



Washington State Department of

Health

Credentialing Unit

PO Box 47877

Olympia, WA 98504-7877

253.395.6746

<http://www.doh.wa.gov/LQA.htm>

Accredited Medical Test Site (MTS) Application Packet

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Important Information:

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

Accredited: If you are applying for an accredited license, your MTS **must** be inspected by the accreditation organization. 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. Proof of accreditation or certification by the accreditation body must be included with your application.

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, **do not** complete this application. Complete the Categorized MTS/CLIA 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 Applications (original copy) to:

Department of Health

Credentialing Unit

PO 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 (7/01/11 through 6/30/13) will be charged the full fee. MTS licenses issued during the second year of the state biennium (7/01/12 through 6/30/13) will be charged half of the full fee. The license categories and corresponding fees are:

Category	Fee – Applies to 1st year of the Biennium 7/01/11 – 6/30/13	Fee – Applies to 2nd Year of the Biennium 7/01/12 – 6/30/13
Low Volume (1-2000)	\$ 165	\$ 83
A (2,001-10,000, 3 SPEC)	211	106
B (2001-10,000, 4 SPEC)	231	116
C (10,001-25,000, 3 SPEC)	531	266
D (10,001-25,000, 4 SPEC)	559	280
E (25,001-50,000)	787	394
F (50,001-75,000)	1,254	627
G (75,001-100,000)	1,722	861
H (100,001-500,000)	2,227	1,114
I (500,001-1,000,000)	6,428	3,214
J (>1,000,000)	8,168	4,084



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Accredited Medical Test Site (MTS) Application Checklist and Instructions

Please indicate type of application. New, change of ownership, or 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. **Note:** 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 Name: Enter the owner's name as it appears on the UBI/Master Business License.

Legal Owner/Operator Mailing Address: Enter the owner's complete mailing address.

Phone and Fax Numbers: Enter the owner's phone and fax number.

Email and Web Address: Enter the owner's email and Web addresses, if applicable.

Facility Name: Enter the lab's name as advertised on signs or Web site.

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

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

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

Section #2: Facility Specific Information:

Site Type: Please check the one applicable site type.

Facility Specific Federal Tax ID (FEIN) #. Enter if different from the Owner FEIN listed on page 1.

Accreditation Agency: Please check the private accreditation organization you wish to inspect your laboratory.

Note: If you want the DOH Laboratory Quality Assurance surveyors to inspect your laboratory, do not complete the Accredited MTS/CLIA application. Complete the Categorized MTS/CLIA application instead.

Multiple Sites: List multiple sites, if applicable, and test performed at each site.

Accredited MTS Application Checklist and Instructions (continued)

Section #3: Key Individuals:

Lab Director: Enter the lab director's (1) name, (2) qualifications, Washington State Professional license number for MD, DO, ND, PA, ARNP, PA, ARNP, LPN, health care assistant or other professional license category and (3) email address.

Lab Contact: Enter the lab contact's (1) name, (2) Washington State professional license number for MD, DO, ND, PA, ARNP, PA, ARNP, LPN, health care assistant or other professional license category, if applicable, and (3) email address.

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

Section #4: Additional Information:

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

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, nurse 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/sub-specialty (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 antibody 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.

Immuno-hematology: 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

Accredited MTS Application Checklist and Instructions (continued)

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: Additional Information (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:

1. University of Iowa Carver College of Medicine

On-line laboratory director course: <http://www.medicine.uiowa.edu/cme/clia/>

2. 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 or (800) 981-9883.

3. University of Wisconsin and COLA

Lab University: On-line laboratory director course 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: Additional Information:

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

Change of Ownership Information: If applicable, list the previous legal owner name, previous name of facility, previous MTS license #, 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, 2013. You will receive a renewal notice for this license approximately 60 days before the expiration date.

Please contact our Seattle office at 252.395.6746 if you have any questions or need assistance in completing the application form. Additional information is available on our Web site at:

<http://www.doh.wa.gov/lqa.htm>.

Proficiency Testing

(not required for Waived or PPMP testing)

Proficiency testing (PT), as required under Medical Test Site rule 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 back 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 your 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, contact Leonard Kargacin at 253.395.6747 or Lori Hudson at 509.458.2131.

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	800.356.6788	California Thoracic Society	714.730.1944
Amer. Acad. of Family Physicians	800.274.7911	College of American Pathologists	800.323.4040
Amer. Assoc. of Bioanalysts	800.234.5315	EXCEL (CAP)	800.323.4040
American Proficiency Institute	800.333.0958	Wisconsin State Lab. of Hygiene	800.462.5261
ASIM Medical Lab Evaluation	800.338.2746		

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
Theophylline
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

Immuno-hematology

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



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Date Stamp Here

- Do not send payment with this application.
- You will be billed for the license fee after review of this application.

