Provider Performed Microscopic Procedures (PPMP) Application Packet

Contents:
1.  505-041 ....Provider Performed Microscopic Procedures (PPMP)
    Application Index Page ................................................................. 1 Page
2.  505-042 ....Provider Performed Microscopic Procedures (PPMP)
    Application Instructions Checklist .............................................. 2 Pages
3.  505-031 ....Provider Performed Microscopic Procedures (PPMP)
    Application ................................................................................... 10 Pages

Important Information:
Laboratories licensed by the Washington Medical Test Site (MTS) licensure program are exempt from the Clinical Laboratory Improvement Amendments of 1988 (CLIA). You do not need to apply to the Centers for Medicare and Medicaid Services (CMS) for a CLIA number. Your MTS license will contain both your MTS license number and your CLIA number.

In order to process your request:
Return Completed Application (original copy) and fee to:
Department of Health
Revenue Section
P.O. Box 1099
Olympia, WA  98507-1099
When your application for a Medical Test Site is received by the Department of Health, you will be notified in writing of any outstanding documentation needed to complete the application process.

All information should be printed clearly in blue or black ink. It is your responsibility to submit the required forms.

☐ **Indicate type of application:**
  - New
  - Change of ownership
  - Change of license type

☐ **Check One:**
Please check your legal owner/operator business structure type according to your Washington State Master Business License.

☐ **Section 1. Demographic Information:**
Uniform Business Identifier Number (UBI #): Enter your Washington State UBI #. All Washington State businesses must have UBI #s. City, county, and state government departments also have UBI #s.

Federal ID Number (FEIN #): Enter your Federal ID Number, if the business has been issued one. If the facility FEIN # is different than the Legal Owner FEIN, enter this number on page two of the application under Facility Specific Federal Tax ID (FEIN) #.

Legal Owner/Operator Entity Name: Enter the owner’s name as it appears on the UBI/Master Business License.

Legal Owner Mailing Address: Enter the owner’s complete mailing address.

Phone and Fax: Enter the owner’s phone and fax numbers.

Email and Web Address: Enter the owner’s email and facility web addresses, if applicable.

Facility Name: Enter the lab’s name as advertised on signs and web site.

Facility Specific Federal Tax ID (FEIN) #: Enter if different from the Owner FEIN listed on page one of the application.

Physical Address: Enter the lab’s physical street location including city, state, zip code, and county.

Phone and Fax Numbers: Enter the lab’s phone and fax number.

Mailing Address: Enter the lab’s mailing address, if different than physical address.

☐ **Section 2. Facility Specific Information:**

Site Type: Please check one applicable site type.

Additional locations under this license: Attach a list of names and addresses for additional locations, if applicable, and test(s) performed at each site.
Section 3. Key Individuals:
Lab Director: Enter the lab director’s:
1. Name
2. Washington State professional license number for MD, DO, ND, PA, ARNP, LPN, health care assistant or other professional license category
3. Email address

Lab Contact: Enter the lab contact’s:
1. Name
2. Washington State professional license number for MD, DO, ND, PA, ARNP, LPN, or other professional license category, if applicable
3. Email address

The lab contact will receive all information that we mail to your medical test site.

Section 4. Additional Information—Waived Tests:

Waived Tests: Place a check mark by all waived tests performed at your facility.

For Drugs of Abuse Testing, please indicate the test system(s) on the lines provided. Please verify the waived status of your test system at https://www.accessdata.fda.gov.

PPMP Tests: Place a checkmark by all PPMP tests performed at your facility by one of the providers listed. The PPMP tests can only be performed in your facility by an MD, DO, DPM, ARNP, midwife, PA, naturopath, or dentist.

If you perform any tests other than the waived tests listed, do not complete this application. See the LQA website: http://www.doh.wa.gov/lqa.htm to help you determine your correct license category or call the LQA office at 253-395-6746.

Section 5. Other Licensure, Certification, or Registration Information:

Legal Owner: List the names, titles, addresses, and phone numbers of the corporate officers, LLC members or manager, partners, etc. Attach additional pages, if necessary.

Change of Ownership Information: If applicable, list the previous legal owner name, previous name of facility, previous MTS license number, effective date of ownership change and physical address.

Signature:
Signature of legal owner or authorized representative
Date signed
Print name of legal owner or authorized representative
Print title of legal owner or authorized representative

Your new MTS license will expire on June 30, 2019. You will receive a renewal notice for this license approximately 60 days before the expiration date.

Please contact our Kent office at 253-395-6746 if you have any questions or need assistance in completing the application form. Additional information is available on our website at: http://www.doh.wa.gov/lqa.htm.
## Provider Performed Microscopic Procedures (PPMP) 
### Medical Test Site License Application

### This is for:
- [ ] New
- [ ] Change of Ownership
- [ ] Change of License Type

### Check One
- [ ] Association
- [ ] Corporation
- [ ] Limited Liability Company
- [ ] Limited Liability Partnership
- [ ] Limited Partnership
- [ ] Municipality (City)
- [ ] Municipality (County)
- [ ] Non-Profit Corporation
- [ ] Partnership
- [ ] Sole Proprietor
- [ ] State Government Agency
- [ ] Trust

### Section 1. Demographic Information

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Legal Owner/Operator Entity Name

Mailing Address

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Facility/Agency Name (Business name as advertised on signs or website)

Facility Specific Federal Tax ID (if different than one entered above.)

Physical Address

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Mailing Address (If different than physical address)

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### For Office Use Only

Medical Test Site # _______________________________ CLIA # _____________________________
Section 2. Facility Specific Information

Site Type (check one only)

___ 1 Ambulance
___ 2 Ambulatory Surgery Center
___ 3 Ancillary Test Site
___ 4 Assisted Living Facility
___ 5 Blood Banks
___ 6 Community Clinic
___ 7 Comprehensive Outpatient Rehab
___ 8 End Stage Renal Disease Dialysis
___ 9 Federally Qualified Health Center
___ 10 Health Fair
___ 11 Health Main. Organization
___ 12 Home Health Agency
___ 13 Hospice
___ 14 Hospital
___ 15 Independent Laboratory
___ 16 Industrial
___ 17 Insurance
___ 18 ICFMR
___ 19 Mobile Lab
___ 20 Pharmacy
___ 21 Physician Office
___ 22 Other Practitioner
___ 23 Prison
___ 24 Public Health Lab
___ 25 Rural Health Clinic
___ 26 Student Health Service
___ 27 Skilled Nursing Facility
___ 28 Tissue Bank/Repository
___ 29 Other
___ 30 Drug Treatment
___ 31 Clinic

Additional locations under this license

If you qualify as a not-for-profit laboratory or state or local government laboratory that performs limited public health testing (total of 15 or less waived or moderate complexity tests) at different locations, you may apply for one license.

