
Program Memorandum Intermediaries/Carriers

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

Transmittal AB-02-091

Date: JULY 2, 2002

CHANGE REQUEST 2263

SUBJECT: New Waived Tests – June 17, 2002

Listed below are the latest tests approved by the Food and Drug Administration as a waived tests under the Clinical Laboratory Improvement Amendments (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.

Enterix InSure™ Fecal Occult Blood Test, Effective: January 1, 2002, CPT code: 82274QW;

Alatex Scientific Peace of Mind Multiple Drugs of Abuse Test, Effective: February 21, 2002, CPT code: 80101QW;

Metrika A1c Now for Prescription Home Use (K020234), Effective: March 8, 2002, CPT code: 83036QW; and

Metrika A1c Now for Professional Use (K020235), Effective: March 8, 2002, CPT code: 83036QW.

The CPT code for the Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick) has been changed to from 82044QW to 83518QW, Effective: June 3, 2002. Effective June 17, 2002, the CPT codes for the Boehringer Mannheim Chemstrip Micral and the Roche Diagnostics Chemstrip Micral (urine dipstick) have also been changed from 82044QW to 83518QW since both tests use methodologies that are similar to the Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick).

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 June 17, 2002.

The *implementation date* of this PM is October 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 October 31, 2003.

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

Attachment

CMS-Pub. 60AB

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 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 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
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	83518QW	Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing 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 (K934484)	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

This list includes updates through 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<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 Gastrocult	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 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 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
BioStar Aceava 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

This list includes updates through 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
LXN Duet Glucose Control Monitoring System	LXN Corporation	82962, 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

This list includes updates through 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<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 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 Pharmcal 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

This list includes updates through 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
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 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/ 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

This list includes updates through 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<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, 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

This list includes updates through 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
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	83518QW	Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing 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 RIM7 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 RIM7 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

This list includes updates through 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
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

This list includes updates through 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
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 Precision9 Xtra9 Advanced Diabetes Management System	Abbott Laboratories, Inc.	82962 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 RIM7 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

This list includes updates through 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
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 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 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
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 Diagnostics/MICROALBUSTIX™ Reagent Strip	Genua 1944 Inc. Bayer Inc.	83001QW 82044QW 82570QW	Detects follicle stimulating hormone in urine 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

This list includes updates through 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
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 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 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 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

This list includes updates through 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<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 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 (K000887)	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)	83518QW	Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease
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

This list includes updates through 6/17/2002

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
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 MHgb Test System	GDS Technology	85018QW	Monitors hemoglobin level in blood
*Enterix InSure™ Fecal Occult Blood Test	Enterix, Inc.	82274QW	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
*Alatex Scientific Peace of Mind Multiple Drugs of Abuse Test	Advantage Diagnostics Corporation, Ltd.	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, methamphetamines, morphine, and phencyclidine (PCP) in urine
*Metrika A1c Now for Prescription Home Use (K020234)	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
*Metrika A1c Now for Professional Use (K020235)	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

* Newly added waived test system

This list includes updates through 6/17/2002