Accredited Medical Test Site License Application

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

- | | | |
|--------------------------------------------------------|-------------------------------------------------|--------------------------------------------------|
| <input type="checkbox"/> Association | <input type="checkbox"/> Limited Partnership | <input type="checkbox"/> Partnership |
| <input type="checkbox"/> Corporation | <input type="checkbox"/> Municipality (City) | <input type="checkbox"/> Sole Proprietor |
| <input type="checkbox"/> Limited Liability Company | <input type="checkbox"/> Municipality (County) | <input type="checkbox"/> State Government Agency |
| <input type="checkbox"/> Limited Liability Partnership | <input type="checkbox"/> Non-Profit Corporation | <input type="checkbox"/> Trust |

1. Demographic Information

UBI #	Federal Tax ID (FEIN) #
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Legal Owner/Operator Name

Mailing Address

City	State	Zip	County
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Phone #	Fax #
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Email Address	Web Address
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Facility/Agency Name (Business name as advertised on signs or Web site)

Physical Address

City	State	Zip	County
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Facility Phone #	Fax #
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Mailing Address (If different than physical address)

City	State	Zip	County
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For Office Use Only

Medical Test Site # _____ CLIA # _____

2. Facility Specific Information

SITE TYPE (check one only)

- | | | |
|--------------------------------------------------------------|------------------------------------------------------|------------------------------------------------------|
| <input type="checkbox"/> 1 Ambulance | <input type="checkbox"/> 12 Home Health Agency | <input type="checkbox"/> 23 Prison |
| <input type="checkbox"/> 2 Ambulatory Surgery Center | <input type="checkbox"/> 13 Hospice | <input type="checkbox"/> 24 Public Health Lab |
| <input type="checkbox"/> 3 Ancillary Test Site | <input type="checkbox"/> 14 Hospital | <input type="checkbox"/> 25 Rural Health Clinic |
| <input type="checkbox"/> 4 Assisted Living Facility | <input type="checkbox"/> 15 Independent Laboratory | <input type="checkbox"/> 26 Student Health Service |
| <input type="checkbox"/> 5 Blood Banks | <input type="checkbox"/> 16 Industrial | <input type="checkbox"/> 27 Skilled Nursing Facility |
| <input type="checkbox"/> 6 Community Clinic | <input type="checkbox"/> 17 Insurance | <input type="checkbox"/> 28 Tissue Bank/Repository |
| <input type="checkbox"/> 7 Comprehensive Outpatient Rehab | <input type="checkbox"/> 18 ICFMR | <input type="checkbox"/> 29 Other |
| <input type="checkbox"/> 8 End Stage Renal Disease Dialysis | <input type="checkbox"/> 19 Mobile Lab | <input type="checkbox"/> 90 Drug Treatment |
| <input type="checkbox"/> 9 Federally Qualified Health Center | <input type="checkbox"/> 20 Pharmacy | <input type="checkbox"/> 91 Clinic |
| <input type="checkbox"/> 10 Health Fair | <input type="checkbox"/> 21 Physician Office | |
| <input type="checkbox"/> 11 Health Main. Organization | <input type="checkbox"/> 22 Other Practitioner _____ | |

Facility Specific Federal Tax ID (FEIN)#

Enter if different from the Owner FEIN listed on page 1 _____

Accreditation Agency

The following contains information only for those laboratories that choose to be inspected and accredited by a private accrediting agency (see list in the box below). **This is strictly a voluntary option.** Complete the information in the box below **ONLY** if you have contracted with one of these accrediting agencies to inspect your laboratory. Check here only if you are inspected and accredited by one of the following:

- AABB AOA ASHI CAP COLA The Joint Commission

To qualify for this type of license you MUST include proof of accreditation of the laboratory testing at your facility with your application (**See information in instructions**). If you have not yet been inspected by the accrediting body, include proof of enrollment with your application, and forward the proof of accreditation after the survey has been completed.

Multiple Sites

List number of sites if you have multiple sites AND the paragraph below applies

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. 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.

3. Key Individuals

Lab Director (include qualifications, i.e., MD, PhD, BS, etc.)

Name:

WA State Professional License # (if applicable):

Email Address

Lab Contact Person

Name

WA State Professional License # for MD, ND, PA, ARNP, RN, LPN, health care assistant, etc.

Email Address

4. Additional Information – Waived Tests

Waived Tests: Place a checkmark by the test kit/system if you perform any of the specific test methods listed below.
(waived test list as of 01/26/12)

Adenovirus

Rapid Pathogen Screening RPS Adeno Detector

Aerobic/Anaerobic Organisms-Vaginal

Genzyme Diagnostics OSOC BVBLUE Test

Gryphus Diagnostics BVBlue

Alanine Aminotransferase (ALT)

Alere Cholestech LDX (ALT)(WB)

Arkray SPOTCHEM EZ Chem Analyzer (ALT) (WB)

Cholestech LDX (ALT) (whole blood)

Piccolo Point of Care/Blood Chem/xpress Chem Analyzer (WB)

(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/xpress Chemistry Analyzer WB

(Liver Panel Plus Reagent Disc, Chem 13, CMP, Renal)

Alkaline Phosphatase (ALP)

Arkray SPOTCHEM EZ Chem Analyzer (WB)

Piccolo Point of Care/Blood Chem/xpress Chem Analyzer (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/xpress Chemistry Analyzer (WB)

(Lipid Panel/Plus, Liver Panel Plus, Chem 6/13, CMP)

B-Type Natriuretic Peptide (BNP)

Biosite Triage Meter/Meterpro (whole blood) BNP

Basic Metabolic Panel

Abbott 1-STAT CHEM8+ Cartridge (ionized calcium) WB

Abaxis Piccolo Blood Chemistry/express (total calcium) WB

Bilirubin, Total

Arkray SPOTCHEM EZ Chem Analyzer (WB)