This license will have additional locations under one license and the paragraph above applies: □ Yes □ No

If yes: Attach a list of names and addresses for each site that will be included under one license, and a list of tests performed at each site. If any of the sites already have a MTS license, include the MTS and CLIA numbers of the sites that will be consolidated under this license. If you are not a state or local government laboratory, you must include a copy of your federal 501(c)(3) determination letter to be licensed in this manner.

Section 3. Key Individuals

Lab Director (include MD, PhD, BS, etc.)

Name

Washington State Professional License (if applicable)

Email Address

Lab Contact Person

Name

Washington State Professional License # for MD, ND, PA, ARNP, RN, LPN, or other professional license category.

Email Address

Note: If you perform any tests other than the waived or PPMP tests listed, do not complete this application. See the LQA website: http://www.doh.wa.gov/lqa.htm to help you determine your correct license category or call the LQA office at 253-395-6746.
Section 4. Additional Information—Waived Tests
Waived Tests: Place a check mark by the test kit/system if you perform any of the specific test methods listed below. (Waived test list as of 04/01/18)

**Adenovirus**
- AdenoPlus (human eye fluid)
- Rapid Pathogen Screening RPS Adeno Detector
- Quidel, AdenoPlus Test, Adeno Detector, Detector Plus (Tear Fluid)

**Aerobic/Aerobic Organisms-Vaginal**
- Genzyme Diagnostics OSOM BVBLUE Test
- Gryphus Diagnostics BVBlue
- OBGYN-Vph Vaginal Ph Screening Kit

**Aerobic/Aerobic/Viral Panel – Respiratory**
- FilmArray Respiratory Panel 2.0 EZ (NP)

**Alanine Aminotransferase (ALT)**
- Alere Cholestech LDX (ALT)(WB)
- Arkray SPOTCHEM EZ Chem Analyzer (ALT)(WB)
- Piccolo Point of Care/Blood Chem/xpress Chem Analyzer (ALT) (Lipid Panel Plus, Liver Panel Plus, CMP, BMP)

**Albumin**
- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Genzyme Diagnostics OSOM ImmunDip Urinary Albumin Test
- HemoCue Albumin 201 System (urinary albumin)
- Piccolo Point of Care/Blood Chemistry Analysers WB (Liver Panel Plus Reagent Disc, Chem 13, CMP, Renal)
- TECO Diagnostics, Albumin Rapid Test Stick and Card

**Alkaline Phosphatase (ALP)**
- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Piccolo Point of Care/Blood Chemistry Analysers (WB) (Liver Panel Plus Reagent Disc, CMP, BMP)

**Amylase**
- Piccolo POC/xpress Chemistry Analyzer WB (Liver Panel Plus)

**Aspartate Aminotransferase (AST)**
- Alere Cholestech LDX (AST) (WB)
- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Cholestech LDX Aspartate Aminotransferase (AST)
- Piccolo Point of Care/Blood Chemistry Analysers WB (Liver Panel Plus Reagent Disc, Chem 6/13, CMP)

**B-Type Natriuretic Peptide (BNP)**
- Biosite Triage Meter/Meter Plus/Meterpro (WB)

**Bilirubin, Total**
- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Piccolo Point of Care/Blood Chemistry Analysers WB (Liver Panel Plus Reagent Disc, Chem 13, CMP)

**Bladder tumor associated antigen**
- Alere NMP22 BladderChek
- Bion Diagnostic Sciences BTA stat Test (for home use)
- LifeSign Status BTA
- Matriech BladderCheck Test (professional & prescription use)

**BUN (Blood Urea Nitrogen)**
- Abbott i-STAT CHEM8+/6+ Cartridge
- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Piccolo xpress/Blood Analyzers (chem 6/13, kidney, CMP, BMP, Metlyte 8, Renal)

**Calcium**
- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Piccolo xpress & Blood Chemistry Analyzers WB (chem 13, CMP, BMP, Renal)

**Calcium - Ionized**
- Abbott i-STAT CHEM8+ Cartridge

**Carbon Dioxide (CO2)**
- Abbott i-STAT CHEM8+ Cartridge
- Piccolo xpress & Blood Analyzers (CMP,BMP,lytes, Metlyte 8, Renal)

**Catalase, urine**
- Accutest Uriscrren Rapid UTI Screen
- Diatech Diagnostics Uriscrren (for OTC use)

**Chloride**
- Abbott i-STAT CHEM8+/6+ Cartridge
- Piccolo xpress & Blood Analyzers (CMP,BMP,lytes,metlyte 8, Renal)

**Cholesterol**
- Accu-Check InstantPlus Cholesterol test system
- Accucheck Instant Plus Dual Testing System
- Advanced Care Cholesterol measuring system
- Alere Cholestech LDX Cholesterol(WB)
- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Biomedix Inc Q Steps Biometer G/C Dual Monitoring System
- ChemTrak AccuMeter cholesterol test system
- Cholestech LDX Test System
- ENA C.T. Total cholesterol or Total cholesterol (PDU)
- Infopia USA LipidPro/Lipid Profile Test Strips/Lipid Profile & Glucose Measuring System
- Jant Pharmacal LipidPlus Lipid Profile and Glucose System
- Lifethread Technologies cholesterol monitors
- Mission cholesterol monitoring system and mission cholesterol pro monitoring system
- Piccolo xpress Chemistry Analyzer WB (Lipid Panel/Plus)
- Piccolo xpress chem analyzer (capillary-fingerstick)
- Polymer Tech. Systems Bioscanner, Bioscanner Plus, Bioscanner 2000 PST, and MTS Bioscanner 1000
- Polymer technology Cardiochek test strips (Plus, home use, and PA)
- Roche Diagnostics Accutrend Plus System (fingerstick WB)
- SD Biosensor USA, Inc., SD LipidoCare (BT) Home Lipid Panel Test Strip
- SD Biosensor USA, Inc., SD LipidoCare (BT) Professional system (SD LipidoCare Professional Lipid Panel Test strip)
- Wako APOLOWAKO Analyzer (WB)

