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# Program Memorandum Intermediaries/Carriers

Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

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Transmittal AB-02-070

Date: MAY 10, 2002

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## CHANGE REQUEST 2163

**SUBJECT: New Waived Tests – April 12, 2002**

Listed below are the latest tests approved by the Food and Drug Administration as waived tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The Current Procedural Terminology (CPT) codes for these new tests must have the modifier QW to be recognized as a waived test. Contractors must include these new tests in their CLIA-covered code files with the QW modifier. The Common Working File system will be updated promptly when the new codes are received in central office. The complete list of waived tests is attached.

Forefront Diagnostics Drugfree@Home THC/COC Test Kit, Effective July 27, 2001, CPT code: 80101QW; and

GDS Technology STAT-Site M<sub>Hgb</sub> Test System, Effective: February 11, 2002, CPT code: 85018QW

The information in the "Use" column explains the purpose of the waived test. If denial is appropriate, this explanation is unacceptable to use as the reason for the denial of a claim. Use the appropriate remittance advice message that describes why the test was denied.

**The *effective date* of this Program Memorandum (PM) is April 12, 2002.**

**The *implementation date* of this PM is July 1, 2002.**

**Carriers need not search their files to either retract payment or retroactively pay claims, however, carriers should adjust claims if they are brought to their attention.**

**These instructions should be implemented within your current operating budget.**

**This PM may be discarded July 31, 2003.**

**The contact person for this PM is Kathy Todd at (410) 786-3385.**

Attachment



## TESTS GRANTED WAIVED STATUS UNDER CLIA

| <u>TEST NAME</u>   | <u>MANUFACTURER</u> | <u>CPT CODE(S)</u>   | <u>USE</u>   |
|--|---------------------|--|--|
| Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen | Various             | 81002  | Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections |
| Fecal occult blood   | Various             | 82270<br>G0107 (contact your Medicare carrier for claims instructions) | Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening)   |
| Ovulation tests by visual color comparison for human luteinizing hormone   | Various             | 84830  | Detection of ovulation (optimal for conception)  |
| Urine pregnancy tests by visual color comparison   | Various             | 81025  | Diagnosis of pregnancy   |
| Erythrocyte sedimentation rate – non-automated   | Various             | 85651  | Nonspecific screening test for inflammatory activity, increased for majority of infections, and most cases of carcinoma and leukemia                         |
| Hemoglobin by copper sulfate – non-automated   | Various             | 83026  | Monitors hemoglobin level in blood   |
| Blood glucose by glucose monitoring devices cleared by the FDA for home use  | Various             | 82962  | Monitoring of blood glucose levels   |
| Blood count; spun microhematocrit  | Various             | 85013  | Screen for anemia  |

**This list includes updates through 4/12/2002**

**TESTS GRANTED WAIVED STATUS UNDER CLIA**

| <b><u>TEST NAME</u></b>   | <b><u>MANUFACTURER</u></b> | <b><u>CPT CODE(S)</u></b>   | <b><u>USE</u></b>   |
|---|----------------------------|---|---|
| Hemoglobin by single instrument with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout | HemoCue                    | 85018QW   | Monitors hemoglobin level in blood  |
| HemoCue B-Glucose Photometer  | HemoCue                    | 82947QW, 82950QW, 82951QW, 82952QW                                      | Diagnosis and monitoring of blood glucose levels (HCPCS codes G0055, G0056, and G0057 should be discontinued for this test 9/30/96)   |
| ChemTrak AccuMeter  | ChemTrak                   | 82465QW   | Cholesterol monitoring  |
| Advanced Care   | Johnson & Johnson          | 82465QW   | Cholesterol monitoring  |
| Boehringer Mannheim Chemstrip Micral  | Boehringer Mannheim        | 82044QW   | Monitors low concentrations of albumin in urine, which is helpful for early detection in patients at risk for renal disease   |
| Cholestech LDX  | Cholestech                 | 82465QW, 83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW, 80061QW, | Measures total cholesterol, HDL cholesterol, triglycerides, and glucose levels in whole blood   |
| Serim Pyloritek Test Kit  | Serim                      | 87077QW   | Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)  |
| QuickVue In-Line One-Step Strep A Test  | Quidel                     | 87880QW   | Rapidly detects Group A streptococcal (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 |
| Boehringer Mannheim Accu-Chek InstantPlus Cholesterol   | Boehringer Mannheim        | 82465QW   | Cholesterol monitoring  |