Piccolo Point of Care/Blood/xpress 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)

Maritech 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 Chem 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

Diatech Diagnostics Uriscreeen (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

Jant Pharmacal LipidPlus Lipid Profile and Glucose System

Lifestream Technologies Cholesterol Monitors

Piccolo POC/xpress Chemistry Analyzer WB (Lipid Panel/Plus)

Polymer Tech. Systems Bioscanner, Bioscanner Plus, Bioscanner 2000 PST, and MTS Bioscanner 1000

Polymer Technology Cardiochek and Cardiochek PA

Roche Diagnostics Accutrend Plus System (fingerstick WB)

Wako APOLOWAKO Analyzer (WB)

Comprehensive Metabolic Panel

Piccolo Blood Chem/express Analyzers WB

Creatine Kinase (CK)

Piccolo Blood Chemistry/express AnalyzersWB (Metlyte 8)

Creatinine

Abbott i-STAT CHEM8+/Crea Cartridge

Arkray SPOTCHEM EZ Chemistry Analyzer (WB)

Bayer Clinitek 50 Urine Chemistry Analyzer for Creatinine

Bayer Diagnostics MICROALBUSTIX Reagent Strips

Bayer MultiStix PRO 11, PRO 10LS, and PRO 7G

Piccolo xpress/Blood Analyzers (chem 6/13, kidney, CMP, BMP, Metlyte 8, Renal)

Drugs of Abuse

1 Step Detect Asoc DTX Drug Test Cup Integrated E-Z Split Key Cup II

Acon Laboratories Drug Home Tests

Acon Mission U120 Urine Analyzer

Accu-Stat Diagnostics Drugs of Abuse Home Test

Advantage Diagnostics

Alatech Scientific Peace of Mind Multiple Drugs of Abuse

Alere Toxicology Services iCassetts Dx Drug Screen

Alfa Scientific Designs - Multiple drug Screen test kits

Amedica Biotech The Amedica Drug Test Cup/AmediCheck

Instant Test Cup/Instant Test Cup

Ameditech Inc ImmuTest Drug Screen Cup

American Bio Medica Rapid TOX

American Screening Corp OneScreen Drug Test Cups/Cards/

Revel Multi-Drug Testing Cups

continued on next page

Waived Tests (continued)**Drugs of Abuse, continued**

___ Applied Biotech
 ___ Aventir Biotech LLC Home Check Multiple Drug Cup Test
 ___ Biotechnostix Rapid Response Drug Screens
 ___ Branan Medical Corp Fastect II/FasTox/QuickTox/ToxCup
 ___ BTNX Know/Rapid Response Multi-Drug One Step Screen
 ___ CLIA-X Multiple Drug Cup Test
 ___ CLIAwaived Inc. Rapid Drug Test Cup (OTC)
 ___ Confirm Biosciences Drugconfirm Instant Multi-Drug of Abuse
 ___ Diag. Test Grp Clarity Multi/SimpleDrug of Abuse Urine Test/Cards
 ___ Drug Detect. Devices Multi-Drug Multi-Line/Screeners AutoCup
 ___ eScreen, Inc. mCheck Multi-Line Screen Test Device
 ___ Express Diag DrugCheck Waive Drug Cards/Cup/Model 9308z
 ___ First Check Diagnostics Drug Screens
 ___ Forefront Diag. Drug Screen
 ___ Graman Medical Corporation
 ___ Greenbrier Intn'l East SCREEN Marijuana Test Strip
 ___ Innovacon Integrated E-Z Split Key Cup II (professional use)
 ___ Innovacon Multi-Clin Drug Screen Test Device
 ___ Insight Medical Drug of Abuse Cassette/Cup (morphine,
 ___ oxycodone) Multi-Drug of Abuse Urine Test
 ___ Instant Tech. iTest/iCassette/iCup/iCupDx/Cassette Dx/iScreen
 ___ Inverness Medical Innovations Signify ER Drug Screen
 ___ Jant Pharmacal Accutest MultiDrug ER11/Multi-Drug of Abuse
 ___ Urine Test/SplitCup Drug Screen/Test Cup/Cassette.Cup
 ___ LifeSign Home Drug Tests
 ___ Med Direct ProXam Drug Test Cards/Multiple Drug Screen Cups
 ___ Micro Distributing II Ltd Multi-Drug of Abuse Urine Test
 ___ Millennium Lab Multi-Drug Pain Med Screen Cup/Multi-Drug of
 ___ Abuse Urine Test
 ___ NexScreen Cup
 ___ Nobel Medical NOBLE 1 Step Cup(OTC)/Split-Specimen Cup
 ___ On the Spot Drug Testing Multi-Drug of Abuse Urine Test
 ___ Phamatec At Home & QuickScreen
 ___ PharmTox Rapid Exam Drug Screen Test Cup
 ___ Physicians' Test Multi-Drug of Abuse Urine Test
 ___ Premier Integrity Solutions P/Tox Drug Screen Cup
 ___ Princeton Biomeditech Drug Tests
 ___ Quest Diag. Integrated E-Z Split Key Cup II/Express Results
 ___ QuickTest USA Multi-Drug of Abuse Urine Screen
 ___ Redwood Tox Lab Reditest 6/Reditest Freedom Cup/Reditest
 ___ Home Drug Tests
 ___ RefuAH U120 Urine Analyzer
 ___ Screen Tox Multi-Drug of Abuse Urine Test
 ___ Syntrol Bioresearch Quikscreen Multiple Drug Cup Test
 ___ TeenSaver Diag. TeenSavers Home Drug Test
 ___ Total Diagnostic Solutions Drug of Abuse Cassette/Cup
 ___ (morphine, oxycodone)/Multi-Drug of Abuse Urine Test
 ___ Twin Spirit Inc DrugSmart Cup
 ___ UCP Home Drug/Multiple/U-Checker Drug Screening Test
 ___ Cards/Cups
 ___ US Diagnostics ProScreen Drugs of Abuse Cup (OTC)
 ___ WayPoint Biomedical, Inc. Health Essist Multi-Drug Tests
 ___ Wolfe Drug Testing RealityCheck Integrated Specimen Cup
 ___ Wondfo Urine Test Cup and Dip Card
 ___ Worldwide Medical Corp. First Check Home Drug Tests

