



Categorized Medical Test Site (MTS) Application Packet

Contents:

1. 505-044Categorized Medical Test Site Application Index and Fee Information..... 2 Pages
2. 505-045Categorized Medical Test Site Application Instructions Checklist..... 3 Pages
3. 505-037Proficiency Testing for Medical Test Site Applicants..... 2 Pages
4. 505-030Categorized Medical Test Site Application 12 Pages

Important Information:

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

In 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.

If your MTS is located in a facility accredited by the Joint Commission, you have the option of being inspected by the Washington state Medical Test Site Program. 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:

Mail your application with initial documentation and your check or money order payable to:

Department of Health
Medical Test Site Credentialing
P.O. Box 47877
Olympia, WA 98504-7877

Contact Us:
360-236-4700

Fee Information

Initial - Submit the fee corresponding to the license Category your site falls into based on your site's test volume and number of testing specialties.

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 (7/01/21 through 6/30/23) will be charged the full fee. MTS licenses issued during the second year of the state biennium (7/01/22 through 6/30/23) will be charged half of the full fee. The license categories and corresponding fees are:

Category	Fee – Applies to first year of the Biennium 7/01/21 – 6/30/23	Fee – Applies to Second year of the Biennium 7/01/22 – 6/30/23
Low Volume (1-2000)	\$560	\$280
A (2,001-10,000, 3 SPEC)	\$1,710	\$855
B (2001-10,000, 4 SPEC)	\$2,210	\$1,105
C (10,001-25,000, 3 SPEC)	\$3,070	\$1,535
D (10,001-25,000, 4 SPEC)	\$3,520	\$1,760
E (25,001-50,000)	\$4,230	\$2,115
F (50,001-75,000)	\$5,230	\$2,615
G (75,001-100,000)	\$6,240	\$3,120
H (100,001-500,000)	\$7,290	\$3,645
I (500,001-1,000,000)	\$12,960	\$6,480
J (>1,000,000)	\$15,550	\$7,775

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.

Hours of Laboratory Testing: List the days and hours of testing for this site.

Additional locations under this license: Attach a list of names, addresses and phone numbers 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 (See Section 5. Personnel Qualification Requirements)
2. Washington State professional license number, if applicable.
3. Email address

Lab Contact: Enter the lab contact's:

1. Name
2. Washington State professional license number, 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:

Indicate the test manufacturer(s) and test system(s) on the lines provided. Be as specific as possible. 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/>
- **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.
- **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. 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.

Section 7. Foreign Ownership: Complete if facility is owned fully or partially by a foreign entity. **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, 2023. 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>.

(This page intentionally left blank.)

Proficiency Testing (not required for Waived or PPMP testing)

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	ASIM Medical Lab Evaluation	800-338-2746
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

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

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



Washington State Department of

Health

Medical Test Site Credentialing
P.O. Box 47877
Olympia, WA 98504-7877
360-236-4700
<http://www.doh.wa.gov/LQA.htm>

Date
Stamp
Here

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)

- | | | |
|--|--|--|
| <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"/> 30 Drug Treatment |
| <input type="checkbox"/> 9 Federally Qualified Health Center | <input type="checkbox"/> 20 Pharmacy | <input type="checkbox"/> 31 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 _____ | |

Hours of Laboratory Testing

List days and times during which **laboratory testing** is performed. If testing 24/7 check here

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
From:							
To:							

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, addresses and phone numbers 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.) Submit evidence of qualifications with application.

