
Program Memorandum Intermediaries/Carriers

Department of Health and
Human Services (DHHS)
HEALTH CARE FINANCING
ADMINISTRATION (HCFA)

Transmittal AB-00-105

Date: NOVEMBER 9, 2000

CHANGE REQUEST 1339

SUBJECT: New Waived Tests -- November 9, 2000

Listed below are the latest tests approved by the Center for Disease Control as 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 also attached.

LifeSign Status H.pylori (for whole blood), Effective: October 5, 1999;

Abbott Laboratories Medisense Products Precision™ Xtra™ Advanced Diabetes Management System, Effective: February 28, 2000;

Polymer Technology Systems (PTS) Bioscanner Test Strips Cholesterol, Effective: April 3, 2000;

Remel RIM® A.R.C. H. pylori Test, Effective: May 16, 2000;

LifeSign LLC Status StrepA, Effective: May 17, 2000; and

PTS, Inc. Bioscanner 2000 for Triglycerides, Effective: July 6, 2000.

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

The *effective date* of this Program Memorandum (PM) is September 15, 2000.

The *implementation date* of this PM is January 1, 2001.

Contact Person: Kathy Todd on (410) 786-3385.

Contractors need not search their files to either retract payment or retroactively pay claims; however, contractors 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 January 1, 2002.

Attachment

HCFA-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 8/24/2000

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 (effective 10/1/96)	Monitors hemoglobin level in blood (HCPCS code Q0116 should be discontinued for this test 9/30/96)
HemoCue B-Glucose Photometer	HemoCue	82947QW, 82950QW, 82951QW, 82952QW (effective 10/1/96)	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 (Contact your Medicare carrier for claims instructions)	Cholesterol monitoring
Advanced Care	Johnson & Johnson	82465QW (Contact your Medicare carrier for claims instructions)	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 (Contact your Medicare carrier for claims instructions), 83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW, 80061QW,	Measures total cholesterol, HDL cholesterol, triglycerides, and glucose levels in whole blood
Serim Pyloritek Test Kit	Serim	87072QW	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

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<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
Boehringer Mannheim Accu-Chek InstantPlus Cholesterol	Boehringer Mannheim	82465QW (Contact your Medicare carrier for claims instructions)	Cholesterol monitoring
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	87072QW	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.	87072QW	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

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

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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
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 (Contact your Medicare carrier for claims instructions)	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 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	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

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<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
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
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.	83518QW	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

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<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
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
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	87072QW	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

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<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
Polymer Technology Systems (PTS) MTM Bioscanner 1000 (for OTC use) for cholesterol	Polymer Technology Systems, Inc.	82465QW (Contact your Medicare carrier for claims instructions)	Cholesterol monitoring
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)	Pharmatech	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)	Pharmatech	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)	Pharmatech	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)	Pharmatech	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

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<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>CPT CODE(S)</u>	<u>USE</u>
Phamatech At Home Drug Test (Model 9083)	Pharmatech	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
Phamatech At Home Drug Test (Model 9133)	Pharmatech	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 82010QW	Monitoring of blood glucose levels and measures ketones in whole blood
*PTS Bioscanner Test Strips Chloesterol	Polymer Technology Systems, Inc.	82465QW (Contact your Medicare carrier for claims instructions)	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
* Newly added waived test system			