**Complete Blood Count (CBC)**
- XW-100 Automated Hematology Analyzer for CLIA Waived Use (Hematocrit, Hemoglobin, Platelet Count, Red blood cell (RBC) count, White blood cell (WBC) count, White blood cell differential)

**Creatine Kinase (CK)**
- Piccolo Blood Chemistry/xpress AnalyzersWB (Metlyte 8)
Waived Tests (continued)

Creatinine
- Abbott i-STAT CHEM8+/Crea Cartridge
- Arkray SPOTCHEM EZ Chemistry Analyzer (WB)
- Piccolo xpress/Blood Analyzers (chem 6/13, kidney, CMP, BMP, Metlyte 8, Renal)
- Siemens Clinitek 50 Urine Chemistry Analyzer for Creatinine
- Siemens Diagnostics MICROALBUSTIX Reagent Strips
- Siemens MultiStix PRO 11, PRO 10LS, and PRO 7G

Drugs of Abuse
(Please indicate the test system(s) on the lines below and verify the waived status of your test system on the FDA/CLIA Test Complexity Database)

Electrolyte Panel
- Piccolo Blood Chemistry/xpress WB

Erythrocyte sedimentation rate (ESR)
- Non-automated

Esterone-3-Glucuronide
- Unipath Limited Clearplan Easy Fertility Monitor

Ethanol
- Acon Laboratories Mission Saliva Alcohol Test Strip
- Alere Toxicology Services iScreen Saliva Alcohol Test Strip
- Alfa Scientific Designs Oral-View Saliva Alcohol Test Strip
- American Screening Corp. Reveal Saliva Alcohol Test Strip
- Chematics Alco-Screen/Alco-Screen 02 Saliva Alcohol Test
- CLIAwaived rapid Saliva Alcohol Test
- Express Diagnostics International, Incorporated Saliva Alcohol Test
- Germaine Laboratories Aim Strip Alcohol Saliva
- Jant Pharmacal Corp Accustrip Saliva Alcohol Test Strip
- OraSure Q.E.D. A-150 and A-350 Saliva Alcohol Tests
- Bruno MD6 Multi-Functional Monitoring System
- CLIAwaived rapid Saliva Alcohol Test
- Express Diagnostics International, Incorporated Saliva Alcohol Test
- Germaine Laboratories Aim Strip Alcohol Saliva
- Jant Pharmacal Corp Accustrip Saliva Alcohol Test Strip
- OraSure Q.E.D. A-150 and A-350 Saliva Alcohol Tests
- Express Diagnostics International, Incorporated Saliva Alcohol Test
- Germaine Laboratories Aim Strip Alcohol Saliva
- Jant Pharmacal Corp Accustrip Saliva Alcohol Test Strip
- OraSure Q.E.D. A-150 and A-350 Saliva Alcohol Tests
- Express Diagnostics International, Incorporated Saliva Alcohol Test

Follicle Stimulating Hormone (FSH)
- Acon Lab FSH Menopause Predictor Test
- Acon Lab FSH One Step Menopause Test/Device
- Applied Biotech Menopause Predictor/Instacheck FSH Test
- Applied Biotech Menopause Predictor and RU25 Plus FSH
- Biotechnostix Rapid Response FSH One Step Test Device
- BTNX Rapid Response FSH Menopausal Test
- Genosis Fertell Female Fertility Test (FSH)
- Genua Menopause Monitor Test, FSH (qualitative)
- IND Diagnostic One Step FSH Menopausal Test (midstream)
- IND Diagnostic One Step FSH (Strip/Cassette)
- IND Diagnostic One Step Strip/Cassette Style FSH (prof use)
- PanProbe Biotech EarlyDetect Menopause Test
- Pharmatech Moments Menopause Check (FSH)
- QuantRx Biomedical QuantRx Female Fertility Test
- RAC Medical Clarity FSH One Step Menopause (prof use)
- Synova Healthcare Menocheck Menopause Indicator Test

Fructosamine
- LXN (Duet and IN CHARGE Test Systems)

Gamma Glutamyl Transferase (GGT)
- Piccolo Point of Care/Blood/xpress Chemistry Analyzer (Liver Panel Plus Reagent Disc, Chem 6, Chem 13)

Glucose
- Alere Cholestech LDX (glucose)(WB)
- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Abbott i-STAT CHEM8+/G/EC4+/6+ Cartridge
- Biomedix, Inc Q Steps Biometer G/C Dual Monitoring System
- Blood glucose monitoring devices cleared by FDA - home use
- Bruno MD6 Multi-Functional Monitoring System
- Cygnus, Inc GlucoWatch Automatic Glucose Biographer
- Diagnostic Test Grp, Clarity Blood Glucose Monitoring System
- Hemocue B-Glucose Photometer & model 201analyzer/201DM
- Jant Pharmacal LipidPlus Lipid Profile and Glucose System
- LXN Duet/IN CHARGE Glucose Monitoring System
- Cholestech LDX
- Nova Biomedical StatStrip Glucose Hospital Meter System
- Piccolo Point of Care/Blood/xpress Chemistry Analyzer WB (Lipid Panel Reagent Disc, Chem 6/13, CMP, BMP, Metlyte 8, Renal)
- Polymer Technology Cardiochek test strips (Plus, Home Use, and PA)
- Roche Diagnostics AccuChek Instant Plus Dual Test System
- SD Biosensor USA, Inc., SD LipidoCare (BT) Home System (SD LipidoCare Home Blood Glucose Test Strip)
- SD Biosensor USA, Inc., SD LipidoCare (BT) Professional System (SD LipidoCare Professional Blood Glucose Test Strip)
- StatStrip Xpress Blood Glucose Monitoring System
- Wako APOLOWAKO Analyzer (WB)