Electrolyte Panel

___ Abaxis Piccolo Blood Chemistry/express WB

Erythrocyte sedimentation rate (ESR)

___ Non-automated

Esterone-3-Glucuronide

___ Unipath Limited Clearplan Easy Fertility Monitor

Ethanol

___ Acon Laboratories Mission Saliva Alcohol Test Strip
 ___ Alfa Scientific Designs Oral-View Saliva Alcohol Test Strip
 ___ 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
 ___ 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)
 ___ Phamatech Moments Menopause Check (FSH)
 ___ PanProbe Biotech EarlyDetect Menopause Test
 ___ 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
 ___ 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
 ___ Piccolo Point of Care/Blood/xpress Chemistry Analyzer WB (Lipid Panel Reagent Disc, Chem 6/13, CMP, BMP, Metlyte 8, Renal)
 ___ Polymer Technology Systems CardioChek PA Analyzer
 ___ Roche Diagnostics AccuChek Instant Plus Dual Test System
 ___ Wako APOLOWAKO Analyzer (WB)

Glycosylated HGB

___ Axis-Shield Afinion AS10 Analyzer
 ___ Bayer A1C Now+ (professional use)
 ___ Bio-Rad Micromat II
 ___ Bristol-Myers Squibb Choice DM
 ___ Cholestech GDx A1C (prescription home use)
 ___ MEC Dynamics Avie A1c Test System
 ___ Metrika A1c Now/DRX HbA1C/InView Multi Test
 ___ Provalis Diagnostics Glycosal/In2it In-office analyzer II/G5 I
 ___ HbA1c/G5 II HbA1c
 ___ Siemens Medical DCA Vantage/2000/2000+ Analyzer
 ___ Wako APOLOWAKO Analyzer (WB)

Waived Tests (continued)**HDL Cholesterol**

Accutech CholesTrak HDL Cholesterol Home Test
 Alere Cholestech LDX (HDL cholesterol)(WB)
 Arkray SPOTCHEM EZ Chem Analyzer (WB)
 Cholestech LDX
 Infopia USA LipidPro/Lipid Profile Test Strips
 Jant Pharmacal LipidPlus Lipid Profile and Glucose System
 Piccolo POC/xpress Chemistry Analyzer WB (Lipid Panel/Plus)
 Polymer Technology Systems BioScanner Plus and 2000
 PolymerTechnology Systems Cardiochek and Cardiochek PA

Helicobacter pylori

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

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
 Alere HemoPoint H2 Hemoglobin Measuring System
 Biosafe Anemiapro Self Screener
 Biotest Hemoglobin Measuring System
 Copper Sulfate (non-automated)
 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
 Stanbio Hemoglobin Analyzer
 Stanbio HemoPoint H2/H2 DM Hemoglobin Measurement Syst

Hepatitis C Virus Antibody

OraQuick Rapid Aby Test/OraQuick HCV Visual Ref Panel

HIV-1

Chembio HIV 1/2 STAT-PAK Assay (WB)
 Clearview COMPLETE HIV 1/2 fingerstick & venipuncture WB
 OraQuick Rapid HIV-1 Antibody Test (oral fluid, WB)
 OraQuick Advance Rapid HIV-1/2 Antibody (oral fluid, WB)
 Trinity Biotech UniGold Recombigen HIV test (WB)

Influenza

BD Veritor Systems Rapid Det Flu A+B (nasal,nasopharyngeal)
 Binax NOW Flu A and Flu B Tests and A&B Tests
 BTNX Rapid Response Influenza A/B Test Cassette
 Clearview Exact II Influenza A&B (nasal swab only)
 EarlyDetect Pro Influenza A Test/Influenza B Test
 Quidel QuickVue Influenza Test (Influenza A/B)
 Quidel QuickVue Influenza A+B Test
 SA Scientific SAS Influenza A/Influenza B Tests
 ZymeTX Zstatflu (Influenza A/B)

Ketones (Blood)

Abbott Laboratories Precision Xtra/Xceed
 Nova Max Plus 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

Lead

ESA Biosciences LeadCare II Blood Lead Testing System (WB)