Name

Washington State Professional License (if applicable)

Email Address

Lab Contact Person

Name

Washington State Professional License (if applicable)

Email Address

Section 4. Additional Information—Waived Tests

Waived Tests: Indicate the test manufacturer(s) and test system(s) on the lines provided. Be as specific as possible and verify the waived status of your test system on the [FDA/CLIA Test Complexity Database](#). e.g. (Rapid Strep, Acme Home Glucose Meter)

Adenovirus _____

Aerobic/Anaerobic Organisms - Vaginal _____

Aerobic/Anaerobic/Viral Panel - Respiratory _____

Alanine Aminotransferase (ALT) _____

Albumin _____

Alkaline Phosphatase (ALP) _____

Amylase _____

Aspartate Aminotransferase (AST) _____

B-Type Natriuretic Peptide (BNP) _____

Bilirubin, Total _____

Bladder Tumor Associated Antigen _____

BUN (Blood Urea Nitrogen) _____

Calcium _____

Calcium - Ionized _____

Carbon Dioxide (CO₂) _____

Catalase, urine _____

Chloride _____

Cholesterol _____

Complete Blood Count (CBC) _____

Creatine Kinase (CK) _____

Creatinine _____

Waived Tests (continued)

Drugs of Abuse _____

Electrolyte Panel _____

Erythrocyte sedimentation rate (ESR) _____

Esterone-3-Glucuronide _____

Ethanol _____

Follicle Stimulating Hormone (FSH) _____

Fructosamine _____

Gamma Glutamyl Transferase (GGT) _____

Glucose _____

Glycosylated HGB _____

HDL Cholesterol _____

Helicobacter pylori _____

Hematocrit _____

Hemoglobin _____

Hepatitis C Virus Antibody _____

HIV-1 _____

Influenza _____

Ketones (Blood) _____

Lactic Acid _____

LDL Cholesterol _____

Lead _____

Lithium _____

Waived Tests (continued)

Lyme Disease _____

Lutenizing Hormone (also see ovulation tests) _____

Matrix metalloproteinases-9 (MMP-9) _____

Microalbumin _____

Mononucleosis _____

Nicotine (or its metabolites) _____

Occult Blood _____

Osmolarity _____

Osteoporosis _____

Ovulation Tests _____

PH _____

Phosphorus _____

Platelet Aggregation _____

Potassium _____

Pregnancy Test (Urine) _____

Protime _____

Protein, Total _____

RSV (Respiratory Syncytial Virus Direct Antigen) _____

SARS-CoV-2 (COVID-19) _____

Semen _____

Sodium _____

Strep Antigen Test _____

Waived Tests (continued)

Syphilis _____

Trichomonas _____

Triglycerides _____

TSH _____

Uric Acid _____

Urinalysis _____

Other Tests Not Listed Above _____

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

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

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.

Microscopic Procedures	Total Volume _____	<input type="checkbox"/> Urine Culture	
(If the following microscopic tests are only done by the provider, Do not complete this section. See Proficiency Testing .		<input type="checkbox"/> Urine Colony Count	
<input type="checkbox"/> Wet Mounts		<input type="checkbox"/> Other Culture/ID	Total Volume _____
<input type="checkbox"/> Fecal Leukocytes		Mycobacteriology	
<input type="checkbox"/> KOH		<input type="checkbox"/> AFB Smear Only	
<input type="checkbox"/> Pinworm		<input type="checkbox"/> AFB Smear/Culture	
<input type="checkbox"/> Post Coital Vaginal Mucous Exam		<input type="checkbox"/> AFB Antibiotic Sensitivities	
<input type="checkbox"/> Fern Tests		<input type="checkbox"/> AFB Culture & ID	Total Volume _____
<input type="checkbox"/> Qualitative Semen Analysis (post vas)		Mycology	
<input type="checkbox"/> Quantitative Semen Analysis		<input type="checkbox"/> DTM Only	
<input type="checkbox"/> Urine Sediment		<input type="checkbox"/> Culture (Growth/No Growth)	
<input type="checkbox"/> Nasal Smear for Granulocytes		<input type="checkbox"/> Fungus	
		<input type="checkbox"/> Yeast	
	Total Volume _____	<input type="checkbox"/> Culture and ID	
Histocompatibility		<input type="checkbox"/> Fungus	
<input type="checkbox"/> Transplant		<input type="checkbox"/> Yeast	Total Volume _____
<input type="checkbox"/> Nontransplant (list specific tests)		Parasitology	
		<input type="checkbox"/> Direct Smear	
	Total Volume _____	<input type="checkbox"/> Concentrate/Stain	
Bacteriology		<input type="checkbox"/> Parasitic Antigens	Total Volume _____
<input type="checkbox"/> Affirm VP (TV, GV, YST)		Virology	
<input type="checkbox"/> Antibiotic Sensitivities		<input type="checkbox"/> Herpes Antigen	
<input type="checkbox"/> Bacterial Antigens		<input type="checkbox"/> Herpes Culture	
<input type="checkbox"/> Clostridium difficile		<input type="checkbox"/> Other Viral Cultures	
<input type="checkbox"/> Group A Strep (Rapid test - nonwaived kits)		<input type="checkbox"/> SARS-CoV-2 (nonwaived kits)	
<input type="checkbox"/> Group B Strep		<input type="checkbox"/> Viral Antigen Detection	
<input type="checkbox"/> Blood Culture		<input type="checkbox"/> HPV	
<input type="checkbox"/> Chlamydia		<input type="checkbox"/> Influenza (nonwaived kits)	
<input type="checkbox"/> CSF Culture		<input type="checkbox"/> RSV (nonwaived kits)	
<input type="checkbox"/> Gram Stain		<input type="checkbox"/> Other (list)	
<input type="checkbox"/> GC			
<input type="checkbox"/> Throat Culture			