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| <u>TEST NAME</u>   | <u>MANUFACTURER</u>               | <u>CPT CODE(S)</u> | <u>USE</u>  |
|--|-----------------------------------|--------------------|---|
| All qualitative color comparison pH testing - body fluids (other than blood)           | Various                           | 83986QW            | pH detection (acid-base balance) in body fluids such as semen, amniotic fluid, and gastric aspirates  |
| SmithKline Gastroccult   | SmithKline                        | 82273QW            | Rapid screening test to detect the presence of gastric occult blood   |
| QuickVue One-Step H. Pylori Test for Whole Blood                                       | Quidel                            | 86318QW            | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood  |
| Binax NOW Strep A Test   | Binax                             | 87880QW            | 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 |
| Delta West CLOtest   | Delta West<br>Tri-Med Specialties | 87077QW            | Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)                      |
| Wampole STAT-CRIT Hct  | Wampole Laboratories              | 85014QW            | Screen for anemia   |
| SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood | SmithKline Diagnostics, Inc.      | 86318QW            | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood  |
| Wyntek Diagnostics OSOM Strep A Test   | Wyntek Diagnostics, Inc           | 87880QW            | 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 |
| GI Supply HP-FAST  | Mycoscience Labs, Inc.            | 87077QW            | Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)                      |
| Abbott FlexPak HP Test for whole blood   | SmithKline Diagnostics, Inc.      | 86318QW            | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood  |
| Chemtrak AccuMeter H. pylori Test (for whole blood)                                    | ChemTrak                          | Pending            | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood  |

**This list includes updates through 4/12/2002**

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| <b><u>TEST NAME</u></b>   | <b><u>MANUFACTURER</u></b>                 | <b><u>CPT CODE(S)</u></b>                                       | <b><u>USE</u></b>  |
|---|--|---|--|
| BioStar Aceveva Strep A Test (direct specimen only)   | Wyntek Diagnostics, Inc.                   | 87880QW   | 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                            |
| LXN Fructosamine Test System  | LXN Corporation                            | 82985QW   | Used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period. Not a useful test for screening diabetes mellitus.  |
| ITC Protime Microcoagulation System for Prothrombin Time  | International Technidyne Corporation (ITC) | 85610QW (contact your Medicare carrier for claims instructions) | Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumarin or warfarin effect; screen for Vitamin K deficiency |
| CoaguChek PST for Prothrombin Time  | Boehringer Mannheim Corporation            | 85610QW (contact your Medicare carrier for claims instructions) | Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumarin or warfarin effect; screen for Vitamin K deficiency |
| SmithKline ICON Fx Strep A Test (from throat swab only)   | Binax                                      | 87880QW   | 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                            |
| Abbott Signify Strep A Test (from throat swab only)   | Wyntek Diagnostics, Inc.                   | 87880QW   | 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                            |
| Bayer Clinitek 50 Urine Chemistry Analyzer – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes - automated | Bayer                                      | 81003QW   | Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections                                       |
| Bayer DCA 2000 – glycosylated hemoglobin (Hgb A1c)  | Bayer                                      | 83036QW   | Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes  |
| Wampole Mono-Plus WB  | Wampole Laboratories                       | 86308QW   | 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                                   |

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| <u>TEST NAME</u>   | <u>MANUFACTURER</u>           | <u>CPT CODE(S)</u>   | <u>USE</u>  |
|--|-------------------------------|--|---|
| LXN Duet Glucose Control Monitoring System                               | LXN Corporation               | 82962,<br>82985QW  | Monitoring of blood glucose levels and measures fructosamine, which is used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period            |
| ENA.C.T Total Cholesterol Test   | ActiMed Laboratories, Inc.    | 82465QW  | Cholesterol monitoring  |
| Genzyme Contrast Mono (whole blood)                                      | Genzyme Diagnostics           | 86308QW  | 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        |
| Applied Biotech SureStep Strep A (II) (direct from throat swab)          | Applied Biotech, Inc.         | 87880QW  | 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 |
| STC Diagnostics Q.E.D. A150 Saliva Alcohol Test                          | STC Technologies Inc.         | 82055QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Quantitative determination of alcohol (ethanol) in saliva   |
| STC Diagnostics Q.E.D. A350 Saliva Alcohol Test                          | STC Technologies Inc.         | 82055QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Quantitative determination of alcohol (ethanol) in saliva   |
| Micro Diagnostics Spuncrit Model DRC-40 Infrared Analyzer for hematocrit | Micro Diagnostics Corporation | Pending  | Screen for anemia   |

