Categorized Medical Test Site (MTS) Application Packet

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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 facilities, such as hospitals, where testing may be performed at different locations, all areas of laboratory testing must be covered by an MTS license. It is the facility’s choice whether to include point of care (ancillary) testing under the same MTS license as the main laboratory, or license separately. Please coordinate with your administration to ensure that all testing is licensed.

The Joint Commission has granted the Washington State MTS licensing program deemed status. If your MTS is located in a facility accredited by the Joint Commission, you have the option of being inspected by the state Office of Laboratory Quality Assurance. If your medical test site is currently accredited by the Joint Commission and you choose to have the MTS program do the laboratory inspection, complete this application.

Contact one of the proficiency testing providers listed to enroll in a proficiency testing program/programs to cover all of the testing performed in your facility.

If you want your laboratory to be inspected by a private accreditation organization, do not complete this application. Complete the Accredited MTS/CLIA license application.

In order to process your request:
Return Completed Application (original copy):
Department of Health
Medical Test Site Credentialing
P.O. Box 47877
Olympia, WA 98504-7877
**Fee Information**

Do not send a check with your application.

The application test information will be reviewed and analyzed to determine the category of license. You will receive a billing statement indicating your license category fee.

The categories are based on the number of specialties (SPEC) performed and the estimated annual volume of testing. MTS licenses issued during the first year of the state biennium (7/01/17 through 6/30/19) will be charged the full fee. MTS licenses issued during the second year of the state biennium (7/01/18 through 6/30/19) will be charged half of the full fee. The license categories and corresponding fees are:

<table>
<thead>
<tr>
<th>Category</th>
<th>Fee – Applies to first year of the Biennium 7/01/17 – 6/30/19</th>
<th>Fee – Applies to Second year of the Biennium 7/01/18 – 6/30/19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Volume (1-2000)</td>
<td>$450</td>
<td>$225</td>
</tr>
<tr>
<td>A (2,001-10,000, 3 SPEC)</td>
<td>$1,364</td>
<td>$682</td>
</tr>
<tr>
<td>B (2001-10,000, 4 SPEC)</td>
<td>$1,769</td>
<td>$885</td>
</tr>
<tr>
<td>C (10,001-25,000, 3 SPEC)</td>
<td>$2,454</td>
<td>$1,227</td>
</tr>
<tr>
<td>D (10,001-25,000, 4 SPEC)</td>
<td>$2,818</td>
<td>$1,409</td>
</tr>
<tr>
<td>E (25,001-50,000)</td>
<td>$3,382</td>
<td>$1,691</td>
</tr>
<tr>
<td>F (50,001-75,000)</td>
<td>$4,187</td>
<td>$2,094</td>
</tr>
<tr>
<td>G (75,001-100,000)</td>
<td>$4,991</td>
<td>$2,496</td>
</tr>
<tr>
<td>H (100,001-500,000)</td>
<td>$5,835</td>
<td>$2,918</td>
</tr>
<tr>
<td>I (500,001-1,000,000)</td>
<td>$10,369</td>
<td>$5,185</td>
</tr>
<tr>
<td>J (&gt;1,000,000)</td>
<td>$12,443</td>
<td>$6,222</td>
</tr>
</tbody>
</table>
Categorized Medical Test Site Application Instructions Checklist

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 2 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: 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.

Non Waived Tests: Place a checkmark by all the non waived tests performed at your medical test site. If the tests performed are not listed, add the tests under the appropriate specialty/subspecialty (bold headings). For volumes, include the yearly number estimate of tests performed. Attach additional sheets if needed. Do not include waived or PPMP tests when counting volumes.

Use the following guidelines for counting tests:
Allergens: count each individual allergen as one test.
Chemistry profiles: count each individual analyte separately.
Complete blood counts: count each measured individual analyte separately that is ordered and reported separately. Differentials are counted as one test. Manual differentials are counted as a separate test.
Cytogenetics: the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests.
Cytology: count each slide (not case) as one test for both pap smears and nongynecologic cytology.
Histocompatibility: count each HLA typing (including disease associated antigens), HLA anti-body screen, or HLA crossmatch as one test.
Histopathology: count each block (not slide) as one test. Autopsy services are not included.

For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.
**Immunohematology:** count each ABO, Rh, antibody screen, crossmatch, or antibody identification as one test.

**Microbiology:** count susceptibility testing as one test per group of antibiotics used to determine sensitivity for one organism. Count cultures as one per specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.

**Urinalysis:** count microscopic and macroscopic examinations as separate tests. Count macroscopics (dipsticks) as one test regardless of the number of reagent pads on the strip.

☐ **Section 5. Personnel Qualification Requirements:**

Personnel Qualification Requirements (Moderate & High Complexity Testing):

These are categories of personnel required for moderate and high complexity testing sites. Place a checkmark by the appropriate personnel qualifications for the complexity of testing in your facility.

If the MD, DO, or DPM needs to obtain the 20-hour CME credits to qualify as the director of a moderate complexity laboratory, the following courses are available:

- **University of Iowa Carver College of Medicine**
  On-line laboratory director course: [http://www.medicine.uiowa.edu/cme/clia/](http://www.medicine.uiowa.edu/cme/clia/)

- **University of Wisconsin and COLA**
  Physician’s Office Laboratory (POL) Symposium: Three-day meeting with national speakers and exhibits containing POL equipment.
  [www.COLA.org](http://www.COLA.org) or 800-981-9883.

- **University of Wisconsin and COLA**
  Lab University: On-line laboratory director course [www.labuniversity.org](http://www.labuniversity.org).

These courses are designed to meet the CLIA requirement at 493.1405(b)(2)(ii)(B). They are accredited by the ACCME and are designated as AMA PRA category 1 credits.

☐ **Section 6. 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](http://www.doh.wa.gov/lqa.htm).
Proficiency testing (PT), as required under Medical Test Site WAC 246-338-050, is a source of external quality control. This practice of testing unknown specimens from an outside source provides an additional means to assure quality laboratory testing results. Although laboratories perform daily internal quality control with their test systems, external quality control provides important interlaboratory comparisons to determine the accuracy and reliability of your testing procedures.

You must enroll in PT for all regulated analytes listed on the next page. A listing of the currently approved PT programs and their phone numbers can also be found on the next page. Call the programs for a free copy of their PT brochure.

You must enroll in programs that cover the testing that you are performing. Generally, most programs are five-sample modules shipped in three test events during the exam. All regulated analytes must be covered by PT under the five-sample program.

Information needed to enroll:

• Complete the order form in the PT brochure which asks for your name (use the name exactly as it appears on your MTS license; no other name is accepted),
• Address,
• CLIA ID number, and;
• MTS license number.

Select the appropriate program for your laboratory. Remember to indicate on the order form that a copy of your PT results be sent to the Office of Laboratory Quality Assurance. This must be done for each analyte.

