



# College of American Pathologists

## CLIA List of Waived Tests

Updated January 16, 2007

### **Hematology**

#### *Erythrocyte Sedimentation Rate*

- Erythrocyte sedimentation rate (non-automated)
- Becton Dickinson SedItainer ESR System

#### *Hematocrit*

- All spun microhematocrit procedures
- Micro Diagnostics Spuncrit Model DRC-40 Infrared Analyzer
- Separation Technology STI HemataSTAT II/C70
- StatSpin Technologies CritSpin
- UltraCrit
- Vulcon Technologies Microspin 24
- Wampole STAT-CRIT Hct

#### *Hemoglobin (Single Analyte)*

- Biosafe Laboratories, Inc. Anemiapro Self Screener
- Biotest Hemoglobin Measuring System
- Copper sulfate, non-automated
- EFK Diagnostic Hemo\_Control Measurements
- EFK Diagnostic Hemo\_Control Microcuvettes
- GDS Diagnostics Hemosite Meter
- GDS Technology STAT-Site MHgb Test System
- HemoCue Donor Hemoglobin Checker System
- HemoCue HB 201 DM Analyzing System
- HemoCue HB 201+ System
- HemoCue Hemoglobin 201+ / HemoCue Hemoglobin Microcuvette System
- HemoCue Hemoglobin System
- HemoCue Plasma/Low Hb System
- Stanbio Hemoglobin Analyzer
- Stanbio HemoPoint H2 Hemoglobin Measurement System

#### *Platelet Aggregation*

- Accumetrics Verifynow-Aspirin Assay

### *Prothrombin Time*

- Avocet AvoSure PT System (prescription home use)
- Avocet AvoSure Pro (Professional Use)
- Hemosense INRatio System
- ITC ProTIME Microcoagulation System
- ITC ProTIME Microcoagulation System (ProTIME 3cuvette)
- Lifescan Harmony™ INR Monitoring System (Prescription and Home Use)
- Lifescan Rubicon Prothrombin Time (prescription and professional use)
- Roche CoaguChek (for Professional Use)
- Roche CoaguChek PST
- Roche CoaguChek S Systems Test (Professional Use)
- Roche CoaguChek and CoaguChek S, PT-S Test Strips

### **Urinalysis/Clinical Microscopy**

*Bilirubin, blood, glucose, ketone, leukocyte esterase, nitrite, pH, protein, specific gravity, and urobilinogen*

- Dipstick or Tablet Reagents (non-automated)
- Bayer CLINITEK 50 Urine Chemistry Analyzer
- Bayer Multistick Pro 7G, Pro 10LS, Pro 11 Reagent Strips
- Biosys Laboratories Optima Urine Analyzer
- Hypoguard Diascreen 50 Urine Chemistry Analyzer
- Physician Sales & Services, Inc. PSS Urine Analyzer
- Roche Chemstrip Mini UA
- Roche Chemstrip 101 Urine Analyzer
- Roche Diagnostics, Urisys 1100 Urine Analyzer
- TECO Diagnostics URITEK TC-101 Urine Strip Reader
- Thermo Biostar PocketChem UA

### *Semi-Quantitative Creatinine*

- Bayer Multistix Pro 10LS, 11, 7G

### *Urine hCG*

- Urine pregnancy test kits (visual comparison)
- Bayer CLINITEK 50 Urine Chemistry Analyzer

### *Microalbumin (Urine)*

- Bayer CLINITEK 50 Urine Analyzer
- Bayer Clinitek Status Urine Analyzer
- Bayer MICROALBUSTIX
- Beckman Coulter Icon Microalb
- Diagnostic Chemicals Immunodip Urinary Albumin (Screen/Test)
- Roche Chemstrip Micral (urine dipstick)

#### *Fecal Occult Blood*

- Fecal occult blood kits

#### *Fern Test, Saliva*

- Luna Fertility Indicator
- O<sub>2</sub> Unlimited Donna Ovulation Tester
- Stesans Maybe? Mom Mini Ovulation Microscope
- TCI Ovulation Tester™ (OTC)

#### *Gastric Occult Blood*

- Aerscher Hemaprompt FG
- Beckman Coulter Primary Care Gastrocult

#### *Vaginal pH*

- Common Sense Ltd. VI-Sense Acidity Test
- FemTek pHEM-ALERT
- Litmus Concepts FemExam Test Card
- Quidel QuickVue Advance pH and Amines Test