Glycosylated HGB
- Alere Technologies AS, Alere Afinion AS100 Analyzer
- Axis-Shield Afinion AS10 Analyzer
- Bayer A1C Now SelfCheck
- Bayer A1C Now+ (professional use)
- Bio-Rad Micromat II and in2it (II) Prescription Home Use
- Bristol-Myers Squibb Choice DM
- Chek Diagnostics A1C Now SelfCheck
- Chek Diagnostics A1C Now+ Professional Use
- Cholestech GDX A1C (prescription home use)
- Cholestech GDX A1C (prescription home use)
- MEC Dynamics Avie A1c Test System
- Metrika A1c Now/DRX HbA1c/Inview Multi Test
- Polymer Technology Systems, Inc., CVS Health At Home A1C Test Kit, At-Home A1C System and Test Kit
- Provalis Diagnostics Glycosal/In2it In-office analyzer II/G5 l HbA1c/G5 II l HbA1c
- PTS Diagnostics A1CNow + Professional Use and Self Check
- Siemens Medical DCA Vantage/2000/2000+ Analyzer
- Wako APOLOWAKO Analyzer (WB)

HDL Cholesterol
- Accutech CholesTrak HDL Cholesterol Home Test
- Alere Cholestech LDX (HDL cholesterol)(WB)
- Arkray SPOTCHEM EZ Chem Analyzer (WB)
Waived Tests (continued)

**Cholestech LDX**
- Infopia USA LipidPro/Lipid Profile Test Strips/Lipid Profile & Glucose Measuring System
- Jant Pharmacal LipidPlus Lipid Profile and Glucose System
- Mission Cholesterol Monitoring System and Mission Cholesterol Pro Monitoring System
- Piccolo POC/xpress Chemistry Analyzer WB (Lipid Panel/Plus)
- Piccolo xpress Chem Analyzer (capillary-fingerstick)
- Polymer Technology Systems BioScanner Plus and 2000
- Polymer Technology Cardiocheck test strips (Plus, Home Use, and PA)
- SD Biosensor USA, Inc., SD LipidoCare Home System (SD LipidoCare Home Lipid Panel Test Strip)
- SD Biosensor USA, Inc., SD LipidoCare (BT) Professional System (SD LipidoCare Professional System (BT) Professional Lipid Panel Test Strip)

**Helicobacter pylori**
- Abbott FlexPack HP, Signify, Cassette, and TestPack Plus (WB)
- Acon H. pylori Rapid Test Device (WB)
- Alfa Scientific Designs Instant View (WB)
- Applied Biotech SureStep (WB)
- ARJ Pylo-Plus Urease (gastric biopsy)
- Ballard (Delta West) CLOtest (gastric biopsy)
- Beckman Coulter Flexsure (WB)
- Becton Dickinson LINK 2 (WB)
- BTNX Inc Rapid Response H. pylori Rapid Test Device(WB)
- Cardinal Health SP Brand Rapid Test (WB)
- ChemTrak AccuMeter (WB)
- Clarity H. pylori Rapid Test Device (WB)
- CLIA waived H. pylori Whole Blood Rapid Test
- De Healthcare Products Truview H. pylori (WB)
- Diagnostic Test Group Clarity H. pylori Rapid Test Device (WB)
- EarlyDetect H. pylori Whole Blood Rapid Test
- Fisher Healthcare Sure-Vue H. pylori Test (WB)
- Germaine Laboratories AimStep (WB)
- GI Supply HP-FAST and HP One (gastric biopsy tissue)
- Henry Schein OneStep+ / Rapid Test Device (WB)
- Immunostics Detector H. pylori (WB)
- Instant Technologies iScreen (WB)
- Inverness BTNX Inc Rapid Response H. pylori Test (WB)
- Inverness Medical Clearview/SIGNIFY H. pylori Test (WB)
- Jant Pharmacal Corp. Accutest Rapid Test Device (WB)/ Rapid Urease Test)
- LifeSign and LifeSign Status (WB)
- McKesson H. pylori Test (WB)
- McKesson Medi-Lab Performance H. pylori Test (WB)
- Medical Instruments Corp Pronto Dry (gastric biopsy)
- Medline H. pylori Test Cassette (WB)
- Meridian Bioscience ImmunoCard STAT! (WB)
- Polymedco Polystat (WB)
- PreMaxim RadiScreen Test Device (WB)
- Princeton BioMeditech BioSign (WB)
- Princeton BioMeditech BioSign H. pylori WB OSOM H. pylori
- Pro-Advantage by NDC H. pylori Device (WB)
- PSS Consult H. pylori Cassette (WB, fingerstick only)
- Quidel QuickVue gII/One-Step/One-Step II (WB)
- Remel RIM A.R.C. (WB)
- Roche Diagnostics AccuStat H. pylori OneStep (WB)
- Select Medical Products Brand Rapid Test H. pylori (WB)
- Serim Pyloritek test Kit and VP Test Kit (gastric biopsy)
- SmithKline FlexSure HP (WB)
- Stanbio RELY H.pylori (WB fingerstick only)
- Trinity Uni-Gold (WB)
- Wampole Laboratories Clearview H. pylori II (WB)

**Hematocrit**
- Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge
- Microhematocrit (spin)
- Micro Diagnostics Spuncrit DRC-40 Infrared Analyzer
- UltraCrit
- Wampole STAT-CRIT for hematocrit

**Hemoglobin**
- Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge
- Aim Strip Hb Hemoglobin (Hb) Testing System
- Alere HemoPoint H2 Hemoglobin Measuring System
- Avie Total Hb Test System (professional use)
- Biosafe Anemiapro Self Screener
- Biotest Hemoglobin Measuring System
- Clarity HbCheck Hemoglobin Testing System
- ClIAwaived Inc. Hemoglobin (Hb) Testing System
- Copper Sulfate (non-automated)
- Diaspect Hemoglobin Measuring System
- EKF Diag. Hemo_Control Measurement & Microcuvettes
- HemoCue hemoglobin test systems (201, 201+, 301)
- HemoCue Donor Hemoglobin Checker System
- GDS Diagnostics HemoSite Meter for hemoglobin
- GDS Technology STAT-Site M Hgb Test System
- ITC HGB PRO Professional Hemoglobin Testing System
- Mission Plus Hemoglobin (Hb) Testing System
- Stanbio Hemoglobin Analyzer
- Stanbio HemoPoint H2/H2 DM Hemoglobin Measurement Syst