For PPMP procedures and moderate and high complexity tests that are not on the regulated analyte list, you must have a means of establishing the accuracy of the procedure two times a year (biannual verification). The two-sample PT programs can be used for this purpose for tests that are not included on the regulated analyte list.

What must I do if I add a new test? You must notify our office within 30 days and if this new test is a regulated analyte, you must cover the test in the next PT event. When you notify us, we will remind you to enroll in PT and ask you for proof of enrollment.

What if I decide to stop testing an analyte? You must notify our office within 30 days that you have stopped testing. If you have signed up for PT for this analyte, be sure to choose the code “test not performed” on the PT answer sheet.

If you have other questions, call 253-395-6746.

Additional information is available at our Web site: http://www.doh.wa.gov/lqa.htm.

Tips for Proficiency Testing Success

Improve your chances for successful participation in PT, by considering the following suggestions:

• Fill in the Method Code.
  Remember to always fill in the method code, do not leave blank.

• Correctly report the reason PT was not done.
  If you are unable to test for some reason, be certain to indicate this on the answer sheet. If you discontinued testing for an analyte, indicate this on the sheet. Immediately notify LQA of any change.

• Be timely.
  Always be sure to meet the deadline for returning your results.

• Review your graded results. Document corrective action when any PT result is unsatisfactory.
Approved Proficiency Testing Providers

- Accutest 800-665-2575
- Amer. Acad. of Family Physicians 800-274-7911
- Amer. Assoc. of Bioanalysts 800-234-5315
- American Proficiency Institute 800-333-0958
- ASIM Medical Lab Evaluation 800-338-2746
- College of American Pathologists 800-323-4040
- EXCEL (CAP) 800-323-4040
- Wisconsin State Lab. of Hygiene 800-462-5261

Regulated Analytes:
These Tests MUST be Covered by PT

**Chemistry**
- ALT/SGPT
- Albumin
- Alkaline phosphatase
- Amylase
- AST/SGOT
- Bilirubin, total (or neonat.)
- Blood gas pO2, pCO2, pH
- Calcium, total
- Chloride
- Cholesterol, total
- HDL cholesterol
- Creatine kinase
- Creatine kinase isoenzymes
- Creatinine
- Glucose
- Iron, total
- LDH
- LDH isoenzymes
- Magnesium
- Potassium
- Sodium
- Total protein
- Triglycerides
- Urea nitrogen
- Uric acid

**Endocrinology**
- Cortisol
- Free thyroxine
- Serum pregnancy (HCG) (qualitative or quantitative)
- T3 uptake
- Triiodothyromine
- TSH Thyroxine

**Toxicology**
- Alcohol, blood
- Blood lead
- Carbamazepine
- Digoxin
- Ethosuximide
- Gentamicin
- Lithium
- Phenobarbital
- Phenytoin
- Primidone
- Procainamide (& metabolite)
- Quinidine
- Tobramycin
- Theophyline
- Valproic acid

**Hematology**
- Cell identification
- Auto or manual WBC diff.
- Erythrocyte count (RBC)
- Hematocrit (automated)
- Hemoglobin
- Leukocyte count (WBC)
- Platelet count
- Fibrinogen
- Partial thromboplastin time
- Prothrombin time

**Immunohematology**
- ABO group
- D (Rh typing)
- Unexpected Antibody detection
- Compatibility testing
- Antibody identification

**Syphilis Serology**
- RPR, VDRL, MHA–TP, etc.

**Immunology**
- Alpha–1 antitrypsin
- AFP (tumor marker)
- Antinuclear antibody
- ASO
- HIV
- Complement C3, C4

**Immunology (cont.)**
- HBsAg, Anti–HBc, HBeAg
- IgA, IgE, IgG, IgM
- Infectious mononucleosis
- Rheumatoid factor
- Rubella

**Bacteriology**
- Chlamydia
- Direct Strep test
- GC
- Throat culture
- Urine culture ID
- Gram stain
- Other culture/combinations
- Antimicrobial tests

**Mycology**
- Yeast ID/culture
- Fungus culture–systemic

**Parasitology**
- Direct only
- Concentration/Stain

**Virology**
- HSV EIA
- Culture or FA
- Other EIA for virus

**Mycobacteriology**
- AFB Smear and/or culture
Categorized Medical Test Site License Application

This is for:  
☐ New  ☐ Change of Ownership  ☐ Change of License Type

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

Section 1. Demographic Information

UBI #  Federal Tax ID (FEIN) #

Legal Owner/Operator Entity Name

Mailing Address

City  State  Zip Code  County

Phone (enter 10 digit #)  Fax (enter 10 digit #)

Email Address  Web Address

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

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

Physical Address

City  State  Zip Code  County

Facility Phone (enter 10 digit #)  Facility Fax (enter 10 digit #)

Mailing Address (If different than physical address)

City  State  Zip Code  County

For Office Use Only

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

Site Type (check one only)

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

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
### 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)

<table>
<thead>
<tr>
<th>Category</th>
<th>Test Kit/System</th>
</tr>
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<tbody>
<tr>
<td><strong>Adenovirus</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Aerobic/Aerobic Organisms</strong></td>
<td></td>
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<tr>
<td><strong>Aerobic/Aerobic/Viral Panel – Respiratory</strong></td>
<td></td>
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<tr>
<td><strong>Alanine Aminotransferase (ALT)</strong></td>
<td></td>
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<tr>
<td><strong>Albumin</strong></td>
<td></td>
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<tr>
<td><strong>Alkaline Phosphatase (ALP)</strong></td>
<td></td>
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<tr>
<td><strong>Amylase</strong></td>
<td></td>
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<tr>
<td><strong>Aspartate Aminotransferase (AST)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>B-Type Natriuretic Peptide (BNP)</strong></td>
<td></td>
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<tr>
<td><strong>Bilirubin, Total</strong></td>
<td></td>
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<tr>
<td><strong>Bladder tumor associated antigen</strong></td>
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<tr>
<td><strong>BUN (Blood Urea Nitrogen)</strong></td>
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<tr>
<td><strong>Calcium</strong></td>
<td></td>
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<tr>
<td><strong>Carbon Dioxide (CO2)</strong></td>
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<tr>
<td><strong>Catalase, urine</strong></td>
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<tr>
<td><strong>Chloride</strong></td>
<td></td>
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<tr>
<td><strong>Cholesterol</strong></td>
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<tr>
<td><strong>Complete Blood Count (CBC)</strong></td>
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<tr>
<td><strong>Creatine Kinase (CK)</strong></td>
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</tbody>
</table>

**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)
- Arkay SPOTCHEM EZ Chem Analyzer (ALT) (WB)
- Piccolo Point of Care/Blood Chem/xpress Chem Analyzer (ALT) (WB) (Lipid Panel Plus, Liver Panel Plus, CMP, BMP)