#### *pH Testing (body fluids except blood)*

- All qualitative color comparison pH testing

#### *Ovulation Tests*

- Ovulation test kits (visual color comparison for luteinizing hormone)

#### *Semen (Sperm Concentration)*

- Embryotech Laboratories FertiMARQ™ Home Diagnostic Screening Test for Male Infertility

## **Chemistry**

### *Alanine Aminotransferase (ALT)*

- Abaxis Piccolo Point of Care Chemistry Analyzer (Lipid Panel Plus Reagent Disc)
- CHOLESTECH LDX

### *Alkaline Phosphatase*

- Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc)

### *Amylase*

- Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc)

### *Aspartate Aminotransferase (AST)*

- Abaxis Piccolo Point of Care Chemistry Analyzer (Lipid Panel Plus Reagent Disc)
- CHOLESTECH LDX

### *B-Type Natriuretic Peptide (BNP)*

- Biosite Triage Meter (WB)
- Biosite Triage Meter Plus (WB)

### *Cholesterol*

- Abaxis Piccolo Point of Care Chem Analyzer (WB, Lipid Panel Reagent Disc)
- ActiMed Laboratories ENA.C.T. Total Cholesterol Test
- ChemTrak AccuMeter
- Cholestech LDX
- Johnson & Johnson ADVANCED CARE Cholesterol Test
- Lifestream Technologies Cholesterol Monitor
- Lifestream Technologies Lifestream Plus Cholesterol Meter
- Polymer Technology Systems Bioscanner Test Strips
- Polymer Technology Systems Bioscanner 2000 PTS Panels
- Polymer Technology Systems Bioscanner Plus (Lipid Panel Test Strips/CHOL +GLU Test Panel)
- Polymer Technology Systems CardioChek Analyzer (Lipid Panel Test Strips/CHOL +GLU Test Panel and PTS Panels HDL Cholesterol)
- Polymer Technology Systems CardioChek PA Analyzer (Lipid Panel Test

Strips/CHOL +GLU Test Panel and PTS Panels HDL Cholesterol)

- Roche Accu-Chek InstantPlus Cholesterol

### *Fructosamine*

- LXN Duet Glucose Control Monitoring System
- LXN Fructosamine Test System
- LXN IN CHARGE Diabetes Control System

### *FSH*

- Acon Labs, Inc. FSH Menopause Predictor Test
- Applied Biotech, Inc., RU25 Plus FSH Menopause Test
- Applied Biotech Instacheck FSH (professional use)
- Biotechnostix, Inc. Rapid response FSH One Step Menopause (professional use)
- Genosis Fertell Female Fertility Test
- Genua Menopause Monitor Test
- IND Diagnostic INC. One Step FSH Menopausal Test (strip and Cassette)
- IND Diagnostic INC. One Step Strip Style FSH Menopausal (professional use)
- Pharmatech Moments Menopause Check
- RAC Medical Clarity FSH One Step Menopause (professional use)
- Synova Healthcare Menocheck Menopause Indicator Test (OTC and professional use)

### *Gamma Glutamyl Transferase*

- Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc)

### *Glucose*

- Abaxis Piccolo Point of Care Chemistry Analyzer (Lipid Panel Plus Reagent Disc)
- Blood Glucose devices cleared by FDA for home use
- Cholestech LDX
- Cygnus Inc. Gluco Watch (prescription home use)
- HemoCue Glucose system
- HemoCue Glucose 201 Analyzer
- HemoCue Glucose 201 DM Analyzer
- Polymer Technology Systems Cardiocheck Analyzer/PA Analyzer

### *Glycated Hemoglobin (Total)*

- Bristol-Myers Squibb Choice DM

- Metrika A1c Now™
- Metrika A1c Now (Home Use)

#### *Glycohemoglobin (HbA<sub>1c</sub>)*

- Axis-Shield Afinion AS100
- Bayer DCA 2000/2000+ Analyzer
- BIO-RAD Micromat II Hemoglobin Alc (prescription use)
- Cholestech GDx A1C Test (prescription use)
- Glycated Hemoglobin, Total
- Metrika A1c Now™
- Metrika A1c Now (Home Use)
- Metrika DRX (professional use)
- Metrika Inview Multi-test A1c Monitor (OTC)
- Metrika Inview Multi-test A1c Monitor (Professional Use)
- Provalis Diagnostics Glycosal™ HbA1c Test (prescription home use)
- Provalis Diagnosis In2it In-Office Analyzer (II) (prescription home use)