**Hepatitis C Virus Antibody**
- OraQuick Rapid Aby Test/OraQuick HCV Visual Ref Panel

**Herdpes**
- OraQuick Rapid HSV-1 IgG Assay (Fingerstick WB Only)

**HIV-1**
- Alere Determine HIV-1/2 Ag/Ab Combo Fingerstick WB
- bioLytical INSTI HIV-1 Antibody Test (fingerstick WB)
- Chembio DPP HIV 1/2 Assay (oral fluid)
- Chembio HIV 1/2 STAT-PAK Assay (WB)
- Clearview COMPLETE HIV 1/2 fingerstick & venipuncture WB
- Orgenics, Alere Determine HIV-1/2 Ag/Ab Combo (Fingerstick WB)
- OraQuick Advance Rapid HIV-1/2 Antibody (oral fluid, WB)
Waived Tests (continued)

**Influenza**
- Alere BinaxNOW Influenza A & B Card (nasal swab/waah/as)
- Alere BinaxNOW Influenza A & B Card 2 with reader (Direct Nasal and NP Swabs)
- Alere Influenza A & B Test (nasal swab only)
- Alere Scarborough Inc. Medline Influenza A & B Test
- BD Veritor Systems Rapid Det Flu A+B (nasal, nasopharyngeal)
- BioSign Flu A+B test (Nasal and NP Swabs)
- BTNX Rapid Response Flu A+B Test Cassette
- Cepheid Gene Xpert Xpress System (Flu + RSV)
- Cepheid Gene Xpert Xpress System (Xpert Flu Xpress)
- Clearview Exact II Influenza A&B (nasal swab only)
- Cobas Influenza A/B Nucleic Acid Test for Use on the cobas System
- EarlyDetect Pro Influenza A Test/Influenza B Test
- Henry Schein OneStep+Influenza A&B Test
- LifeSign LLC, Status Flu A+B
- McKesson Consult Diagnostic Influenza A&B (Nasal and Nasopharyngeal Swabs)
- McKesson Consult Influenza A & B (Nasal and Nasopharyngeal)
- Medline Industries, Inc. Medline Influenza A &B Test
- Meridian Bioscience Inc., ImmunoCard STAT! Flu A&B (Nasal and Nasopharyngeal Swabs)
- PBM Princeton Biomedical Corp. ImmunoCard STAT! Flu A&B (Nasal and Nasopharyngeal Swabs)
- Quidel QuickVue Influenza Test (Influenza A/B)
- Quidel QuickVue Influenza A+B Test
- SA Scientific SAS Influenza A/Influenza B Tests
- Sekisui Diagnostics LLC, OSOM Ultra Flu A
- Sofia for use with Sofia Influenza A+B FIA
- Sofia Analyzer & Influenza A+B FIA (nasal, nasopharyngeal)
- ZymeTX Zstatflu (Influenza A/B)

**Ketones (Blood)**
- Abbott Freestyle Precision Pro/Xtra/Xceed
- Bruno MD6 Multi-Functional Monitoring System
- Nova Max Plus/Mini Glucose and B-Ketone Monitoring System
- Polymer Technology Systems BioScanner 2000

**Lactic Acid**
- KDK Corporation Lactate Pro System (for OTC use)

**LDL Cholesterol**
- Polymer Tech. Systems Cardiocheck/Cardiocheck PA Analyzer

**Lyme Disease**
- Wampole PreVue B. burgdorferi Antibody

**Luteinizing Hormone (also see ovulation tests)**
- BTNX Inc Rapid Response LH Ovulation Test
- Chembio Sure Check Ovulation Predictor
- Inverness Medical Early Ovulation Predictor Stix
- Saless Enterprises New Choice Ovulation Predictor
- Unipath Limited Clearplan Easy Fertility Monitor

**Matrix metalloproteinases-9 (MMP-9)**
- Quidel Corporation, InflammaDry
- Rapid Pathogen Screen Inc. InflammaDry

**Microalbumin**
- Beckman Coulter ICON Microalb
- Diagnostic Chemicals ImmunoDip & Urinary Albumin Screen
- Genzyme Diagnostics OSOM ImmunoDip Urinary Albumin Test
- HemoCue Albumin 201 System
- Roche/Boehringer Mannheim Micral Chemstrip
- Siemens Clinitek 50 Urine Chemistry Analyzer
- Siemens Clinitek Status Urine Chemistry Analyzer
- Siemens Diagnostics MICROALBUSTIX Reagent Strips