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

**Alkaline Phosphatase (ALP)**
- Arkay SPOTCHEM EZ Chem Analyzer (ALT) (WB)
- Piccolo Point of Care/Blood Chem/xpress Chem Analyzer (ALT) (WB) (Lipid Panel Plus, Liver Panel Plus, CMP, BMP)

**Aspartate Aminotransferase (AST)**
- Alere Cholestech LDX (AST) (WB)
- Arkay SPOTCHEM EZ Chem Analyzer (AST) (WB)
- Cholestech LDX Aspartate Aminotransferase (AST)

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

**Bilirubin, Total**
- Arkay SPOTCHEM EZ Chem Analyzer (WB)
- Piccolo Point of Care/Blood Chemistry Analyzer 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
- Piccolo xpress/Blood Analyzers (chem 6/13, kidney, CMP, BMP, Metlyte 8, Renal)

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

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

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

**Chloride**
- Abbott i-STAT CHEM8+6+ Cartridge
- Piccolo xpress & Blood Analyzers (CMP,BMP,lytes,metylte 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)
- Arkay 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
- Lifestream Technologies Cholesterol Monitors
- 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 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 (Metyle 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
- Teco Diagnostics Saliva Alcohol Test

Follicle Stimulating Hormone (FSH)
- Acon Lab FSH Menopause Predictor Test
- Acon Lab FSH One Step Menopause Test Strip/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
- Phamatech 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+/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 Biogapher
- 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 Monitor 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 I HbA1c/G5 II 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)

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholestech LDX</td>
<td>Infopia USA LipidPro/Lipid Profile Test Strips/Lipid Profile &amp; Glucose Measuring System</td>
</tr>
<tr>
<td>Jant Pharmacal LipidPlus Lipid Profile and Glucose System</td>
<td>Mission Cholesterol Monitoring System and Mission Cholesterol Pro Monitoring System</td>
</tr>
<tr>
<td>Piccolo POC/xpress Chemistry Analyzer WB (Lipid Panel/Plus)</td>
<td>Piccolo xpress Chem Analyzer (capillary-fingerstick)</td>
</tr>
<tr>
<td>Polymedco Polystat</td>
<td>Polymer Technology Systems BioScanner Plus and 2000 Polymer Technology Cardiochek test strips (Plus, Home Use, and PA)</td>
</tr>
<tr>
<td>SD Biosensor USA, Inc., SD LipidoCare Home System (SD LipidoCare Home Lipid Panel Test Strips)</td>
<td>SD Biosensor USA, Inc., SD LipidoCare (BT) Professional System (SD LipidoCare Professional System (SD LipidoCare (BT) Professional Lipid Panel Test Strip)</td>
</tr>
<tr>
<td>Helicobacter pylori</td>
<td>Abbott FlexPack HP, Signify, Cassette, and TestPack Plus (WB)</td>
</tr>
<tr>
<td>Acon H. pylori Rapid Test Device (WB)</td>
<td>Alfa Scientific Designs Instant View (WB)</td>
</tr>
<tr>
<td>Applied Biotech SureStep (WB)</td>
<td>ARJ Pylo-Plus Urease (gastric biopsy)</td>
</tr>
<tr>
<td>Ballard (Delta West) CLOtest (gastric biopsy)</td>
<td>Beckman Couler Flexsure (WB)</td>
</tr>
<tr>
<td>Becton Dickinson LINK 2 (WB)</td>
<td>BTNX Inc Rapid Response H. pylori Rapid Test Device(WB)</td>
</tr>
<tr>
<td>Cardinal Health SP Brand Rapid Test (WB)</td>
<td>Clarity H. pylori Rapid Test Device (WB)</td>
</tr>
<tr>
<td>ChemTrak AccuMeter (WB)</td>
<td>CLIA waived H. pylori Whole Blood Rapid Test</td>
</tr>
<tr>
<td>De Healthcare Products Truvue H. pylori (WB)</td>
<td>Diagnostic Test Group Clarity H. pylori Rapid Test Device (WB)</td>
</tr>
<tr>
<td>EarlyDetect H. pylori Whole Blood Rapid Test</td>
<td>Fisher Healthcare Sure-Vue H. pylori Test (WB)</td>
</tr>
<tr>
<td>Germaine Laboratories AimStep (WB)</td>
<td>GI Supply HP-FAST and HP One (gastric biopsy tissue)</td>
</tr>
<tr>
<td>Henry Schein OneStep+ / Rapid Test Device (WB)</td>
<td>Immunostics Detector H. pylori (WB)</td>
</tr>
<tr>
<td>Instant Technologies iScreen (WB)</td>
<td>Inverness BTN Inc Rapid Response H. pylori Test (WB)</td>
</tr>
<tr>
<td>Inverness Medical Clearview/SIGNIFY H. pylori Test (WB)</td>
<td>Jant Pharmacal Corp. Accutest Rapid Test Device (WB)/ Rapid Urease Test</td>
</tr>
<tr>
<td>LifeSign and LifeSign Status (WB)</td>
<td>McKesson H. pylori Test (WB)</td>
</tr>
<tr>
<td>McKesson Medi-Lab Performance H. pylori Test (WB)</td>
<td>McKesson Medi-Lab Performance H. pylori Test (WB)</td>
</tr>
<tr>
<td>Medical Instruments Corp Pronto Dry (gastric biopsy)</td>
<td>Medline H. pylori Test Cassette (WB)</td>
</tr>
<tr>
<td>Meridian Bioscience ImmunoCard STAT! (WB)</td>
<td>Polymedco Polystat (WB)</td>
</tr>
<tr>
<td>PreMaxim RadiScreen Test Device (WB)</td>
<td>Princeton BioMeditech BioSign (WB)</td>
</tr>
<tr>
<td>PRO-Advantage by NDC H. pylori Device (WB)</td>
<td>PSS Consult H. pylori Cassette (WB, fingerstick only)</td>
</tr>
<tr>
<td>Quidel QuickVue gII/One-Step/One-Step II (WB)</td>
<td>Remel RIM A.R.C. (WB)</td>
</tr>
<tr>
<td>Roche Diagnostics AccuStat H. pylori OneStep (WB)</td>
<td>Select Medical Products Brand Rapid Test H. pylori (WB)</td>
</tr>
<tr>
<td>Serim Pyloritek test Kit and VP Test Kit (gastric biopsy)</td>
<td>SmithKline FlexSure HP (WB)</td>
</tr>
<tr>
<td>Stanbio RELY H.pylori (WB fingerstick only)</td>
<td>Trinity Uni-Gold (WB)</td>
</tr>
<tr>
<td>Wampole Laboratories Clearview H. pylori II (WB)</td>
<td>Hematocrit</td>
</tr>
<tr>
<td>Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge</td>
<td>Microhematocrit (spun)</td>
</tr>
<tr>
<td>Alere HemoPoint H2 Hemoglobin Measuring System</td>
<td>Micro Diagnostics Spuncrit DRC-40 Infrared Analyzer</td>
</tr>
<tr>
<td>Avie Total Hb Test System (professional use)</td>
<td>UltraCrit</td>
</tr>
<tr>
<td>Biosafe Anemipro Self Screener</td>
<td>Wampole STAT-CRIT for hematocrit</td>
</tr>
<tr>
<td>Biotest Hemoglobin Measuring System</td>
<td>Hemoglobin</td>
</tr>
<tr>
<td>Clarity HbCheck Hemoglobin Testing System</td>
<td>Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge</td>
</tr>
<tr>
<td>CLIAwaived Inc. Hemoglobin (Hb) Testing System</td>
<td>Aim Strip Hb Hemoglobin (Hb) Testing System</td>
</tr>
<tr>
<td>Copper Sulfate (non-automated)</td>
<td>Alere HemoPoint H2 Hemoglobin Measuring System</td>
</tr>
<tr>
<td>Diaspect Hemoglobin Measuring System</td>
<td>Avie Total Hb Test System (professional use)</td>
</tr>
<tr>
<td>EKF Diag. Hemo_Control Measurement &amp; Microcuvettes</td>
<td>Biosafe Anemipro Self Screener</td>
</tr>
<tr>
<td>HemoCue hemoglobin test systems (201, 201+, 301)</td>
<td>Biotest Hemoglobin Measuring System</td>
</tr>
<tr>
<td>HemoCue Donor Hemoglobin Checker System</td>
<td>Clarity HbCheck Hemoglobin Testing System</td>
</tr>
<tr>
<td>GDS Diagnostics HemoSite Meter for hemoglobin</td>
<td>CLIAwaved Inc. Hemoglobin (Hb) Testing System</td>
</tr>
<tr>
<td>GDS Technologies STAT-Site M Hgb Test System</td>
<td>Copper Sulfate (non-automated)</td>
</tr>
<tr>
<td>ITC HGB PRO Professional Hemoglobin Testing System</td>
<td>Diaspect Hemoglobin Measuring System</td>
</tr>
<tr>
<td>Mission Plus Hemoglobin (Hb) Testing System</td>
<td>EKF Diag. Hemo_Control Measurement &amp; Microcuvettes</td>
</tr>
<tr>
<td>Stanbio Hemoglobin Analyzer</td>
<td>HemoCue hemoglobin test systems (201, 201+, 301)</td>
</tr>
<tr>
<td>Stanbio HemoPoint H2/H2 DM Hemoglobin Measurement Syst</td>
<td>HemoCue Donor Hemoglobin Checker System</td>
</tr>
<tr>
<td>Hepatitis C Virus Antibody</td>
<td>HemoCue hemoglobin test systems (201, 201+, 301)</td>
</tr>
<tr>
<td>OraQuick Rapid Aby Test/OraQuick HCV Visual Ref Panel</td>
<td>Hemoglobin</td>
</tr>
<tr>
<td>Herpes</td>
<td>Herpes</td>
</tr>
<tr>
<td>Theranos anti-HSV-1 IgG Assay (Fingerstick WB Only)</td>
<td>Hemoglobin</td>
</tr>
<tr>
<td>HIV-1</td>
<td>Hemoglobin</td>
</tr>
<tr>
<td>Alere Determine HIV-1/2 Ag/Ab Combo Fingerstick WB</td>
<td>Alere Determine HIV-1/2 Ag/Ab Combo Fingerstick WB</td>
</tr>
<tr>
<td>bioLytical INSTI HIV-1 Antibody Test (fingertick WB)</td>
<td>Chembio DPP HIV 1/2 Assay (oral fluid)</td>
</tr>
<tr>
<td>Chembio HIV 1/2 STAT-PAK Assay (WB)</td>
<td>Chembio HIV 1/2 STAT-PAK Assay (WB)</td>
</tr>
<tr>
<td>Clearview COMPLETE HIV 1/2 fingerstick &amp; venipuncture WB</td>
<td>Clearview COMPLETE HIV 1/2 fingerstick &amp; venipuncture WB</td>
</tr>
<tr>
<td>Organics, Alere Determine HIV-1/2 Ag/Ab Combo (Fingertick WB)</td>
<td>OraQuick Advance Rapid HIV-1/2 Antibody (oral fluid, WB)</td>
</tr>
<tr>
<td>OraQuick Advance Rapid HIV-1/2 Antibody (oral fluid, WB)</td>
<td>HIV-1</td>
</tr>
</tbody>
</table>