#### *HDL Cholesterol*

- Abaxis Piccolo Point of Care Chem Analyzer (WB, Lipid Panel Reagent Disc)
- Cholestech LDX
- Polymer Technology Systems BioScanner (for OTC use)
- Polymer Technology Systems BioScanner 2000 PTS Panels
- Polymer Technology Systems BioScanner Plus (Lipid Panel Test Strips)
- Polymer Technology Systems BioScanner CardioCheck Analyzer (Lipid Panel Test Strips)
- Polymer Technology Systems BioScanner CardioCheck PA Analyzer (Lipid Panel Test Strips)

#### *Ketones (Blood)*

- Medisense Precision Xtra Advanced Diabetes Management System (OTC use)
- Polymer Technology Systems BioScanner (OTC use)
- Polymer Technology Systems BioScanner 2000 PTS Panels

#### *LDL Cholesterol*

- Polymer Technology Systems Cardiochek Analyzer/PA Analyzer

#### *Nicotine*

- DynaGen NicCheck I Test Strips

### *Triglyceride*

- Cholestech LDX
- Piccolo Point of Care Chem Analyzer (WB, Lipid Panel Reagent Disc)
- Polymer Technology Systems BioScanner (for OTC use)
- Polymer Technology Systems BioScanner 2000 PTS Panels
- Polymer Technology Systems BioScanner Plus
- Polymer Technology Systems BioScanner CarioCheck Analyzer
- Polymer Technology Systems BioScanner CardioCheck PA Analyzer

### *TSH*

- ThyroTec, Inc. ThyroTest Whole Blood TSH Test

### **Toxicology**

#### *Ethanol (Alcohol) - Saliva*

- OraSure Technology Q.E.D. A150 Saliva Alcohol Test
- OraSure Technology Q.E.D. A 350 Saliva Alcohol Test
- STC Diagnostics Q.E.D. A150 Saliva Alcohol Test
- STC Diagnostics Q.E.D. A350 Saliva Alcohol Test

#### *Home Drug Tests (For Over the counter use)*

- ACON Laboratories, On Call Multi-Drug Home Test Cup
- ACON Laboratories, On Call Multi-Drug Home Kit
- ACON Multi-Drug Multi-Line Screen Test Card w/Integrated Cup (Professional Use)
- ACON Laboratorie Tri-Fect Drug Screen
- Accu-Stat Drugs of Abuse Home Test
- Accu-Stat Drugs of Abuse Home Test Cup
- Accu-Stat Home Drug Test
- ADC CLIA Waived Marijuana and Cocaine
- ADC CLIA Waived Multiple Drug Test Card
- Advantage Diagnostics Advantage Marijuana and Cocaine Home Drug Test
- Advantage Diagnostics Advantage THC Test
- Advantage Diagnostics Advantage Multiple Drugs of Abuse (MOA) Test
- Alatec Scientific Marijuana Home Drug Test
- Alatec Scientific Peace of Mind Multiple Drugs of Abuse Test
- Alatec Scientific Peace of Mind THC and Cocaine
- Applied Biotech DrugFree at Home THC and Cocaine Test
- Biotechnostix, Rapid Response One Step Multi-Drug, Multi-Line Screen
- Branan Medical Corp., Fastec Drug Screen Dipstick
- Branan Medical Corp., Fastox Multiple Drug Dipcard
- Branan Medical Corp., QuickTox Drug Screen Dipcard

- First Check Multi Drug Cup 12
- Forefront Diagnostic DrugFree at Home THC/COC
- Forefront Diagnostic Instacheck Drug Screen THC
- iCassette Multidrug, Multi-Line Screen test device
- Instant Technologies OTC Inc. i-Test for Drugs of Abuse
- Nobile Medical, Inc. Split-Specimen Cup
- Pharmatech At Home Drug Test  
(Models 9063T, 9064, 9068T, 9069, 9073T, 9074, 9078T, 9079, 9083T, 9084, 9133T, 9147T AWT, 9150T, 9150X, 9175T)
- Pharmatech At Home Drug Cocaine and THC Screening Test
- Pharmatech At Work Drug Test (Models 9147T AWT, 9177T AWT)
- Pharmatech QuickScreen At Home Drug Test (Models 9149, 9150, 9171)
- Pharmatech QuickScreen One Step
- Pharmatech QuickScreen Pro Multidrug Screening Test (Models 9177,9178)
- Princeton Biomeditech: (Accusign, Accusign Stik, Accustik, Accustrip, Lifesign Home Drug Test, Status DS, Status Stik)
- Redi-Screen Multi-Drug Multi-Line Screen Test Device
- Redi-Test Cassette Multi-Line Screen Test Device
- WayPoint Biomedical, Inc. Health Essist Home Drug Test
- Worldwide Medical Corp., First Check Home Drug Test (Panels: Amphetamines; THC-COC-Met; THC-COC; THC)
- Worldwide Medical Corp., First Check Multi Drug Cup 7