Lithium

Akers Laboratory Inc InstaRead Lithium System (WB)
 ReliaLAB Inc. InstaRead Lithium System (WB)

Lyme Disease

Wampole PreVue *B. burgdorferi* Antibody

Lutenizing 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

Microalbumin

Roche/Boehringer Mannheim Micral Chemstrip
 Bayer Clinitek 50 Urine Chemistry Analyzer
 Bayer Clinitek Status Urine Chemistry Analyzer
 Bayer Diagnostics MICROALBUSTIX Reagent Strips
 Diagnostic Chemicals ImmunoDip & Urinary Albumin Screen
 HemoCue Albumin 201 System

Waived Tests (continued)**Mononucleosis**

- Acceava Mono II (whole blood)
- Acon Mono rapid Test Strip/Device (whole blood)
- Applied Biotech One Step+, SureStep, Truview Mono Test
- BioStar Acceava Mono/Mono II Test (whole blood)
- Cardinal SP Brand Rapid Test (whole blood)
- Clarify MONO Mononucleosis Rapid Test (WB)
- Clearview Mono-Plus II / Mono Test Whole Blood (WB)
- Consult Diagnostics Mononucleosis Cassette (WB)
- Genzyme Contrast/OSOM/Rapid/Sure-Vue Signature MonoTest
- Henry Schein One Step+ Mono Test (whole blood)
- Immuno Detector Mono/BioSign Mono WB
- Instant Technologies iScreen (whole blood)
- Jant Accutest Valeu+/Infectious Mononucleosis Test (WB)
- LifeSign Status/UniStep Mono Test (whole blood)
- McKesson Medi-Lab Performance Infectious Mono Test
- Meridian ImmunoCard STAT Mono (whole blood)
- Polymedco, Inc. Poly stat Mono (whole blood)
- Poly Stat Mono Test (WB)
- PreMaxin RediScreen Mononucleosis (WB)
- Princeton BioMeditech BioSign Mono WB (whole blood)
- ProAdvantage by NDC Infectious Mono Test Device (WB)
- Quidel CARDS O.S. and QuickVue+ Mono (whole blood)
- RAC Medical Clarity MONO Rapid Test Device (WB)
- Rapid Response Mono Rapid Test Device (whole blood)
- Remel RIM A.R.C. Mono Test
- Seradyn Color Q Mono (whole blood)
- Signify Mono Test / Mono Whole Blood / Mono Cassette (WB)
- Wampole Mono-Plus WB (whole blood)
- Wyntek Diagnostics OSOM and Signify Mono test (WB)

Nicotine (or its metabolites)

- DynaGen NicCheck 1 Test Strips
- Mossman Associates NicCheck I Test Strips

Occult blood

- Fecal Occult Blood
- Fecal Occult Blood Immunochemical/Immunological Tests
- Aerscher Hemaprompt FG Gastric Occult Blood
- Alfa Scientific Designs Instant-View FOB Self-Test Cassette
- Alfa Scientific Designs FOB Self-Test
- Beckman Coulter Primary Care Diagnostics Gastrocull/
- Hemocult Sensa Elite (gastric occult blood)
- Clarity Fecal Occult Blood Self Test
- Immunostics hema screen ER
- Know Fecal Occult Blood Self Test
- Rapid Response Fecal Occult Blood Self Test
- Siemens Hematest Reagent Tablets
- Smithkline Gastrocull

Osmolarity

- TearLab Osmolarity System

Osteoporosis

- Ostex International Osteomark NTX

Ovulation Tests

- Visual color comparison tests for human luteinizing hormone
- BTNX Inc rapid Response LH Ovulation Test
- Luna Fertility Indicator (saliva)
- O2 Unlimited Donna Ovulation Test (saliva)
- Stesans Maybe?Mom Mini Ovulation Microscope (saliva)
- TCI Ovulation Tester (saliva)

PH

- All qual. color comparison pH - body fluids (not blood)
- Common Sense FemV/VI/VA/VS/Norma Sense (vag pH)
- Duramed AmniScreen Home Dection Liner Kit
- Femtek Phem-Alert (vaginal pH)
- Lil' Drug Store Prod. Vagi-Screen Vaginal Health Test (vag pH)
- Litmus Concepts FemExam Test Card (vaginal pH & amines)
- Quicek QuickVue Advance pH and Amines Test

Phosphorus

- Piccolo xpress/Blood Analyzers (Renal panel)

Platelet Aggregation

- Accumetrics VerifyNow Aspirin Assay

Potassium

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

Pregnancy Test (Urine)

- Urine pregnancy test: visual color comparison
- Siemens Clinitek 50/Status Urine Chemistry Analyzer

Protine

- Alere INRatio2 PT/INR Monitoring System (Professional Use)
- AvoSure Pro and PT
- CoaguSense Prothrombin Time/Self-Test Protine/INR
- Hemosense INRATIO
- International Technidyne Corporation Protine Microcoagulation System and ProTime 3 Cuvette System
- Lifescan Harmony INR Monitoring System
- Lifescan Rubicom Prothrombin Time Monitoring System
- Roche Diag CoaguChek & CoaguChek S Sytems, PT-S Strips, XS, XS PST, **XS Plus Patient Self Test**