### Hematocrit

- Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge
- Microhematocrit (spun)
- 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 Anemipro Self Screener
- Biotest Hemoglobin Measuring System
- Clarity HbCheck Hemoglobin Testing System
- CLIAwaved 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 Technologies 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

### Herpes

- Theranos anti-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 (fingertick 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
- Organics, Alere Determine HIV-1/2 Ag/Ab Combo (Fingertick WB)
- OraQuick Advance Rapid HIV-1/2 Antibody (oral fluid, WB)
Waived Tests (continued)

**Influenza**
- OraQuick In-Home HIV Test (oral fluid)
- OraQuick Rapid HIV-1 Antibody Test (oral fluid, WB)
- Trinity Biotech UniGold Recombigen HIV test (WB)

**Influenza**
- Alere BinaxNOW Influenza A & B Card (nasal swab/waah/aspirate)
- 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)
- Binax NOW Flu A and Flu B Tests and A&B Tests
- BioSign Flu A+B test (Nasal and NP)
- BTNX Rapid Response Influenza 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 Liastat 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
- sofa 2 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
- PEM Princeton Biomedical Corp. 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
- sofa 2 for use with Sofia Influenza A+B FIA
- Sofia Analyzer & Influenza A+B FIA (nasal, nasopharyngeal)
- ZymeTX Zstatflu (Influenza A/B)

**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)
- RemiLAB Inc. InstaRead Lithium System (WB)
- ReliaLAB Inc. InstaRead Lithium System (WB)
**Waived Tests (continued)**