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| <u>TEST NAME</u>   | <u>MANUFACTURER</u>             | <u>CPT CODE(S)</u> | <u>USE</u>  |
|--|---------------------------------|--------------------|---|
| Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated | Boehringer Mannheim Corporation | 81003QW            | Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections            |
| Litmus Concepts FemExam TestCard (from vaginal swab)   | Litmus Concepts, Inc.           | 82120QW<br>83986QW | Qualitative test of a vaginal fluid sample for elevated pH (pH greater than or equal to 4.7) and the presence of volatile amines  |
| Wyntek Diagnostics OSOM Mono Test (whole blood)  | Wyntek Diagnostics, Inc.        | 86308QW            | 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        |
| Meridian Diagnostics ImmunoCard STAT Strep A (direct from throat swab)   | Applied Biotech, Inc.           | 87880QW            | 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 |
| Seradyn Color Q Mono (whole blood)   | Genzyme Diagnostics             | 86308QW            | 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        |
| Jant Pharmacal AccuStrip Strep A (II) (direct from throat swab)  | Applied Biotech, Inc.           | 87880QW            | 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 |
| BioStar Acceava Mono Test (whole blood)  | Wyntek Diagnostics, Inc.        | 86308QW            | 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        |
| LifeSign UniStep Mono Test (whole blood)   | Princeton BioMeditech Corp.     | 86308QW            | 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        |
| Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab)   | Applied Biotech, Inc.           | 87880QW            | Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever |

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|---|---|---|--|
| DynaGen NicCheck I Test Strips  | Dynagen, Inc.   | 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | 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 |
| Mainline Confirms Strep A Dots Test (direct from throat swab)             | Applied Biotech, Inc.                                 | 87880QW   | 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  |
| Quidel Cards O.S. Mono (for whole blood)                                  | Quidel Corporation                                    | 86308QW   | 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   |
| Bayer Clinitek 50 Urine Chemistry Analyzer - for HCG, urine               | Bayer Corp  | 84703QW   | Diagnosis of pregnancy   |
| Bayer Clinitek 50 Urine Chemistry Analyzer - for microalbumin, creatinine | Bayer Corp.   | 82044QW<br>82570QW  | Detection of patients at risk for developing kidney damage   |
| Bayer DCA 2000+ - glycosylated hemoglobin (Hgb A1c)                       | Bayer Corp.   | 83036QW   | Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes  |
| GDS Diagnostics HemoSite Meter - for hemoglobin                           | GDS Technology, Inc.                                  | 85018QW   | Measures hemoglobin level in whole blood   |
| ActiMed Laboratories ENA.C.T. Total Cholesterol Test (PDU)                | ActiMed Laboratories, Inc.                            | 82465QW (Contact your Medicare carrier for claims instructions)   | Cholesterol monitoring   |
| Genzyme Contrast Strep A (direct from throat swab)                        | Genzyme Diagnostics                                   | 87880QW   | 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  |
| Roche/Boehringer Mannheim CoaguChek System for Professional Use           | Roche Diagnostics/<br>Boehringer Mannheim Corporation | 85610QW (contact your Medicare carrier for claims instructions)   | Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumarin or warfarin effect; screen for Vitamin K deficiency             |

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| <u>TEST NAME</u>  | <u>MANUFACTURER</u>                               | <u>CPT CODE(S)</u>  | <u>USE</u>   |
|---|---|---|--|
| Applied Biotech SureStep Mono Test (whole blood)                      | Applied Biotech, Inc.                             | 86308QW   | 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                                 |
| Becton Dickinson Link 2 <i>H. pylori</i> Rapid Test (for whole blood) | Cortecs Diagnostics Limited                       | 86318QW   | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood   |
| Bion Diagnostic Sciences BTA stat Test (for home use)                 | Bion Diagnostic Sciences, Inc.                    | 86294QW   | 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 |
| Diatech Diagnostics Uriscreen (for OTC use)                           | Savyon/USA  | 81007QW   | 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.                          |
| Lifestream Technologies Cholesterol Monitor                           | Lifestream Technologies                           | 82465QW (Contact your Medicare carrier for claims instructions) | Cholesterol monitoring   |
| Abbott TestPack Plus <i>H. pylori</i> (for whole blood)               | Abbott Laboratories                               | 86318QW   | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood   |
| Jant Accutest Infectious Mononucleosis Test (whole blood)             | Applied Biotech, Inc.                             | 86308QW   | 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                                 |
| Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer    | Roche Diagnostics/Boehringer Mannheim Corporation | 81003QW   | Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections                                     |
| LXN IN CHARGE Diabetes Control System                                 | LXN Corporation                                   | 82962,<br>82985QW   | Monitoring of blood glucose levels and measures fructosamine, which is used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period                                     |
| Fisher HealthCare Sure-Vue Strep A (direct from throat swab)          | Applied Biotech, Inc.                             | 87880QW   | Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever                          |