Non-Waived Tests (continued)

<p>Syphilis Serology</p> <p><input type="checkbox"/> RPR</p> <p><input type="checkbox"/> VDRL</p> <p><input type="checkbox"/> MHA-TP (TP-PA)</p> <p><input type="checkbox"/> FTA</p>	<p>Total Volume</p> <hr/>	<p><input type="checkbox"/> Creatinine</p> <p><input type="checkbox"/> Glucose</p> <p><input type="checkbox"/> Glycohemoglobin (Hgb A₁C or equivalent)</p> <p><input type="checkbox"/> Iron, Total</p> <p><input type="checkbox"/> LDH</p> <p><input type="checkbox"/> LDH Isoenzymes</p> <p><input type="checkbox"/> Magnesium</p> <p><input type="checkbox"/> Potassium</p> <p><input type="checkbox"/> Sodium</p> <p><input type="checkbox"/> Total Protein</p> <p><input type="checkbox"/> Triglycerides</p> <p><input type="checkbox"/> Urea Nitrogen (BUN)</p> <p><input type="checkbox"/> Uric Acid</p> <p><input type="checkbox"/> CEA</p> <p><input type="checkbox"/> Cholinesterase: RBC methodology _____</p> <p><input type="checkbox"/> CRP/HSCRP</p> <p><input type="checkbox"/> Ferritin</p> <p><input type="checkbox"/> GGT</p> <p><input type="checkbox"/> Phosphorus</p> <p><input type="checkbox"/> Protein Electrophoresis</p> <p><input type="checkbox"/> Myoglobin</p> <p><input type="checkbox"/> Troponin</p> <p><input type="checkbox"/> BNP</p> <p><input type="checkbox"/> Other (list)</p>
<p>Gen. Immunology</p> <p><input type="checkbox"/> Allergy Testing (count individual allergens tested)</p> <p><input type="checkbox"/> Alpha-1 Antitrypsin</p> <p><input type="checkbox"/> AFP/Tumor</p> <p><input type="checkbox"/> AFP/Other</p> <p><input type="checkbox"/> ANA</p> <p><input type="checkbox"/> ASO</p> <p><input type="checkbox"/> HIV</p> <p><input type="checkbox"/> C3</p> <p><input type="checkbox"/> C4</p> <p><input type="checkbox"/> HBsAg</p> <p><input type="checkbox"/> Anti-HBc</p> <p><input type="checkbox"/> HBeAg</p> <p><input type="checkbox"/> HCV</p> <p><input type="checkbox"/> Anti-HCV</p> <p><input type="checkbox"/> IgA</p> <p><input type="checkbox"/> IgG</p> <p><input type="checkbox"/> IgE</p> <p><input type="checkbox"/> IgM</p> <p><input type="checkbox"/> Infectious Mononucleosis (nonwaived kits)</p> <p><input type="checkbox"/> Rheumatoid Factor</p> <p><input type="checkbox"/> H. pylori (nonwaived kits)</p> <p><input type="checkbox"/> Rubella Antibody</p> <p><input type="checkbox"/> SARS-CoV-2</p> <p><input type="checkbox"/> Other (list)</p>	<p>Total Volume</p> <hr/>	<p><input type="checkbox"/> Urinalysis</p> <p><input type="checkbox"/> Strip by nonwaived instrument</p>
<p>Routine Chemistry</p> <p><input type="checkbox"/> ALT/SGPT</p> <p><input type="checkbox"/> Albumin</p> <p><input type="checkbox"/> Alkaline Phosphatase</p> <p><input type="checkbox"/> Amylase</p> <p><input type="checkbox"/> AST/SGOT</p> <p><input type="checkbox"/> Bilirubin, Total/Neonatal</p> <p><input type="checkbox"/> pH (blood gas)</p> <p><input type="checkbox"/> pO₂ (blood gas)</p> <p><input type="checkbox"/> pCO₂ (blood gas)</p> <p><input type="checkbox"/> Calcium, Total</p> <p><input type="checkbox"/> Carbon Dioxide</p> <p><input type="checkbox"/> Chloride</p> <p><input type="checkbox"/> Cholesterol, Total</p> <p><input type="checkbox"/> HDL Cholesterol</p> <p><input type="checkbox"/> Creatine Kinase</p> <p><input type="checkbox"/> CK Isoenzymes</p>	<p>Total Volume</p> <hr/>	<p><input type="checkbox"/> Total Volume</p> <hr/> <p><input type="checkbox"/> Total Volume</p> <hr/> <p>Endocrinology</p> <p><input type="checkbox"/> Cortisol</p> <p><input type="checkbox"/> Free Thyroxine</p> <p><input type="checkbox"/> HCG (Serum Pregnancy or nonwaived urine HCG)</p> <p><input type="checkbox"/> T3 Uptake</p> <p><input type="checkbox"/> T3 (Triiodothyronine)</p> <p><input type="checkbox"/> TSH</p> <p><input type="checkbox"/> Thyroxine</p> <p><input type="checkbox"/> PSA</p> <p><input type="checkbox"/> Other (list)</p> <p><input type="checkbox"/> Estradiol</p> <p><input type="checkbox"/> FSH</p> <p><input type="checkbox"/> Luteinizing Hormone</p> <p><input type="checkbox"/> Progesterone</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)