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Brand and Description</th>
</tr>
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<tbody>
<tr>
<td>Seradyn Color Q Mono (WB)</td>
<td>Signify Mono Test / Mono Whole Blood / Mono Cassette (WB)</td>
</tr>
<tr>
<td>Stanbio Rely Mono Rapid Test (WB)</td>
<td>Wampole Mono-Plus WB (WB)</td>
</tr>
<tr>
<td>Wyntek Diagnostics OSOM and Signify Mono test (WB)</td>
<td>Femtek Phem-Alert (vaginal pH)</td>
</tr>
<tr>
<td></td>
<td>Li’l Drug Store Prod. Vagi-Screen Vaginal Health Test (vag pH)</td>
</tr>
<tr>
<td></td>
<td>Litmus Concepts FemExam Test Card (vaginal pH &amp; amines)</td>
</tr>
<tr>
<td></td>
<td>Quicke QuickVue Advance pH and Amines Test</td>
</tr>
<tr>
<td></td>
<td>RightBio Metrics Right Spot Infant pH Indicator/PH Indicator/ Detector</td>
</tr>
<tr>
<td><strong>Nicotine (or its metabolites)</strong></td>
<td><strong>Phosphorus</strong></td>
</tr>
<tr>
<td></td>
<td>Piccolo xpress/Blood Analyzers (Renal panel)</td>
</tr>
<tr>
<td>CLIAwaived Instant Nicotine Detection Test</td>
<td><strong>Platelet Aggregation</strong></td>
</tr>
<tr>
<td>DynaGen NicCheck 1 Test Strips</td>
<td><strong>Accumetrics VerifyNow Aspirin Assay</strong></td>
</tr>
<tr>
<td>Mossman Associates NicCheck I Test Strips</td>
<td><strong>Potassium</strong></td>
</tr>
<tr>
<td></td>
<td>Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge</td>
</tr>
<tr>
<td></td>
<td>Piccolo xpress/Blood Analyzers (CMP, BMP, lytes, Metlyte 8, Renal)</td>
</tr>
<tr>
<td><strong>Occult Blood</strong></td>
<td><strong>Pregnancy Test (Urinary)</strong></td>
</tr>
<tr>
<td>Aerscher Hemaprompt FG Gastric Occult Blood</td>
<td><strong>Urine pregnancy test: visual color comparison</strong></td>
</tr>
<tr>
<td>Alfa Scientific Designs Instant-View FOB Self-Test Cassette</td>
<td>Siemens Clinitek 50/Status Urine Chemistry Analyzer</td>
</tr>
<tr>
<td>Alfa Scientific Designs FOB Self-Test</td>
<td><strong>Protime</strong></td>
</tr>
<tr>
<td>Beckman Coulter Primary Care Diagnostics Gastrooccult/ Hemoccult Sensa Elite (gastric occult blood) Clarity Fecal Occult Blood Self Test</td>
<td>Alere INRatio2 PT/INR Monitoring System (Professional/ Home)</td>
</tr>
<tr>
<td>Compliance Gold Fecal Occult Blood Test – ER</td>
<td>AvoSure Pro and PT</td>
</tr>
<tr>
<td>Enterix Inc. InSure One – One Day Fecal Immunochemical Test</td>
<td>CoaguSense Prothrombin Time/Self-Test/Protime/INR</td>
</tr>
<tr>
<td></td>
<td>Hemosense INRATIO</td>
</tr>
<tr>
<td></td>
<td>International Technidyne Corporation Protime</td>
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<tr>
<td></td>
<td>Microcoagulation System and ProTime 3 Cuvette System</td>
</tr>
<tr>
<td></td>
<td>Lifescan Harmony INR Monitoring System</td>
</tr>
<tr>
<td></td>
<td>Lifescan Rubicom Prothrombin Time Monitoring System</td>
</tr>
<tr>
<td></td>
<td>Roche Diag CoaguChek &amp; CoaguChek S Sytems, PT-S Strips, XS, XS PST, XS Plus</td>
</tr>
<tr>
<td></td>
<td>Roche Diagnostics CoaguChek Vantus System (prothrombin)</td>
</tr>
<tr>
<td><strong>Osmolarity</strong></td>
<td><strong>Protein, Total</strong></td>
</tr>
<tr>
<td></td>
<td>Arkray SPOTCHEM EZ Chem Analyzer (WB)</td>
</tr>
<tr>
<td></td>
<td>Piccolo POC/xpress Chemistry Analyzer WB (Liver Panel Plus Reagent Disc, Chem 13, CMP)</td>
</tr>
<tr>
<td>TearLab Osmolarity System</td>
<td><strong>RSV (Respiratory Syncytial Virus Direct Antigen)</strong></td>
</tr>
<tr>
<td>Ostex International Osteomark NTX</td>
<td>Alere BinaxNOT RSV Card</td>
</tr>
<tr>
<td>Ovulation Tests</td>
<td>Alere i System</td>
</tr>
<tr>
<td></td>
<td>BD Veritor System for Rapid Detection RSV (nasopharyngeal)</td>
</tr>
<tr>
<td></td>
<td>Binax NOW RSV Test</td>
</tr>
<tr>
<td></td>
<td>Cepheid Gene Xpert Xpress System (Flu+RSV)</td>
</tr>
<tr>
<td></td>
<td>Cobas RSV Nucleic Acid Test for Use on the cobas Liat System</td>
</tr>
<tr>
<td></td>
<td>Fisher Scientific Sure-Vue RSV Test</td>
</tr>
<tr>
<td></td>
<td>Integrated Biotechnology Quick Lab RSV Test</td>
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<tr>
<td></td>
<td>Meridian Bioscience Immunocard Stat! RSV Plus</td>
</tr>
<tr>
<td></td>
<td>Quidel Quick Vue RSV Test</td>
</tr>
<tr>
<td></td>
<td>Quidel Sofia 2 (Sofia RSV FIA)</td>
</tr>
<tr>
<td></td>
<td>Quidel Sofia RSV</td>
</tr>
<tr>
<td></td>
<td>Rapid Response RSV Test</td>
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<td></td>
<td>Remel Xpect RSV</td>
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<tr>
<td></td>
<td>SA Scientific SAS RSV Test/RSVAlert</td>
</tr>
<tr>
<td></td>
<td>Sofia 2 for use with the Sofia RSV FIA</td>
</tr>
<tr>
<td></td>
<td>Wampole Laboratories Clearview RSV</td>
</tr>
<tr>
<td>Visual color comparison tests for human luteinizing hormone</td>
<td><strong>PH</strong></td>
</tr>
<tr>
<td>BTNX Inc rapid Response LH Ovulation Test</td>
<td>All qual. color comparison pH - body fluids (not blood)</td>
</tr>
<tr>
<td>Luna Fertility Indicator (saliva)</td>
<td>Common Sense Fem’V/VIA/VS/Norma Sense (vag pH)</td>
</tr>
<tr>
<td>O2 Unlimited Donna Ovulation Test (saliva)</td>
<td>Dale Med Products RightSpot/RightLevel (gastric pH)</td>
</tr>
<tr>
<td>Stesans Maybe?Mom Mini Ovulation Microscope (saliva)</td>
<td>Duramed AmniScreen Home Dection Liner Kit</td>
</tr>
<tr>
<td>TCI Ovulation Tester (saliva)</td>
<td><strong>SA Scientific SAS RSV Test/RSVAlert</strong></td>
</tr>
<tr>
<td><strong>PH</strong></td>
<td><strong>Sofia 2 for use with the Sofia RSV FIA</strong></td>
</tr>
<tr>
<td>All qual. color comparison pH - body fluids (not blood)</td>
<td><strong>Wampole Laboratories Clearview RSV</strong></td>
</tr>
</tbody>
</table>
Waived Tests (continued)