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|--|----------------------------------|---|--|
| Meridian ImmunoCard STAT Mono (for whole blood)                                    | Applied Biotech, Inc.            | 86308QW   | 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                                   |
| Applied Biotech SureStep H. pylori WB Test (whole blood)                           | Applied Biotech, Inc.            | 86318QW   | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood   |
| Roche Diagnostics Chemstrip Micral (urine dipstick)                                | Roche Diagnostics Corporation    | 82044QW   | Monitors low concentrations of albumin in urine, which is helpful for early detection in patients at risk for renal disease  |
| Quidel QuickVue One-Step H.pylori II Test.   | Quidel Corporation               | 86318QW   | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood   |
| Ballard Medical Products CLOtest   | Ballard Medical Products         | 87077QW   | Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)   |
| AvoSure PT System (prescription home use)  | Avocet Medical, Inc.             | 85610QW (contact your Medicare carrier for claims instructions) | Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumarin or warfarin effect; screen for Vitamin K deficiency |
| AvoSure Pro (professional use)   | Avocet Medical, Inc.             | 85610QW (contact your Medicare carrier for claims instructions) | Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumarin or warfarin effect; screen for Vitamin K deficiency |
| Remel RIM? A.R.C. Mono Test  | Applied Biotech, Inc.            | 86308QW   | 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                                   |
| Remel RIM? A.R.C. Strep A Test   | Applied Biotech, Inc.            | 87880QW   | 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                            |
| JANT Pharmacal Corp. H. pylori WBTest  | Applied Biotech, Inc.            | 86318QW   | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood   |
| Polymer Technology Systems (PTS) MTM Bioscanner 1000 (for OTC use) for cholesterol | Polymer Technology Systems, Inc. | 82465QW   | Cholesterol monitoring   |

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|--|----------------------------------|--|---|
| PTS Bioscanner (for OTC use) - for HDL cholesterol | Polymer Technology Systems, Inc. | 83718QW  | Measures HDL cholesterol in whole blood                                   |
| PTS Bioscanner (for OTC use) - for blood ketones   | Polymer Technology Systems, Inc. | 82010QW  | Measures ketones in whole blood   |
| Phamatech At Home Drug Test (Model 9063)           | Phamatech                        | 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Screening test for the presence/detection of amphetamine in urine         |
| Phamatech At Home Drug Test (Model 9068)           | Phamatech                        | 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Screening test for the presence/detection of methamphetamines in urine    |
| Phamatech At Home Drug Test (Model 9073)           | Phamatech                        | 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Screening test for the presence/detection of cocaine metabolites in urine |
| Phamatech At Home Drug Test (Model 9078)           | Phamatech                        | 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Screening test for the presence/detection of cannabinoids (THC) in urine  |
| Phamatech At Home Drug Test (Model 9083)           | Phamatech                        | 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Screening test for the presence/detection of opiates in urine             |

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|--|----------------------------------|--|---|
| Phamatech At Home Drug Test (Model 9133)   | Phamatech                        | 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Screening test for the presence/detection of phencyclidine in urine   |
| LifeSign Status H.pylori (for whole blood)   | Princeton BioMeditech            | 86318QW  | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood  |
| Abbott Laboratories, Medisense Products Precision? Xtra? Advanced Diabetes Management System | Abbott Laboratories, Inc.        | 82962<br>82010QW   | Monitoring of blood glucose levels and measures ketones in whole blood  |
| PTS Bioscanner Test Strips Chloesterol   | Polymer Technology Systems, Inc. | 82465QW  | Cholesterol monitoring  |
| Remel RIM? A.R.C. H.pylori Test  | Remel                            | 86318QW  | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood  |
| LifeSign LLC Status Strep A  | Princeton BioMeditech            | 87880QW  | 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 |
| PTS, Inc. Bioscanner 2000 for Triglycerides  | Polymer Technology Systems, Inc. | 84478QW  | Measures triglycerides in whole blood   |
| Polymedco, Inc. Poly stat H.pylori   | Applied Biotech, Inc.            | 86318QW  | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood  |
| Polymedco, Inc. Poly stat Mono   | Applied Biotech, Inc.            | 86308QW  | 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        |
| Polymedco, Inc. Poly stat A (II)   | Applied Biotech, Inc.            | 87880QW  | 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 |
| Trinity Uni-Gold™ H.pylori   | Trinity BioTech                  | 86318QW  | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood  |