**Mononucleosis**
- Acceava Mono II (WB)
- Acon Mono rapid Test Strip/Device (WB)
- AimStep Mono (WB)
- Applied Biotech One Step+, SureStep, Truvue Mono Test
- Beckman Coulter Icon Mono Test (WB)
- BioStar Acceava Mono/Mono II Test (WB)
- Cardinal SP Brand Rapid Test (WB)
- Clarity MONO Mononucleosis Rapid Test (WB)
- Clearview Mono-Plus II / Mono Test Whole Blood (WB)
- Consult Diagnostics Mononucleosis Cassette (WB)
- De Healthcare Products Truvue Mono Test (WB)
- Genzyme Contrast/OSOM/Rapid/Sure-Vue Signature MonoTest
- Henry Schein One Step+ Mono Test (WB)
- Immuno Detector Mono/BioSign Mono WB
- Instant Technologies iScreen (WB)
- Jant Accutest Value/Infectious Mononucleosis Test (WB)
- LifeSign Status/UniStep Mono Test (WB)
- Mckesson Consult Mononucleosis Test Cassette (WB)
- Mckesson Medi-Lab Performance Infectious Mono Test
- Medline Mono Test Cassette (WB)
- Meridian ImmunoCard STAT Mono (WB)
- OneStep Pro+ Mono (WB)
- PerMaxin RediScreen Mononucleosis (WB)
- Polymedco, Inc. Poly stat Mono (WB)
- Poly Stat Mono Test (WB)
- Princeton BioMeditech BioSign Mono WB (WB)
- ProAdvantage by NDC Infectious Mono Test Device (WB)
- Quidel CARDS O.S. and QuickVue+ MONO (WB)
- RAC Medical Clarity MONO Rapid Test Device (WB)
- Rapid Response Mono Rapid Test Device (WB)
- Remel RIM A.R.C. Mono Test
<table>
<thead>
<tr>
<th>Waived Tests (continued)</th>
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<tbody>
<tr>
<td>__ Seradyn Color Q Mono (WB)</td>
<td>__ Fentek Phem-Alert (vaginal pH)</td>
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<tr>
<td>__ Signify Mono Test / Mono Whole Blood / Mono Cassette (WB)</td>
<td>__ Lil' Drug Store Prod. Vagi-Screen Vaginal Health Test (vag pH)</td>
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<tr>
<td>__ Stanbio Rely Mono Rapid Test (WB)</td>
<td>__ Litmus Concepts FemExam Test Card (vaginal pH &amp; amines)</td>
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<tr>
<td>__ Wampole Mono-Plus WB (WB)</td>
<td>__ Quicke QuickVue Advance pH and Amines Test</td>
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<tr>
<td>__ Wyntek Diagnostics OSOM and Signify Mono test (WB)</td>
<td>__ RightBio Metrics Right Spot Infant pH Indicator/PH Indicator/ Detector</td>
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<tr>
<td>Nicotine (or its metabolites)</td>
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<tr>
<td>__ CLIawaeid Instant Nicotine Detection Test</td>
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<tr>
<td>__ DynaGen NicCheck 1 Test Strips</td>
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<td>__ Mossman Associates NicCheck I Test Strips</td>
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<tr>
<td>Occult Blood</td>
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<tr>
<td>__ Aerscher Hemaprompt FG Gastric Occult Blood</td>
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<tr>
<td>__ Alfa Scientific Designs Instant-View FOB Self-Test Cassette</td>
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<td>__ Alfa Scientific Designs FOB Self-Test</td>
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<tr>
<td>__ Beckman Coulter Primary Care Diagnostics Gastroccult/ Hemoccult Sensa Elite (gastric occult blood) Clarity Fecal Occult Blood Self Test</td>
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<tr>
<td>__ Compliance Gold Fecal Occult Blood Test – ER</td>
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<td>__ Eiken Chemical Co., LTD OC-Light S FIT (1)</td>
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<tr>
<td>__ Enterix Inc. InSure One – One Day Fecal Immunochemical Test</td>
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<td>__ Fecal Occult Blood</td>
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<tr>
<td>__ Fecal Occult Blood Immunochemical/Immunological Tests</td>
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<tr>
<td>__ Germaine Laboratories AimStep Immunological Fecal Occult Blood Test (iFOBT)</td>
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<td>__ Hema Screen Specific iFOBT</td>
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<td>__ Henry Schein One Step Pro+FIT(1)</td>
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<td>__ Immunostics hema screen ER</td>
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<tr>
<td>__ Jant Pharmacal Corporation Accutest ValuPak Immunochimical Fecal Occult Blood Test</td>
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<tr>
<td>__ Know Fecal Occult Blood Self Test</td>
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<tr>
<td>__ Medical Disposables Co., MD IFOB One Step Rapid Test</td>
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<tr>
<td>__ Medline iFOB TEST</td>
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<tr>
<td>__ Rapid Response Fecal Occult Blood Self Test</td>
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<tr>
<td>__ Sekisui Dagonstics, LLC OSOM iFOB Test</td>
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<td>__ Siemens Hematest Reagent Tablets</td>
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<td>__ Smithkline Gastroccult</td>
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<td>__ Tanner Scientific iFOB One Step Rapid Test</td>
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<td>Osmolarity</td>
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<td>__ TearLab Osmolarity System</td>
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<td>Osteoporosis</td>
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<td>__ Ostex International Osteomark NTX</td>
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<td>Ovulation Tests</td>
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<tr>
<td>__ Visual color comparison tests for human luteinizing hormone</td>
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<tr>
<td>__ BTNX Inc rapid Response LH Ovulation Test</td>
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<tr>
<td>__ Luna Fertility Indicator (saliva)</td>
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<tr>
<td>__ O2 Unlimited Donna Ovulation Test (saliva)</td>
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<tr>
<td>__ Stesans Maybe?Mom Mini Ovulation Microscope (saliva)</td>
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<td>__ TCI Ovulation Tester (saliva)</td>
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<td>PH</td>
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<td>__ All qual. color comparison pH - body fluids (not blood)</td>
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<tr>
<td>__ Common Sense Fem’V/VI/VA/VS/Norma Sense (vag pH)</td>
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<tr>
<td>__ Dale Med Products RightSpot/RightLevel (gastric pH)</td>
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<tr>
<td>__ Duramed AmniScreen Home Dection Liner Kit</td>
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<tr>
<td>__ Fisher Scientific Sure-Vue RSV Test</td>
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<td>__ Integrated Biotechnology Quick Lab RSV Test</td>
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<td>__ Meridian Bioscience Immunocard Stat! RSV Plus</td>
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<tr>
<td>__ Binax NOW RSV Test</td>
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<tr>
<td>__ Cepheid Gene Xpert Xpress System (Flu+RSV)</td>
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<td>__ Cobas RSV Nucleic Acid Test for Use on the cobas Liat System</td>
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<tr>
<td>__ Fisher Scientific Sure-Vue RSV Test</td>
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<td>__ General Diagnostics Quick Lab RSV Test</td>
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<td>__ Meridian Bioscience Immunocard Stat! RSV Plus</td>
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<td>__ Quidel Quick Vue RSV Test</td>
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<tr>
<td>__ Quidel Sofia 2 (Sofia RSV FIA)</td>
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<tr>
<td>__ Quidel Sofia RSV</td>
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<tr>
<td>__ Rapid Response RSV Test</td>
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<td>__ Remel Xpect RSV</td>
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<td>__ SA Scientific SAS RSV Test/RSVAlert</td>
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<td>__ Sofia 2 for use with the Sofia RSV FIA</td>
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<tr>
<td>__ Wampole Laboratories Clearview RSV</td>
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<td>Waived Tests (continued)</td>
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<td><strong>Semen</strong></td>
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<tr>
<td>- Embryotech Laboratories FertilMARQ for male infertility</td>
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<td>- Fertell Male Fertility Test</td>
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<tr>
<td>- Fertility Solutions Semen Analysis (qualitative)</td>
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<td>- SpermCheck Fertility</td>
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<td>- SpermCheck Vasectomy</td>
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<td>- Trak Male Fertility Testing System</td>