**Semen**
- Embryotech Laboratories FertilMARQ for male infertility
- Fertell Male Fertility Test
- Fertility Solutions Semen Analysis (qualitative)
- SpermCheck Fertility
- SpermCheck Vasectomy
- Trak Male Fertility Testing System
- YO Home Sperm Test

**Sodium**
- Abbott i-STAT CHEM8+/3+/4+/6+ Cartridge
- Piccolo xpress & Blood Analyzers (CMP, BMP, lytes, Metlyte 8, Renal)

**Strep Antigen Test**
- Abbott Signify Strep A Test / Dipstick
- Accu-chek Strep A
- ACON Strep A Rapid, Strep A Twist Rapid, and ICON DS
- Alere, Strep A, Alere I Instrument
- Applied Biotech SureStep Strep A (II)/Strep A Exact
- Beckman Coulter ICON Fx (formerly SmithKline)
- Beckman Coulter Primary Care Diag. DS, FX, and SC
- Becton Dickinson Chek Group A Strep Test
- Becton Dickinson LINK 2 Strep A Rapid Test
- BD LINK 2/Chek Strep A Rapid test /Veritor System
- Binax NOW/Clearview Advanced Strep A Test
- BioStar Acceava™ Strep A Test
- Biotechnostix Rapid Resp. Strep A Rapid Test Device/Strip
- BTNX Rapid Response Strep A Rapid Test Strips
- Cardinal Health CP Brand Rapid Test Dipstick/Cassette
- Clarity Strep A Rapid Test
- Clearview Strep A Exact Dipstick
- CLIA Waived Inc Rapid STREP A Test
- Consult Diagnostics STREP A RAPID Dipstick
- CTMI (Cole-Taylor Marketing Inc) Strep A Rapid Test Strip
- DE Healthcare Products, TruView Strep A Test/Cassette
- Diagnostic Test Group Clarity Strep A Rapid Test Strips
- Fisher HealthCare Sure-Vue Strep A
- Genzyme Contrast Strep A and OSOM Ultra Strep A
- Germaine Laboratories Strep AIM Rapid Dipstick Test
- Germaine Laboratories Strep AIM Tower
- Henry Schein OneStep+/OneStep + Strep A Test/Strep A Dipstick
- IMCO Strep A Rapid Test
- IMI Signify Strep A Dipstick
- Immunostics Immuno/Strap A Detector, Strep A Direct
- Instant Technologies Isstrept Strep A Test
- Inverness Medical BioStar Acceava Strep A Test/Twist
- Inverness Medical Clearview Strep A Exact II Dipstick
- Inverness Medical Signify Strep A Cassette
- Jant Pharm. AccuStrip Strep A (II), Accutest Integrated Strep A Rapid Test, CliniPak Rapid Test Strip, Value+ Test
- Laboratory Supply Co PEP Strep A Cassette, Dipstick
- LABSCO Advantage Strep A
- LifeSign LLC Status Strep A
- Mainline Confirms Strep A Dots test
- McKesson Consult Diagnostics Strep A Test Dipstick
- McKesson Strep A Medi-lab Performance Dipstick/Cassette/Strep A Test - Twist/Dipstick
- MediLab Performance Strep A Twist Rapid Test
- Medline Strep A Test Strips (Throat Swabs)
- Meridian Diag. ImmunoCard STAT Strep A
- Moore Medical Strep A Rapid Test - Dipstick/Cassette
- OneStep Pro+ Mono (WB)
- Performance Enhanced Products Strep A Cassette, Dipstick
- PerMaxin Rediscreen Strep A Rapid/Strep A Twist Cassette
- Polymedco Poly stat A (II), Strep A Liquid Test, Strep A Dipstick
- Poly stat Strep A Flip Test
- Princeton BioMediTech BioStrep A /Status First Strep A
- ProAdvantage by NDC Strep A Test
- PSS Consult Diag Strep A Dipstick
- PSS World Medical Strep A Dipstick/Twist
- Quidel QuickVue In-Line and Dipstick and In-Line one-step
- Quidel Sofia 2 (Sofia Strep A+ FIA) throat swab only
- Quidel Sofia Strep A+ FIA (from throat swab only)
- RAC Medical Clarity Strep A Twist Rapid Test Device/Strip
- Remel RIM A.R.C. Strep A Test
- Roche Molecular, Cobas Liat System
- Sacks Medical Refuah Strep A Rapid Test
- SA Scientific SAS Strep A
- Sekisui Diagnostics OSOM Strep A Test (direct - throat swab)
- Sekisui Diagnostics OSOM Ultra Strep A Test
- Select Medical Products Brand Rapid Test Strep A Dipstick
- Select Medical Products Brand Rapid Test Strep A Twist
- Signify Strep A Dipstick
- SMC Direct, LLC, RefuAH Strep A Rapid
- Stanbio Qustick Strep A, E-Z Well Strep A Rapid Test
- StatusFirst Strep A
- SterpAim
- Wondfo Biotech Co., Ltd, Preview Strep A Test Kit
- Wondfo Biotech Co., Ltd, WondView Strep A Test Kit
- Wondofo One Step Strep A Swab Test
- Wyntek Diag. OSOM Strep A and OSOM Ultra Strep A Test

**Syphilis**
- Diagnostics Direct LLC Syphilis Health Check (Fingerstick WB Only)

**Trichomonas**
- Genzyme Osm Trichomonas Rapid Test
- Sekisui Diagnostcs OSOM Trichomonas Rapid Test
### 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 Cardiochek 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 ThyroTeset 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 Urocheck 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/Urispec 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 Urinary 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. If these tests are performed by any other personnel in your office, complete Non-waived and Non-PPMP test section below.

**Check all that apply**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Total Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>— Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements</td>
<td></td>
</tr>
<tr>
<td>— Fecal leukocyte examinations</td>
<td></td>
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<tr>
<td>— Fern tests</td>
<td></td>
</tr>
<tr>
<td>— Nasal Smears for granulocytes</td>
<td></td>
</tr>
<tr>
<td>— Pinworm examinations</td>
<td></td>
</tr>
</tbody>
</table>

### Non–waived and Non–PPMP Tests

Place a checkmark by all the non–waived and non–PPMP tests that are performed at your medical test site. If the tests that you perform are not listed on the checklist, list them under the appropriate specialty/subspecialty. For volumes, include the yearly estimate of the number of tests performed. Attach additional sheets if needed.