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| <b><u>TEST NAME</u></b>  | <b><u>MANUFACTURER</u></b>    | <b><u>CPT CODE(S)</u></b>   | <b><u>USE</u></b>  |
|--|-------------------------------|---|--|
| Lifestream Technologies Personal Cholesterol Monitor                                 | Lifestream Technologies, Inc. | 82465QW   | Cholesterol monitoring   |
| Teco Diagnostics URITEK TC-101 Urine Strip Reader                                    | Teco Diagnostics              | 81003QW   | Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections                                       |
| Quidel QuickVue® Influenza Test  | Quidel Corporation            | 87804QW   | 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                  |
| Clearplan Easy Fertility Monitor (for luteinizing hormone and estrone 3 glucuronide) | Unipath Limited               | 83002QW<br>82679QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Detection of luteinizing hormone and estrone 3 glucuronide in urine to identify the optimal time for conception  |
| Metrika DRx® HbA1c (Professional Use Test System)                                    | Metrika, Inc.                 | 83036QW   | Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes  |
| ZymeTx Zstatflu® Test  | Zymetx, Inc.                  | 87449QW   | Qualitative determination of influenza types A and B from throat swab specimens that does not differentiate between types A and B  |
| 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)            | Screening test for the presence/detection of cannabinoids (THC) in urine   |
| 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)            | Screening test for the presence/detection of cannabinoids (THC) and cocaine metabolites in urine   |
| Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time)                   | Roche Diagnostics Corporation | 85610QW (contact your Medicare carrier for claims instructions)   | Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumarin or warfarin effect; screen for Vitamin K deficiency |
| Wyntek Signify Mono Test   | Wyntek Diagnostics, Inc.      | 86308QW   | 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                                   |

**This list includes updates through 4/12/2002**

## TESTS GRANTED WAIVED STATUS UNDER CLIA

| <b><u>TEST NAME</u></b>  | <b><u>MANUFACTURER</u></b>    | <b><u>CPT CODE(S)</u></b>   | <b><u>USE</u></b>   |
|--|-------------------------------|---|---|
| Worldwide Medical Corporation, First Check® Home Drug Test Panel 4 (THC-COC-OPI-MET) | Worldwide Medical Corporation | 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions)  | Screening test for the presence/detection of cannabinoids (THC), cocaine metabolites, opiates and methamphetamines in urine   |
| OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test                                | OraSure Technologies, Inc.    | 82055QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Quantitative determination of alcohol (ethanol) in saliva   |
| OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test                                | OraSure Technologies, Inc.    | 82055QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) | Quantitative determination of alcohol (ethanol) in saliva   |
| Genua Menopause Monitor Test, Bayer  | Genua 1944 Inc.               | 83001QW   | Detects follicle stimulating hormone in urine   |
| Diagnosics/MICROALBUSTIX™ Reagent Strip  | Bayer Inc.                    | 82044QW<br>82570QW  | Semi-quantitative measurement of microalbumin and creatinine in urine for the detection of patients at risk for developing kidney damage                                |
| Cholestech LDX® Alanine Aminotransferase (ALT) Test                                  | CHOLESTECH Corporation        | 84460QW   | Quantitative determination of alanine aminotransferase in whole blood   |
| Wyntek OSOM® Ultra Strep A Test  | Wyntek Diagnostics, Inc.      | 87880QW   | 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 |
| Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test | Beckman Coulter               | 87880QW   | 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 |
| Phamatech At Home Drug Test (Model 9073T)  | Phamatech                     | 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions)  | Screening test for the presence/detection of cocaine metabolite in urine  |