Protein, Total

- Arkray SPOTCHEM EZ Chem Analyzer (WB)
- Piccolo POC/xpress Chemistry Analyzer WB (Liver Panel Plus Reagent Disc, Chem 13, CMP)

RSV (Respiratory Syncytial Virus Direct Antigen)

- Binax NOW RSV Test
- Fisher Scientific Sure-Vue RSV Test
- Integrated Biotechnology Quick Lab RSV Test
- Meridian Bioscience Immunocard Stat! RSV Plus
- Quidel Quick Vue RSV Test
- Rapid Response RSV Test
- Remel Xpect RSV
- SA Scientific SAS RSV Test/RSVAlert
- Wampole Laboratories Clearview RSV

Semen

- Embryotech Laboratories FertilMARQ for male infertility
- Fertil Male Fertility Test
- Fertility Solutions Semen Analysis (qualitative)
- SpermCheck Fertility
- SpermCheck Vasectomy

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
- Acceava Strep A Test/Twist Rapid Test
- ACON Strep A Rapid, Strep A Twist Rapid, and ICON DS
- Applied Biotech SureStep Strep A (II)/Strep A Exact

continued on next page

Waived Tests (continued)

Strep Antigen Test, continued

Beckman Coulter ICON Fx (formerly SmithKline)
 Beckman Coulter Primary Care Diag. DS, FX, and SC
 Becton Dickinson LINK 2/Chek Strep A Rapid test
 Binax NOW/Clearview Advanced Strep A Test
 BioStar Aceava™ 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
 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 Inc, One Step+ Strep A Test , Strep A Dipstick
 IMI Signify Strep A Dipstick
 Immunostics Immuno/Strep A Detector, Strep A Direct
 Instant Technologies Istrep Strep A Test
 Inverness Medical BioStar Aceava 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
 LifeSign LLC Status Strep A
 Mainline Confirms Strep A Dots test
 McKesson Strep A Medi-lab Performance Dipstick/Cassette/
Strep A Test - Twist
 Meridian Diag. ImmunoCard STAT Strep A
 MediLab Performance Strep A Twist Rapid Test
 Moore Medical Strep A Rapid Test - Dipstick/Cassette
 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
 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

RAC Medical Clarity Strep A Twist Rapid Test Device/Strip
 Remel RIM A.R.C. Strep A Test
 Sacks Medical Refuah Strep A Rapid Test
 SA Scientific SAS Strep A
 Select Medical Products Brand Rapid Test Strep A Dipstick
 Select Medical Products Brand Rapid Test Strep A Twist
 Signify Strep A Dipstick
 Stanbio Qustick Strep A, E-Z Well Strep A Rapid Test
 Wyntek Diag. OSOM Strep A and OSOM Ultra Strep A Test

Trichomonas

Genzyme Osom Trichomonas Rapid Test

Triglycerides

Alere Cholestech LDX (triglyceride)(WB)
 Arkray SPOTCHEM EZ Chem Analyzer (WB)
 Cholestech LDX
 Infopia USA LipidPro/Lipid Profile Test Strips
 Jant Pharmacal LipidPlus Lipid Profile and Glucose System
 Piccolo POC/xpressAnalyzer (Lipid Panel/Plus)
 Polymer Tech . Systems Bioscanner, Bioscanner Plus, & 2000
 Polymer Tech. Systems Cardiochek and Cardiochek PA
 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)
 Jant Pharmacal Corp Accutest TSH (WB)
 Little Nell Labs ThyroChek TSH (WB)
 Qualigen Inc FastCheck TSH (WB)
 ThyroTest Whole Blood TSH Test (WB)

Uric Acid

Piccolo xpress & Blood Chem Analyzers (chem 13)WB

Urinalysis

Urinalysis: Dipstick or tablet reagent (nonautomated)
 Acon Lab. Mission UTI Urinary Tract Infection Test Strips
 Acon Mission U120 Urine Analyzer
 Biosys Laboratories Optima/Optima II Urine Analyzer
 Cole-Taylor Marketing Inc CTI-120 Urine Strip Analyzer
 Consult diagnostics Urine Analyzer
 Diagnostic Group Clarity Uruclick 120 Urine Analyzer
 Germaine Laboratories AimStrip Urine Analyzer
 Henry Schein OneStepPlus Urine Analyzer
 Hypoguard Diascreen 50 Urine Chemistry Analyzer

Provider-Performed Microscopic Procedures (PPMP)

These tests can **only** be performed in your office by an MD, DO, DPM, ARNP, nurse midwife, PA, naturopath, or dentist.
If these tests are performed by any other personnel in your office, fill out page 8 of this application.