All analytes listed in bold print are regulated and must be covered by proficiency testing.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Total Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mycobacteriology</td>
<td></td>
</tr>
<tr>
<td>— AFB Smear Only</td>
<td></td>
</tr>
<tr>
<td>— AFB Smear/Culture</td>
<td></td>
</tr>
<tr>
<td>— AFB Antibiotic Sensitivities</td>
<td></td>
</tr>
<tr>
<td>— AFB Culture &amp; ID</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mycology</th>
<th>Total Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>— DTM Only</td>
<td></td>
</tr>
<tr>
<td>— Culture (Growth/No Growth)</td>
<td></td>
</tr>
<tr>
<td>— Fungus</td>
<td></td>
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<tr>
<td>— Yeast</td>
<td></td>
</tr>
<tr>
<td>— Culture and ID</td>
<td></td>
</tr>
<tr>
<td>— Fungus</td>
<td></td>
</tr>
<tr>
<td>— Yeast</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parasitology</th>
<th>Total Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>— Direct Smear</td>
<td></td>
</tr>
<tr>
<td>— Concentrate/Stain</td>
<td></td>
</tr>
<tr>
<td>— Parasitic Antigens</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Virology</th>
<th>Total Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>— Herpes Antigen</td>
<td></td>
</tr>
<tr>
<td>— Herpes Culture</td>
<td></td>
</tr>
<tr>
<td>— Other Viral Cultures</td>
<td></td>
</tr>
<tr>
<td>— Viral Antigen Detection</td>
<td></td>
</tr>
<tr>
<td>— HPV</td>
<td></td>
</tr>
<tr>
<td>— Influenza (nonwaived kits)</td>
<td></td>
</tr>
<tr>
<td>— RSV (nonwaived kits)</td>
<td></td>
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<tr>
<td>— Other (list)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Syphilis Serology</th>
<th>Total Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>— RPR</td>
<td></td>
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<tr>
<td>— VDRL</td>
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<tr>
<td>— MHA-TP (TP-PA)</td>
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<tr>
<td>— FTA</td>
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</tr>
</tbody>
</table>
## Non-Waived Tests (continued)

### Gen. Immunology
- Allergy Testing (count individual allergens tested)
- Alpha-1 Antitrypsin
- AFP/Tumor
- AFP/Other
- ANA
- ASO
- HIV
- C3
- C4
- HBsAg
- Anti-HBc
- HBeAg
- HCV
- Anti-HCV
- IgA
- IgG
- IgE
- IgM
- Infectious Mononucleosis (nonwaived kits)
- Rheumatoid Factor
- H. pylori (nonwaived kits)
- Rubella Antibody
- Protein Electrophoresis
- Other (list)

### Routine Chemistry
- ALT/SGPT
- Albumin
- Alkaline Phosphatase
- Amylase
- AST/SGOT
- Bilirubin, Total/Neonatal
- pH (blood gas)
- pO₂ (blood gas)
- pCO₂ (blood gas)
- Calcium, Total
- Carbon Dioxide
- Chloride
- Cholesterol, Total
- HDL Cholesterol
- Creatine Kinase
- CK Isoenzymes
- Creatinine
- Glucose
- Glycohemoglobin (Hgb A,C or equivalent)
- Iron, Total
- LDH
- LDH Isoenzymes
- Magnesium
- Potassium

### Urinalysis
- Strip by nonwaived instrument

### Endocrinology
- Cortisol
- Free Thyroxine
- HCG (Serum Pregnancy or nonwaived urine HCG)
- T3 Uptake
- T3 (Triiodothyronine)
- Estradiol
- TSH
- FSH
- Thyroxine
- Luteinizing Hormone
- PSA
- Progesterone
- Other (list)

### Toxicology
- Alcohol, Blood
- Blood Lead
- Carbamazepine
- Digoxin
- Ethosuximide
- Gentamicin
- Lithium
- Phenobarbital
- Phenytoin
- Primidone
- Procainamide/metabolites
- Quinidine
- Theophylline
- Tobramycin
- Valproic Acid
- Drugs of Abuse (urine)
- Other (list)

---

**Note:** Each measured parameter must be counted as a separate test, added together, and included in the Routine Chemistry total volume above.
### Non-Waived Tests (continued)

#### Hematology
- **Cell Identification/Manual Differential**
  - CBC (Complete Blood Count):
    - Automated WBC Differential
    - RBC
    - Hematocrit
    - Hemoglobin
    - WBC
    - Platelet Count

  - Reticulocyte Count
  - Hemoglobin Electrophoresis
  - Flow Cytometry
  - Other (list)

#### Coagulation
- Fibrinogen
  - PTT
- Prothrombin Time
  - Thrombin Time
  - Factor Assays
  - Activated Clotting Time
  - D-dimer
  - Other (list)

#### Immunohematology
- Antibody Detection (Screen)
- ABO Group
- D (Rh) Typing
- Antibody Identification
- Compatibility Test (Crossmatch)
- Other (list)

#### Pathology
- Histopathology
  - Dermatopathology
- Oral Pathology
- Gyn Cytology
- Non-gyn Cytology

#### Radiobioassay
(list in vitro tests, i.e. blood volume by Cr 51, Schilling test, etc.)
  - Do not include routine RIA tests

#### Genetic Testing
- Biochemical Genetic Tests (list tests)
- Cytogenetic Tests (list tests)
- Molecular Genetic Tests (list tests)
  - (add HPV testing under Virology)
  - (add Chlamydia and/or GC testing under Bacteriology)

---

**Note:** Each measured parameter (automated differential, RBC, hematocrit (or MCV), hemoglobin, WBC, platelets) must be counted as a separate test, added together, and included in the Hematology total volume above.
Complete this form if:
1) Your medical test site performs any tests other than the waived tests listed.
2) Personnel other than MD, DO, DPM, ARNP, PA, midwife, naturopath, or dentist perform the tests listed under PPMP.