- Toxicology** **Total Volume**

- 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)

Hematology **Total Volume**

- Cell Identification/Manual Differential

<p>CBC (Complete Blood Count):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Automated WBC Differential <input type="checkbox"/> RBC <input type="checkbox"/> Hematocrit <input type="checkbox"/> Hemoglobin <input type="checkbox"/> WBC <input type="checkbox"/> Platelet Count 	<p>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</p>
--	--

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

Coagulation **Total Volume**

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

- Immunohematology** **Total Volume**

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

- Pathology** **Total Volume**

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

Radiobioassay **Total Volume**

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

Genetic Testing **Total Volume**

- 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)

Section 5. 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. 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

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 high complexity testing director before 2/24/03
- 5. 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

Technical Supervisor Qualifications:

Histocompatibility, Cytogenetics, Immunohematology and Pathology (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
- ___ 2. MD, DO, DPM 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 + 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

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
- ___ 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 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

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 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

Section 6. Other Licensure, Certification, or Registration Information

Legal Owner Information—attach additional sheets as needed

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

Name	Address	Phone #	Title

Section 7. Foreign Ownership

Does this facility have partial or full ownership by a foreign entity or foreign government? Yes No
If yes, what is the country of origin for the foreign entity? _____

Change of Ownership Information

Previous Name of Legal Owner

Previous Name of Facility	Previous MTS License #	Effective Date of Ownership Change
Physical Address		
City	State	Zip Code

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