#### *Drug Tests (Professional use)*

- ACON One-Step Multi-Drug Multi-Line Screen (Professional Use)
- Advantage Diagnostics Corp. ADC Multiple Drug Test Card

#### *Lead*

- ESA Biosciences LeadCare II Blood Lead Testing

#### *Lithium*

- Akers Laboratories Inc InstaRead Lithium System (Fingerstick or WB)
- ReliaLAB Inc. InstaRead Lithium System (WB)

### **Bacteriology**

#### *Helicobacter pylori (Biopsy specimens)*

- ACON Helicobacter pylori Rapid Test Device
- Applied Biotech SureStep
- Ballard Medical Products CLOtest
- Delta West CLOtest

- GI Supply, Div. Chek- Med Systems HP ONE
- GI Supply HP-FAST
- Medical Instrument Corp. Pronto Dry H. pylori
- Serim PyloriTek Test Kit
- Serim PyloriTek VP Test Kit

*Helicobacter pylori (Stool)*

- Meridian Bioscience Immunocard STAT HpSA

*Lyme Disease Antibodies (Borrelia burgdorferi)*

- Wampole PreVue B. burgdorferi Antibody Detection Assay

*Streptococcus Group A (Antigen Testing direct from throat swab)*

- Abbott Signify Strep A Test
- Acon® Strep A Rapid Strip Test
- Acon® Strep A Twist Rapid Test
- Applied Biotech SureStep Strep A (II)
- Beckman ICON Fx Strep A Test
- Beckman Coulter ICON DS Strep A
- Beckman Coulter ICON SC Strep A Test
- Beckman Coulter Primary Care Diagnostics ICON DSStrep
- Beckman Coulter Primary Care Diagnostics ICON SC Strep
- Becton Dickinson LINK 2 Strep A Rapid Test
- Binax NOW Strep A Test
- BioStar Aceava Strep A Test
- Biotechnostix Rapid Response Strep A Test Device/Strip
- Cardinal Health SP Brand Rapid Strep A (Cassette & Dipstick)
- Clearview Strep A Exact Dipstick
- DE Healthcare Products TruView Strep A Dipstick & Cassette Test
- DE Healthcare Products TruView Strep A Test
- Fisher HealthCare Sure-View Strep A
- Genzyme Contrast Strep A
- Genzyme OSOM Strep A Ultra Test (25)
- Genzyme OSOM Ultra Strep A
- Germaine Labs StrepAim Rapid Dipstick Test
- Germaine Labs Strep AIM Tower
- Henry Schein, Inc. - One Strep+ Strep Test
- Immunostics Immuno Strep A Detector
- Instant Technologies Istep One Step Strep A
- Inverness Medical Biostar Aceava Strep A
- Jant Pharmacal AccuStrip Strep A (II)
- Jant Pharmacal Corp. Clinipak Strep A Rapid Test Strip
- Laboratory Supply Company PEP Strep A Cassette Test

- Laboratory Supply Company PEP Strep A Dipstick Test
- LifeSign LLC Strep A
- Mainline Confirms Strep A Dots Test
- McKesson Medi-Lab Performance Strep A Test Dipstick or Cassette
- McKesson Medi- McKesson Strep A Test Cassette
- Meridian Diagnostics ImmunoCard STAT Strep A
- PEP Performance Enhanced Products Strep A Cassette
- PEP Performance Enhanced Products Strep A Dipstick
- Permaxin Rediscreen Strep A
- Polymedco, Inc. Poly stat A(II)
- Polymedco Poly Stat Strep A Liquid Test
- Princeton BioMediTech BioStrep A
- Princeton BioMediTech Status First Strep A
- Quidel QuickVue Dipstick Strep A
- Quidel QuickVue In-Line Strep A
- Quidel QuickVue In-Line One-Step Strep A (25)
- RAC Medical Clarity Strep A Twist Rapid Test Device
- RAC Medical Clarity Strep A Rapid Test Strip
- Remel RIM A.R.C. Strep A Test
- SA Scientific SAS Strep A
- Sacks Medical Refuah Strep A
- Signify Strep A Dipstick
- Stanbio QuStrip A
- Wyntek Diagnostics OSOM Strep A Test
- Wyntek Diagnostics OSOM Ultra Strep