### Moderate Complexity Testing

**Director** (check only one)

1. Pathologist w/ State license
2. MD, DO, DPM with State license and 1 year directing or supervising non-waived testing:
   - Which lab
   - Dates
3. MD, DO, DPM with State license and 20 CMEs in laboratory practice:
   - Which program
   - Dates
4. MD, DO, DPM with State license and lab training during residency equivalent to 20 CMEs:
   - Which program
   - Dates
5. Doctor of Optometry performing testing only within their scope of practice.
6. PhD in science + board certification (ABB, ABMM, ABCC, ABMLI) or 1 yr directing or supervising non-waived testing
7. Master in science + 1 yr lab training and/or experience; and 1 yr laboratory supervisory experience
8. Bachelor in science + 2 yrs lab training and/or experience and 2 yrs laboratory supervisory experience
9. On 2/28/92, serving as a lab director and qualified or could have qualified as director under previous Medicare/CLIA independent lab personnel requirements
10. On 2/28/92, was qualified under State law to direct lab

**Clinical Consultant** (check only one)

1. Pathologist w/ State license
2. MD, DO, DPM w/ State license
3. PhD in science + board certification (ABB, ABMM, ABCC, ABMLI)
4. DDS certified in oral pathology (ABOP, ABP, AOBP)

### Technical Supervisor Qualifications:

- Chemistry, Hematology, Bacteriology, Mycology, Mycobacteriology, Parasitology, Virology, and Diagnostic Immunology
- Histocompatibility, Cytogenetics, Immunohematology and Pathology

**Testing Personnel** (include total # of personnel performing testing in front of appropriate categories)

1. MD, DO, DPM, PhD, master or bachelor degree in science, or associate degree in science or medical lab technology
2. H.S. graduate or equivalent + 50 week military medical laboratory procedures course
3. H.S. graduate or equivalent with documented training for testing performed

### High Complexity Testing

**Director** (check only one)

1. Pathologist w/ State license
2. MD, DO, DPM with State license and 1 year lab training in medical residency:
   - Which program
   - Dates
3. MD, DO, DPM with State license and 2 years directing or supervising high complexity testing:
   - Which lab
   - Dates
4. PhD in science + board certification by HHS approved board; or served as high complexity testing director before 2/24/03
5. On 2/28/92, serving as a lab director and qualified or could have qualified as director under previous Medicare/CLIA independent lab personnel requirements
6. On 2/28/92, was qualified under State law to direct lab
7. For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology (dentists), American Board of Pathology, or American Osteopathic Board of Pathology or equivalent

**Clinical Consultant** (check only one)

1. Pathologist w/ State license
2. MD, DO, DPM w/ State license
3. PhD in science + board certification (ABB, ABMM, ABCC, ABMLI)
4. DDS certified in oral pathology (ABOP, ABP, AOBP)

**Technical Supervisor Qualifications:**

- Chemistry, Hematology, Bacteriology, Mycology, Mycobacteriology, Parasitology, Virology, and Diagnostic Immunology
- Histocompatibility, Cytogenetics, Immunohematology and Pathology

**Testing Personnel** (include total # of personnel performing testing in front of appropriate categories)
## High Complexity Test (continued)

### Histocompatibility
- 1. MD, DO, DPM w/State license or PhD
  - 4 yrs of training and/or experience in histocompatibility; or 2 yr in general immunology + 2 yr in histocompatibility

### Cytogenetics
- 1. MD, DO, DPM w/State license or PhD
  - 4 yrs of training and/or experience in genetics, 2 of which have been in clinical cytogenetics

### Immunohematology
- 1. Pathologist w/State license
  - 1 yr of training and/or experience in high complexity immunohematology

### Pathology
- 1. For histopathology, anatomic pathologist;*
  - 2. For dermatopathology, anatomic pathologist, dermatopathologist, or dermatologist certified by American Board of dermatology*
  - 3. For oral pathology, anatomic pathologist or oral path.*
  - 4. For ophthalmic pathology, anatomic pathologist or certified by American Board of Ophthalmology*
  - 5. For cytology, anatomic pathologist or MD/DO certified by American Society of Cytology**

* Can delegate responsibility for examination and interpretation to a resident
** Can delegate some responsibilities to resident in final year of full-time training

### General Supervisor (include total # of personnel performing duties in front of appropriate categories)
- 1. Pathologist w/State license
  - 2. MD, DO, DPM w/State license + 1 yr of training and/or experience in high complexity testing
  - 3. PhD, master or bachelor in science
  - 4. AS/AA in lab science or medical technology + 2 yr training and/or exper. in high complexity testing
  - 5. Education equivalent to AA degree (60 semester hrs) in lab science + documented lab training program (at least 3 mos); + 2 yr T/or E in high complex testing
  - 6. On 2/28/92, qualified or could have qualified under previous Medicare/CLIA independent lab personnel requirements.
  - 7. On 9/1/92, served as TS in cytology and prior to 1/1/69:
    - 6 mos of training in cytotechnology
    - 6 mos FT supervised experience in cytology

### General supervisor: Blood Gas Analysis (include total # of personnel performing duties in front of appropriate categories)
- 1. Qualify as a general supervisor of high complexity testing listed above
  - 2. Bachelor degree in respiratory therapy or cardiovascular technology + 1 yr training and/or exper. in blood gases

### Testing Personnel (include total # of personnel performing testing in front of appropriate categories)
- 1. MD, DO, DPM w/State license, PhD, master, or bachelor degree in science
  - 2. Associate degree in lab science or medical lab technology or 60 semester hrs in science + approved lab training program
  - 3. On 2/28/92, previously qualified or could have qualified as a technologist under previous Medicare/CLIA independent lab personnel requirements
  - 4. On 4/24/95, H.S. graduate performing high complexity testing + completed med lab clinical training program or 50 week US military program
  - 5. On 4/24/95, H.S. graduate performing high complexity testing + appropriate training
  - 6. Until 9/1/97, H.S. graduate or equivalent with documented training for the testing performed (if hired before 1/19/93, no direct on-site supervision if results reviewed by general supervisor within 24 hours)
  - 7. For blood gas analysis, qualify under 1, 2, 3, 4, 5, 6; or bachelor in resp. therapy or cardiovascular technology; or associate degree in pulmonary function

### Cytotechnology (include total # of personnel performing testing in front of appropriate categories)
- 1. Anatomic pathologist or cytopathologist or resident
  - 2. Graduate from an accredited school of cytotechnology
  - 3. Certified in cytotechnology by an approved agency
  - 4. Prior to 9/1/92:
    - 2 yrs of college (12 semester hrs in science, 8 of whicha are biology, + 12 mos training in an approved school of cytotechnology
    - 6 mos of formal training in an approved school of cytotechnology + 6 mos FT experience in cytotechnology in lab acceptable to pathologist who directed training.
    - achieved a satisfactory grade in an HHS proficiency exam for cytotechnologist
  - 5. Prior to 9/1/94:
    - 2 yrs FT exp. within preceding 5 yrs examining slide preps under supervision of a TS in cytology and prior to 1/1/69:
      - graduated from high school.
      - completed 6 mos training in cytotechnology directed by a pathologist or other MD providing cytology services.
    - 2 yrs FT supervised experience in cytotechnology
  - 6. Prior to 9/1/94:
    - 2 yrs of FT experience under supervision of a TS in cytology in US in past 5 yrs; and by 9/1/95 graduate from an accredited school or be certified by an approved agency
### 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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### Change of Ownership Information

Previous Name of Legal Owner

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<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

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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

______________________________  ______________________________
Print Name  Print Title