In-Line Strep A | Quidel Corporation | |
| | 28. Remel RIM® A.R.C. Strep A Test | Applied Biotech, Inc. | |
| | 29. SmithKline ICON Fx Strep A Test (from throat swab only) | Binax | |
| | 30. Stanbio QuStick Strep A | Stanbio Laboratory | |

This list includes updates through 6/17/2004

* 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> |
|---|---|--------------------------------|---|
| 87880QW (cont.) | 31. Wyntek Diagnostics OSOM Strep A Test | 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 |
| | 32. Wyntek OSOM® Ultra Strep A Test | Wyntek Diagnostics, Inc. | |
| 87899QW | 1. Binax NOW RSV Test | Binax | Rapid immunoassay of the qualitative detection of respiratory syncytial virus antigen |
| | 2. Integrated Biotechnology Quick Lab RSV Test | Integrated Biotechnology Corp. | |
| 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 |

This list includes updates through 6/17/2004

* Newly added waived test system