Categorized Medical Test Site (MTS) Application Packet

Contents:

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 1099
Olympia, WA 98507-1099

Contact Us:
360-236-4985

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 (7/01/23 through 6/30/24) will be charged the full fee. MTS licenses issued during the second year of the state biennium (7/01/24 through 6/30/25) are required to submit half of the full fee. The license categories and corresponding fees are:

Category	Fee – Applies to first year of the Biennium 7/01/23 – 6/30/24	Fee – Applies to Second year of the Biennium 7/01/24 – 6/30/25
Low Volume (1-2000)	$620	$310
A (2,001-10,000, 3 SPEC)	$1,900	$950
B (2001-10,000, 4 SPEC)	$2,450	$1,225
C (10,001-25,000, 3 SPEC)	$3,410	$1,705
D (10,001-25,000, 4 SPEC)	$3,910	$1,955
E (25,001-50,000)	$4,700	$2,350
F (50,001-75,000)	$5,810	$2,905
G (75,001-100,000)	$6,930	$3,465
H (100,001-500,000)	$8,090	$4,045
I (500,001-1,000,000)	$14,390	$7,195
J (>1,000,000)	$17,260	$8,630

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. Indicate if you wish to retain the CLIA number if switching to a new license type.
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. Indicate if you wish to retain the CLIA number if changing ownership.

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

☐ **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.

You will receive a renewal notice for this license approximately 60 days before the expiration date.

Please contact Customer Service at 360-236-4985 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**.

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 360-236-4985.

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	College of American Pathologists (CAP)	847-832-7000
Amer. Assoc. of Bioanalysts - MLE	800-234-5315	Wisconsin State Lab. of Hygiene	800-462-5261
American Proficiency Institute (API)	800-333-0958		

Regulated Analytes: These Tests MUST be Covered by PT

Chemistry

ALT/SGPT
Albumin
Alkaline phosphatase
Amylase
AST/SGOT
Bilirubin, total (or neonat.)
Blood gas p02, pC02, pH
Calcium, total
Chloride
Cholesterol, total
HDL cholesterol
Creatine kinase
Creatine kinase isoenzymes
Creatinine
Glucose
Iron, total
LDH
LDH isoenzymes
Magnesium
Potassium
Sodium
Total protein
Triglycerides
Urea nitrogen
Uric acid

Endocrinology

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

Toxicology

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

Hematology

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

Immunohematology

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

Syphilis Serology

RPR, VDRL, MHA–TP, etc.

Immunology

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

Immunology (cont.)

HBsAg, Anti–HBc, HBeAg
IgA, IgE, IgG, IgM
Infectious mononucleosis
Rheumatoid factor
Rubella

Bacteriology

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

Mycology

Yeast ID/culture
Fungus culture–systemic

Parasitology

Direct only
Concentration/Stain

Virology

HSV EIA
Culture or FA
Other EIA for virus

Mycobacteriology

AFB Smear and/or culture

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)

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

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

__ 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 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** _____

Write the volume for each microscopic procedure performed. Include these numbers in the total volume.
(If the following microscopic tests are only done by the provider, Do not complete this section.
See **Proficiency Testing**.

__ Wet Mounts Volume ____
__ Fecal Leukocytes Volume ____
__ KOH Volume ____
__ Pinworm Volume ____
__ Post Coital Vaginal Mucous Exam Volume ____
__ Fern Tests Volume ____
__ Qualitative Semen Analysis (post vas) Volume ____
__ Quantitative Semen Analysis Volume ____
__ Urine Sediment Volume ____
__ Nasal Smear for Granulocytes Volume ____

Histocompatability **Total Volume** _____

__ Transplant
__ Nontransplant
(list specific tests)

Bacteriology **Total Volume** _____

__ **Affirm VP (TV, GV, YST)**
__ **Antibiotic Sensitivities**
__ **Bacterial Antigens**
  __ **Clostridium difficile**
  __ **Group A Strep (Rapid test - nonwaived kits)**
  __ **Group B Strep**
__ **Blood Culture**
__ **Chlamydia**
__ **CSF Culture**
__ **Gram Stain**
__ **GC**
__ **Throat Culture**
__ **Urine Culture**
__ Urine Colony Count
__ **Other Culture/ID**