#### *Trichomonas*

- Genzyme OSOM Trichomonas Rapid Test

## **Virology**

#### *Adenovirus*

- Rapid Pathogen Screening RPS Adeno Detector

#### *Influenza A/B Antigen Detection*

- Binax NOW Flu A Test (Influenza)
- Binax NOW Flu B Test (Influenza B)
- Binax NOW Influenza A&B Test (nasopharyngeal and nasal wash/aspirate)
- Quidel QuickVue Influenza Test
- Quidel QuickVue Influenza A + B Test
- SA Scientific SAS Influenza A

- SA Scientific SAS Influenza B
- ZymeTx ZstatFlu Test

*Respiratory Syncytial Virus AB (RSV)*

- Binax NOW RSV Test
- Fisher Scientific Sure-Vue RSV Test
- Integrated Biotechnology Quick Lab RSV Test
- Meridian Bioscience Immunocard STAT RSV Plus
- Remel Xpect RSV
- SA Scientific SAS RSV Alert
- SA Scientific SAS RSV Test
- Wampole Laboratories Clearview RSV

**Immunology**

*Helicobacter pylori Antibodies (for whole blood)*

- Abbott FlexPack HP Test
- Abbott TestPack Plus H. pylori
- ALFA Scientific Designs Instant View
- Applied Biotech SureStep
- Beckman Coulter Primary Care Diagnostic Flexsure HP
- Becton Dickinson LINK 2 H. pylori Rapid Test
- BTNX Inc. Rapid Response H. pylori
- Cardinal Health SP Brand Rapid Test
- ChemTrak AccuMeter H. pylori Test
- Clarity H. pylori Rapid Test
- DE Healthcare Products Truview
- Germaine Laboratories, AIMSTEP, H. Pylori
- Henry Shein OneStep+ H. Pylori Test
- ICON MONO
- JANT Pharmacal H. pylori Test
- LifeSign Status H. pylori
- Meridian Bioscience Immunocard Stat H. pylori WB Test
- PerMaxim Radiscreen H. pylori Test Device
- Polymedco, Inc. Poly stat H. pylori
- Princeton Biomeditech BioSign H. pylori
- Quidel QuickVue One-Step H. pylori Test
- Quidel QuickVue One-Step H. pylori II Test
- Remel RIM A.R.C. H. pylori Test
- Roche AccuStat H. pylori OneStep
- Trinity Uni-Gold H. Pylori
- Wampole Clearview H. pylori II (Fingerstick or WB)

### *HIV Antibody*

- Chembio HIV 1/2 STAT-PAK
- OraSure OraQuick Advance Rapid HIV 1/2 Ab Test (oral fluid, WB fingerstick or venipuncture)
- OraSure Technologies OraQuick Rapid HIV - I Antibody Test
- Trinity Biotech Uni-Gold HIV
- Trinity Biotech Uni-Gold Recombigen HIV Test (WB)

### *Infectious Mononucleosis Antibodies (For whole blood)*

- ACON Mononucleosis Rapid Test Strip or Device
- Applied Biotech One Step+ Mono Test
- Applied Biotech SureStep Mono Test
- Applied Biotech Truview Mono Test
- BioStar Aceava Mono Test
- Clearview Mono-Plus II
- Genzyme Contrast Mono
- Genzyme OSOM Mono Test
- Genzyme Rapid Mono
- Genzyme Sure-View Signature Mono
- Instant Technologies iScreen Mononucleosis Rapid Test Strip or Device
- Jant Accutest
- LifeSign Status Mono
- LifeSign UniStep Mono
- McKesson Medi-Lab Performance Infectious Mono Test
- Meridian ImmunoCard STAT Mono
- PerMaxim Rediscreen
- Polymedco, Inc. Poly stat mono
- Princeton BioMeditech BioSign Mono
- RAC Medical Clarity Mono
- Rapid Response Mononucleosis Rapid Test Device
- Quidel CARDS O.S. Mono
- Quidel QuickVue+
- Remel RIM A.R.C Mono Test
- Seradyn Color Q Mono
- Signify Mono Test
- SP Brand Rapid Test Mono
- Wampole Mono-Plus WB
- Wyntek Diagnostics OSOM Mono Test
- Wyntek Diagnostics Signify Mono Test