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<td>- YO Home Sperm Test</td>
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<td><strong>Sodium</strong></td>
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<tr>
<td>- Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge</td>
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<tr>
<td>- Piccolo xpress &amp; Blood Analyzers (CMP, BMP, lytes, Metlyte, 8, Renal)</td>
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<td><strong>Strep Antigen Test</strong></td>
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<td>- Abbott Signify Strep A Test / Dipstick</td>
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<td>- Acceava Strep A Test/Twist Rapid Test</td>
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<tr>
<td>- AccuStrip Strep A</td>
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<tr>
<td>- ACON Strep A Rapid, Strep A Twist Rapid, and ICON DS</td>
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<td>- Alere, Strep A, Alere I Instrument</td>
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<td>- Applied Biotech SureStep Strep A (II)/Strep A Exact</td>
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<tr>
<td>- Beckman Coulter ICON Fx (formerly SmithKline)</td>
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<tr>
<td>- Beckman Coulter Primary Care Diag. DS, FX, and SC</td>
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<td>- Becton Dickinson Chek Group A Strep Test</td>
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<td>- Becton Dickinson LINK 2 Strep A Rapid Test</td>
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<td>- BD LINK 2/Chek Strep A Rapid test /Veritor System</td>
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<td>- Binax NOW/Clearview Advanced Strep A Test</td>
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<td>- BioStar Acceava™ Strep A Test</td>
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<tr>
<td>- Biotechnostix Rapid Resp. Strep A Rapid Test Device/Strip</td>
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<td>- BTNX Rapid Response Strep A Rapid Test Strips</td>
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<td>- Cardinal Health CP Brand Rapid Test Dipstick/Cassette</td>
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<td>- Clarity Strep A Rapid Test</td>
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<td>- Clearview Strep A Exact Dipstick</td>
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<td>- CLIA Waived Inc Rapid STREP A Test</td>
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<td>- Consult Diagnostics STREP A RAPID Dipstick</td>
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<td>- CTMI (Cole-Taylor Marketing Inc) Strep A Rapid Test Strip</td>
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<td>- DE Healthcare Products, TruView Strep A Test/Cassette</td>
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<td>- Diagnostic Test Group Clarity Strep A Rapid Test Strips</td>
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<td>- Fisher HealthCare Sure-Vue Strep A</td>
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<tr>
<td>- Genzyme Contrast Strep A and OSOM Ultra Strep A</td>
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<td>- Germaine Laboratories Strep AIM Rapid Dipstick Test</td>
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<td>- Germaine Laboratories Strep AIM Tower</td>
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<tr>
<td>- Henry Schein OneStep+/OneStep + Strep A Test/Strep A Dipstick</td>
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<td>- IMCO Strep A Rapid Test</td>
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<td>- IMI Signify Strep A Dipstick</td>
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<td>- Immunostics Immuno/Strep A Detector, Strep A Direct</td>
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<td>- Instant Technologies Istep Strep A Test</td>
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<td>- Inverness Medical BioStar Acceava Strep A Test/Twist</td>
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<tr>
<td>- Inverness Medical Clearview Strep A Exact II Dipstick</td>
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<tr>
<td>- Inverness Medical Signify Strep A Cassette</td>
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<td>- Jant Pharm. AccuStrip Strep A (II), Accutest Integrated Strep A Rapid Test, Clinipak Rapid Test Strip, Value+ Test</td>
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<tr>
<td>- Laboratory Supply Co PEP Strep A Cassette, Dipstick</td>
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<td>- LABSCO Advantage Strep A</td>
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<td>- LifeSign LLC Status Strep A</td>
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<td>- Mainline Confirms Strep A Dots test</td>
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<td>- McKesson Consult Diagnostics Strep A Test Dipstick</td>
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<td>- McKesson Strep A Medi-lab Performance Dipstick/Cassette/ Strep A Test - Twist/Dipstick</td>
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<td>- MediLab Performance Strep A Twist Rapid Test</td>
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<td>- Medline Strep A Test Strips (Throat Swabs)</td>
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<td>- Meridian Diag. ImmunoCard STAT Strep A</td>
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<td>- Moore Medical Strep A Rapid Test - Dipstick/Cassette</td>
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<td>- OneStep Pro+ Mono (WB)</td>
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<td>- Performance Enhanced Products Strep A Cassette, Dipstick</td>
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<tr>
<td>- PerMaxin Rediscreen Strep A Rapid/Strep A Twist Cassette</td>
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<tr>
<td>- Polymedco Poly stat a (II), Strep A Liquid Test, Strep A Dipstick</td>
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<td>- Poly stat Strep A Flip Test</td>
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<td>- Princeton BioMediTech BioStrep A /Status First Strep A</td>
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<td>- ProAdvantage by NDC Strep A Test</td>
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<td>- PSS Consult Diaq Strep A Dipstick</td>
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<td>- PSS World Medical Strep A Dipstick/Twist</td>
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<tr>
<td>- Quidel QuickVue In-Line and Dipstick and In-Line one-step</td>
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<tr>
<td>- Quidel Sofia 2 (Sofia Strep A+ FIA) throat swab only</td>
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<td>- Quidel Sofia Strep A+ FIA (from throat swab only)</td>
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<td>- RAC Medical Clarity Strep A Twist Rapid Test Device/Strip</td>
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<td>- Remel RIM A.R.C. Strep A Test</td>
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<td>- Roche Molecular, Cobas Lat System</td>
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<td>- Sacks Medical Refuah Strep A Rapid Test</td>
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<td>- SA Scientific SAS Strep A</td>
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<td>- Sekisui Diagnostics OSOM Strep A Test (direct - throat swab)</td>
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<td>- Sekisui Diagnostics OSOM Ultra Strep A Test</td>
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<td>- Select Medical Products Brand Rapid Test Strep A Dipstick</td>
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<td>- Select Medical Products Brand Rapid Test Strep A Twist</td>
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<tr>
<td>- Signify Strep A Dipstick</td>
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<td>- SMC Direct, LLC, RefuAH Strep A Rapid</td>
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<tr>
<td>- Stanbio Qustick Strep A, E-Z Well Strep A Rapid Test</td>
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<td>- StatusFirst Strep A</td>
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<td>- Wondfo Biotech Co., Ltd, Preview Strep A Test Kit</td>
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<td>- Wondfo Biotech Co., Ltd, WondView Strep A Test Kit</td>
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<td>- Wondofo One Step Strep A Swab Test</td>
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<td>- Wyntek Diag. OSOM Strep A and OSOM Ultra Strep A Test</td>
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<tr>
<td><strong>Syphilis</strong></td>
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<tr>
<td>- Diagnostics Direct LLC Syphilis Health Check (Fingerstick WB Only)</td>
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<tr>
<td><strong>Trichomonas</strong></td>
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<tr>
<td>- Genzyme Osm Trichomonas Rapid Test</td>
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<tr>
<td>- Sekisui Diagnostcs OSOM Trichomonas Rapid Test</td>
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</table>
### Waived Tests (continued)