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

Non-Waived & 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.**

<p>Microscopic Procedures <i>(If the following microscopic tests are ONLY done by the provider, DO NOT complete this section. See page 6 - PPMP)</i></p> <p><input type="checkbox"/> Wet Mounts <input type="checkbox"/> Fecal Leukocytes <input type="checkbox"/> KOH <input type="checkbox"/> Pinworm <input type="checkbox"/> Post Coital Vaginal Mucous Exam <input type="checkbox"/> Fern Tests <input type="checkbox"/> Qualitative Semen Analysis (post vas) <input type="checkbox"/> Quantitative Semen Analysis <input type="checkbox"/> Urine Sediment <input type="checkbox"/> Nasal Smear for Granulocytes</p>	<p>Total Volume <hr style="border: 1px solid black;"/></p>	<p>Parasitology (continued) <input type="checkbox"/> Concentrate/Stain <input type="checkbox"/> Parasitic Antigens</p> <p>Virology <input type="checkbox"/> Herpes Antigen <input type="checkbox"/> Herpes Culture <input type="checkbox"/> Other Viral Cultures <input type="checkbox"/> Viral Antigen Detection <input type="checkbox"/> HPV <input type="checkbox"/> Influenza (<i>nonwaived kits</i>) <input type="checkbox"/> RSV (<i>nonwaived kits</i>) <input type="checkbox"/> Other (list)</p>	<p>Total Volume <hr style="border: 1px solid black;"/></p>
<p>Histocompatibility <input type="checkbox"/> Transplant <input type="checkbox"/> Nontransplant (list specific tests)</p>	<p>Total Volume <hr style="border: 1px solid black;"/></p>	<p>Syphilis Serology <input type="checkbox"/> RPR <input type="checkbox"/> VDRL <input type="checkbox"/> MHA-TP (TP-PA) <input type="checkbox"/> FTA</p>	<p>Total Volume <hr style="border: 1px solid black;"/></p>
<p>Bacteriology <input type="checkbox"/> Affirm VP (TV, GV, YST) <input type="checkbox"/> Antibiotic Sensitivities <input type="checkbox"/> Bacterial Antigens <input type="checkbox"/> Clostridium difficile <input type="checkbox"/> Group A Strep (<i>Rapid test - nonwaived kits</i>) <input type="checkbox"/> Group B Strep <input type="checkbox"/> Blood Culture <input type="checkbox"/> Chlamydia <input type="checkbox"/> CSF Culture <input type="checkbox"/> Gram Stain <input type="checkbox"/> GC <input type="checkbox"/> Throat Culture <input type="checkbox"/> Urine Culture <input type="checkbox"/> Urine Colony Count <input type="checkbox"/> Other Culture/ID</p>	<p>Total Volume <hr style="border: 1px solid black;"/></p>	<p>Gen. Immunology <input type="checkbox"/> Allergy Testing (count individual allergens tested) <input type="checkbox"/> Alpha-1 Antitrypsin <input type="checkbox"/> AFP/Tumor <input type="checkbox"/> AFP/Other <input type="checkbox"/> ANA <input type="checkbox"/> ASO <input type="checkbox"/> HIV <input type="checkbox"/> C3 <input type="checkbox"/> C4 <input type="checkbox"/> HBsAg <input type="checkbox"/> Anti-HBc <input type="checkbox"/> HBeAg <input type="checkbox"/> HCV <input type="checkbox"/> Anti-HCV <input type="checkbox"/> IgA <input type="checkbox"/> IgG <input type="checkbox"/> IgE <input type="checkbox"/> IgM <input type="checkbox"/> Infectious Mononucleosis (<i>nonwaived kits</i>) <input type="checkbox"/> Rheumatoid Factor <input type="checkbox"/> H. pylori (<i>nonwaived kits</i>) <input type="checkbox"/> Rubella Antibody <input type="checkbox"/> Protein Electrophoresis <input type="checkbox"/> Other (list)</p>	<p>Total Volume <hr style="border: 1px solid black;"/></p>
<p>Mycobacteriology <input type="checkbox"/> AFB Smear Only <input type="checkbox"/> AFB Smear/Culture <input type="checkbox"/> AFB Antibiotic Sensitivities <input type="checkbox"/> AFB Culture & ID</p>	<p>Total Volume <hr style="border: 1px solid black;"/></p>	<p>Routine Chemistry <input type="checkbox"/> ALT/SGPT <input type="checkbox"/> Albumin <input type="checkbox"/> Alkaline Phosphatase <input type="checkbox"/> Amylase <input type="checkbox"/> AST/SGOT <input type="checkbox"/> Bilirubin, Total/Neonatal <input type="checkbox"/> pH (blood gas) <input type="checkbox"/> pO₂ (blood gas)</p>	<p>Total Volume <hr style="border: 1px solid black;"/></p>
<p>Mycology <input type="checkbox"/> DTM Only <input type="checkbox"/> Culture (Growth/No Growth) <input type="checkbox"/> Fungus <input type="checkbox"/> Yeast <input type="checkbox"/> Culture and ID <input type="checkbox"/> Fungus <input type="checkbox"/> Yeast</p>	<p>Total Volume <hr style="border: 1px solid black;"/></p>	<p>Parasitology <input type="checkbox"/> Direct Smear</p>	

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)**Routine Chemistry (continued)**

- ___ pCO₂ (blood gas)
- ___ Calcium, Total
- ___ Carbon Dioxide
- ___ Chloride
- ___ Cholesterol, Total
- ___ HDL Cholesterol
- ___ Creatine Kinase
- ___ CK Isoenzymes
- ___ Creatinine
- ___ Glucose
- ___ Glycohemoglobin (Hgb A₁C or equivalent)
- ___ Iron, Total
- ___ LDH
- ___ LDH Isoenzymes
- ___ Magnesium
- ___ Potassium
- ___ Sodium
- ___ Total Protein
- ___ Triglycerides
- ___ Urea Nitrogen (BUN)
- ___ Uric Acid
- ___ CEA
- ___ Cholinesterase: RBC methodology _____
- ___ plasma/serum methodology _____
- ___ CRP/HSCRP
- ___ Ferritin
- ___ GGT
- ___ Phosphorus
- ___ Myoglobin
- ___ Troponin
- ___ BNP
- ___ Other (list)