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|--|-----------------------|--|--|
| Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to H. Pylori in Whole Blood | Beckman Coulter, Inc. | 86318QW  | Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood   |
| Wampole PreVue™ <i>B. burgdorferi</i> Antibody Detection Assay   | Wampole Laboratories  | 86618QW  | Qualitative detection of IgG/IgM antibodies to <i>Borrelia burgdorferi</i> (causative agent of Lyme disease) in whole blood  |
| Phamatech At Home Drug Test (Model 9150T)  | Phamatech             | 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Screening test for the presence/detection of amphetamines, cannabinoids (THC), cocaine metabolites, methamphetamines, and opiates in urine   |
| Phamatech At Home Drug Test (Model 9078T)  | Phamatech             | 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Screening test for the presence/detection of cannabinoids (THC) in urine   |
| KDK Corporation Lactate Pro System   | KDK Corporation       | 83605QW  | Quantitative measurement of lactate in whole blood   |
| QuickVue® Dipstick Strep A   | Quidel Corporation    | 87880QW  | 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  |
| Bayer Multistick Pro 10LS Reagent Strips   | Bayer Diagnostics     | 81002<br>82570QW   | 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 |
| Bayer Multistick Pro 11 Reagent Strips   | Bayer Diagnostics     | 81002<br>82570QW   | 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 |
| Bayer Multistick Pro 7G Reagent Strips   | Bayer Diagnostics     | 81002<br>82570QW   | 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 |

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| <u>TEST NAME</u>   | <u>MANUFACTURER</u>                  | <u>CPT CODE(S)</u>   | <u>USE</u>   |
|--|--------------------------------------|--|--|
| Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test                         | Advantage Diagnostics Corporation    | 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Screening test for the presence/detection of cannabinoids (THC) and cocaine metabolites in urine   |
| Beckman Coulter Primary Care Diagnostics Gastrocult®   | Beckman Coulter, Inc.                | 82273QW<br>83986QW   | Rapid screening test to detect the presence of gastric occult blood and determine the pH (acid-base balance) of gastric aspirates  |
| Medical Instruments Corporation Pronto Dry <i>H. pylori</i>  | Medical Instruments Corporation      | 87077QW  | Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)   |
| International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Prescription Home Use | International Technidyne Corporation | 85610QW (contact your Medicare carrier for claims instructions)  | Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumarin or warfarin effect; screen for Vitamin K deficiency |
| International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Professional Use      | International Technidyne Corporation | 85610QW (contact your Medicare carrier for claims instructions)  | Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumarin or warfarin effect; screen for Vitamin K deficiency |
| Ostex International Osteomark NTX Point of Care Prescription Home Use                              | Ostex International Inc.             | 82523QW  | Measures normalized cross-linked N-telopeptides of type 1 collagen in urine  |
| Embryotech Laboratories FertilMARQ™ Home Diagnostic Screening Test for Male Infertility            | Embryotech Laboratories, Inc.        | 89300QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Screening test to measure sperm concentration.   |
| Metrika A1c Now™ -Professional Use   | Metrika, Inc.                        | 83036QW  | Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes  |
| Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick)                            | Diagnostic Chemicals Limited (USA)   | 82044QW  | Semi-quantitative measurement of microalbumin in urine for the detection of patients at risk for developing kidney damage  |
| FemTek pHEM-ALERT®   | FemTek, LLC                          | 83986QW  | Vaginal pH detection (acid-base balance)   |
| Provalis Diagnostics Glycosal™ HbA1c Test  | Provalis Diagnostics Ltd.            | 83036QW  | 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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| <b><u>TEST NAME</u></b>                                  | <b><u>MANUFACTURER</u></b>  | <b><u>CPT CODE(S)</u></b>  | <b><u>USE</u></b>   |
|--|-----------------------------|--|---|
| Quidel QuickVue+ Infectious Mononucleosis (Whole Blood)  | Quidel Corporation          | 86308QW  | 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        |
| Acon® Strep A Rapid Strip Test                           | Acon Laboratories, Inc.     | 87880QW  | 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 |
| Beckman Coulter Primary Care Diagnostics ICON DS Strep A | Acon Laboratories, Inc.     | 87880QW  | 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 |
| * Forefront Diagnostics Drugfree@Home THC/COC Test Kit   | Forefront Diagnostics, Inc. | 80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) | Screening test for the presence/detection of cannabinoids (THC) and cocaine metabolites in urine  |
| *GDS Technology STAT-Site M <sub>Hgb</sub> Test System   | GDS Technology              | 85018QW  | Monitors hemoglobin level in blood  |

\* Newly added waived test system