#### Triglycerides
- Alere Cholestech LDX (triglyceride) (WB)
- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Cholestech LDX
- Infopia USA LipidPro/Lipid Profile Test Strips/Lipid Profile & Glucose Measuring System
- Jant Pharmacal LipidPlus Lipid Profile and Glucose System
- Mission Cholesterol Monitoring and Mission Cholesterol Pro Monitoring System
- Piccolo POC/xpressAnalyzer (Lipid Panel/Plus)
- Piccolo xpress Chem Analyzer (capillary-fingerstick)
- Polymer Tech. Systems Bioscanner, Bioscanner Plus, & 2000
- Polymer Technology Cardiocheck test strips (Plus, Home Use, and PA)
- SD Biosensor USA, Inc., SD LipidoCare Home System (SD LipidoCare (BT) Home and Professional Lipid Panel Test Strip)
- Wako APOLOWAKO Analyzer (WB)

#### TSH
- Aventir Biotech LLC FORSURE TSH (WB)
- BTNX Inc Rapid Response TSH test cassette (WB)
- CLIA Waived Inc Thyroid Test Rapid TSH Cassette (WB)
- Germaine Laboratories, Inc AimStep Thyroid Screen (WB)
- Jant Pharmacal Corp Accutest TSH (WB)
- Little Nell Labs ThyroChek TSH (WB)
- Pharmaceutical Marketing Thyroset TSH (WB)
- Qualigen Inc FastCheck TSH (WB)
- ThyroTest Whole Blood TSH Test (WB)

#### Uric Acid
- Nova Max Uric Acid Monitoring System (Fingerstick Whole Blood)
- Piccolo xpress & Blood Chem Analyzers (chem 13)WB

#### Urinalysis
- Urinalysis: Dipstick or tablet reagent (nonautomated)
- Acon Lab Insight U120 Urine Analyzer
- Acon Lab. Mission UTI Urinary Tract Infection Test Strips
- Acon Mission U120/Foresight U120 Urine Analyzer
- Biosys Laboratories Optima/Optima II Urine Analyzer
- BTNX Rapid Response U120 Urine Analyzer
- Chemstrip Mini UA
- Clarity Diagnostics LLC, Clarify U122 Urine Analyzer
- Clarity Diagnostics LLC, Clarity Urocheck U120C Urine Analyzer Test System Urinalysis Reagent Strips
- McKesson Medical-Surgical Inc., Consult Diagnostic Microalbumin/Creatinine Urine Reagent Strips 2 Parameter
- NDC Inc., Pro Advantage Urine Analyzer Test System
- Cole-Taylor Marketing Inc CTI-120 Urine Strip Analyzer
- Consult diagnostics Urine Analyzer
- Diagnostic Group Clarity Urucheck 120 Urine Analyzer
- Express Diagnostics International, Incorporated UTI Test Strips
- Express Diagnostics International, Incorporated Urine Reagent Strips 10 for Urinalysis
- Germaine Laboratories AimStrip Urine Analyzer
- Germaine Laboratories, Inc. AimStrip Urine Analyzer 2 System
- Henry Schein OneStepPlus/Uriscpec Plus Urine Analyzer
- Hypoguard Diascreen 50 Urine Chemistry Analyzer
- Immunostics Inc Detector Uristrip+ Analyzer
- Jant Pharmacal Corporation Accustrip URS Reader
- McKesson 120 Urine Analyzer
- Mediwatch urinewatch Urine Analyzer
- Medline 120 Urine Analyzer
- Moore Medical Urine Analyzer U120
- NDC Pro Advantage by NDC Urine Analyzer
- PSS Select Urine Analyzer
- RefuAH U120 Urine Analyzer
- Roche/BMC Mini UA and Chemstrip 101 Urine Analyzer
- Roche Diagnostics Urisys 1100 Urine Analyzer
- Siemens Clinitek 50/Status/Status+/Status Connect Analyzers
- Stanbio Uri-Trak 120 Urine Analyzer
- ThermoBiostar PocketChem UA
Provider-Performed Microscopic Procedures (PPMP)

These tests can only be performed in your office by an MD, DO, DPM, ARNP, midwife, PA, naturopath, or dentist. You do not qualify for this license type if these tests are performed by any other personnel in your office. See the LQA Web site: http://www.doh.wa.gov/lqa.htm to help you determine your correct license category or call the LQA office at 253-395-6746.

Check all that apply

- Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- Fecal leukocyte examinations
- Fern tests
- Nasal Smears for granulocytes
- Pinworm examinations
- Post-coital direct, qualitative examinations of vaginal or cervical mucous
- Potassium hydroxide (KOH) preparations
- Qualitative semen analysis (limited to the presence/absence of sperm and detection of motility)
- Urine sediment examinations

Section 5. Other Licensure, Certification or Registration Information

Legal Owner Information—attach additional sheets as needed

List names, addresses, phone numbers, and titles of corporate officers, partners, members, managers, etc.

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Phone #</th>
<th>Title</th>
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<tbody>
<tr>
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Change of Ownership Information

Previous Name of Legal Owner

<table>
<thead>
<tr>
<th>Previous Name of Facility</th>
<th>Previous MTS License #</th>
<th>Effective Date of Ownership Change</th>
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Physical Address

City | State | Zip Code
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Signature

I certify that I have received, read, understood, and agree to comply with state law and rule regulating this licensing category. I also certify that the information herein submitted is true to the best of my knowledge and belief.

Signature of Owner/Authorized Representative of Medical Test Site | Date
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Print Name | Print Title
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