Total Volume**Urinalysis**

- ___ Strip by nonwaived instrument

Total Volume**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)

Total Volume**Toxicology**

- ___ Alcohol, Blood
- ___ Blood Lead
- ___ Carbamazepine
- ___ Digoxin
- ___ Ethosuximide
- ___ Gentamicin
- ___ Lithium
- ___ Phenobarbital
- ___ Phenytoin
- ___ Primidone
- ___ Procainamide/metabolites

Toxicology (continued)

- ___ Quinidine
- ___ Theophylline
- ___ Tobramycin
- ___ Valproic Acid
- ___ Drugs of Abuse (urine)
- ___ Other (list)

Total Volume**Hematology****___ Cell Identification/Manual Differential****CBC (Complete Blood Count):**

- ___ Automated WBC Differential
- ___ RBC
- ___ Hematocrit
- ___ Hemoglobin
- ___ WBC
- ___ Platelet Count

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.

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

Total Volume**Coagulation**

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

Total Volume**Immunochemistry**

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

Total Volume**Pathology**

- ___ Histopathology _____
- ___ Dermatopathology _____
- ___ Oral Pathology _____
- ___ Gyn Cytology _____
- ___ Non-gyn Cytology _____

Total Volume**Radiobioassay**

(list in vitro tests, i.e. blood volume by Cr 51, Schilling test, etc.) **Do NOT include routine RIA tests**

Total Volume**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)

5. Additional Information – Personnel Qualification Requirements

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. PhD in science
+ board certification (ABB, ABMM, ABCC, ABMLI); or
1 yr directing or supervising non-waived testing
- 6. Master in science
+ 1 yr lab training and/or experience; and
1 yr laboratory supervisory experience
- 7. Bachelor in science
+ 2 yrs lab training and/or experience; and
2 yrs laboratory supervisory experience
- 8. 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
- 9. 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)

Technical Consultant (check only one)

- 1. Pathologist w/State license
- 2. MD, DO, DPM w/State license
+ 1 yr training and/or exper. in the laboratory specialty
- 3. PhD or Master in science
+ 1 yr training and/or exper. in the laboratory specialty
- 4. Bachelor in science
+ 2 yr training and/or exper. in the laboratory specialty
- 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

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 highcomplexity 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 (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 training and/or experience in high complexity testing in laboratory specialty
- 3. PhD in science
+ 1 yr training and/or experience in high complexity testing in laboratory specialty
- 4. Master in science
+ 2 yrs training and/or experience in high complexity testing in laboratory specialty
- 5. Bachelor in science
+ 4 yrs training and/or experience in high complexity testing in laboratory specialty
- 6. 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

High Complexity Test (continued)

Technical Supervisor Qualifications:

Histocompatibility, Cytogenetics, Immunoematology and Pathology (include total # of personnel performing testing in front of appropriate categories)

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

Immunoematology

- ___ 1. Pathologist w/State license
___ 2. MD, DO, DPM w/State licens
+ 1 yr of training and/or experience in high complexity im-
munoematology

Pathology

- ___ 1. For histopathology, anatomic pathologist;*
___ 2. For dermatopathology, anatomic pathologist, dermato-
pathologist, 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
+ 1 yr training and/or exper. in high complexity testing
___ 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 gen supv + on 4/24/95 graduated from
med lab clinical training program or 50 week US military
pgm + have 2 yrs
T/or E in high complex testing
___ 8. On 9/1/92 served as G.S. + high school graduate + 10 years
T&E in high complex. testing, including 6 yrs supervisory
between 9/1/82 – 9/1/92.

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

General supervisor: Blood Gas Analysis (continued)

- ___ 2. Bachelor degree in respiratory therapy or cardiovascular
technology + 1 yr training and/or exper. in blood gases
___ 3. Associate degree related to pulmonary function
+ 2 yrs training and/or experience in blood gas analysis

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 test-
ing + completed med lab clinical training program or 50 week
US military program
___ 5. On 4/24/95, H.S. graduate performing high complexity test-
ing + 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 bach-
elor in resp. therapy or cardiovascular technology; or associ-
ate degree in pulmonary function

Cytology General Supervisor

- ___ 1. Qualify as a technical supervisor in cytology
___ 2. Qualify as a cytotechnologist + 3 yrs full time
(2080 hrs/yr) experience within preceding 10 yrs

Cytotechnologist (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 which are biology, + 12 mos training in an approved school of cytotechnology
 - 6 mos of formal training in an approved school of cyto-
technology + 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 cytol-
ogy in US in past 5 yrs; and by 9/1/95 graduate from an
accredited school or be certified by an approved agency

6. Additional Information (continued)

Legal Owner Information—attach additional sheets as needed

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

Name	Address	Phone #	Title

Change of Ownership Information

Previous Name of Legal Owner

Previous Name of Facility	Previous MTS License #	Effective Date of Ownership Change
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Physical Address

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