Mycobacteriology **Total Volume** _____

__ **AFB Smear Only**
__ **AFB Smear/Culture**
__ **AFB Antibiotic Sensitivities**
__ **AFB Culture & ID**

Mycology **Total Volume** _____

__ DTM Only
__ Culture (Growth/No Growth)
  __ Fungus
  __ Yeast
__ **Culture and ID**
  __ Fungus
  __ Yeast

Parasitology **Total Volume** _____

__ **Direct Smear**
__ **Concentrate/Stain**
__ **Parasitic Antigens**

Virology **Total Volume** _____

__ **Herpes Antigen**
__ **Herpes Culture**
__ **Other Viral Cultures**
__ SARS-CoV-2 (nonwaived kits)
__ **Viral Antigen Detection**
  __ HPV
  __ Influenza (nonwaived kits)
  __ RSV (nonwaived kits)
__ Other (list)

Non-Waived Tests (continued)

Syphilis Serology — **Total Volume** _____

__ **RPR**
__ **VDRL**
__ **MHA-TP (TP-PA)**
__ **FTA**

Gen. Immunology — **Total Volume** _____

__ Allergy Testing (count individual allergens tested)
__ **Alpha-1 Antitrypsin**
__ **AFP/Tumor**
__ **AFP/Other**
__ **ANA**
__ **ASO**
__ **HIV**
__ **C3**
__ **C4**
__ **HBsAg**
__ **Anti-HBc**
__ **HBeAg**
__ **HCV**
__ **Anti-HCV**
__ **IgA**
__ **IgG**
__ **IgE**
__ **IgM**
__ **Infectious Mononucleosis (nonwaived kits)**
__ **Rheumatoid Factor**
__ H. pylori (nonwaived kits)
__ **Rubella Antibody**
__ SARS-CoV-2
__ Other (list)

Routine Chemistry — **Total Volume** _____

__ **ALT/SGPT**
__ **Albumin**
__ **Alkaline Phosphatase**
__ **Amylase**
__ **AST/SGOT**
__ **Bilirubin, Total/Neonatal**
__ **pH** (blood gas)
__ **pO_2** (blood gas)
__ **pCO_2** (blood gas)
__ **Calcium, Total**
__ Carbon Dioxide
__ **Chloride**
__ **Cholesterol, Total**
__ **HDL Cholesterol**
__ **Creatine Kinase**
__ **CK Isoenzymes**

Note: Each measured parameter must be counted as a separate test, added together, and included in the Routine Chemistry total volume above.

__ **Creatinine**
__ **Glucose**
__ Glycohemoglobin (Hgb A_1C or equivalent)
__ **Iron, Total**
__ **LDH**
__ **LDH Isoenzymes**
__ **Magnesium**
__ **Potassium**
__ **Sodium**
__ **Total Protein**
__ **Triglycerides**
__ **Urea Nitrogen (BUN)**
__ **Uric Acid**
__ CEA
__ Cholinesterase: RBC methodology_____
__ CRP/HSCRP
__ Ferritin
__ GGT
__ Phosphorus
__ Protein Electrophoresis
__ Myoglobin
__ Troponin
__ BNP
__ Other (list)

Urinalysis — **Total Volume** _____

__ Strip by nonwaived instrument

Endocrinology — **Total Volume** _____

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

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**

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)

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 and **provide a copy of evidence of credentials with application submission**)

___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)

___7. PhD in science (choosing this option requires a clinical consultant)
+ 1 yr directing or supervising non-waived testing

___8. Master in science (choosing this option requires a clinical consultant)
+ 1 yrs lab training and/or experience and
1 yrs laboratory supervisory experience

___9. Bachelor in science (choosing this option requires a clinical consultant)
+ 2 yrs lab training and/or experience and
2 yrs laboratory supervisory experience

Clinical Consultant (check only one and **provide a copy of evidence of credentials with application submission**)

__ 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 and **provide a copy of evidence of credentials with application submission**)

___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 and **provide a copy of evidence of credentials with application submission**)

___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 whicha are biology, + 12 mos training in an approved school of cytotechnology
- 6 mos of formal training in an approved school of cytotechnology + 6 mos FT experience in cytotechnology in lab acceptable to pathologist who directed training.
- achieved a satisfactory grade in an HHS proficiency exam for cytotechnologist

__ 5. Prior to 9/1/94:

- 2 yrs FT exp. within preceding 5 yrs examining slide preps under supervision of a TS in cytology and prior to 1/1/69:
  - graduated from high school.
  - completed 6 mos training in cytotechnology directed by a pathologist or other MD providing cytology services.
  - 2 yrs FT supervised experience in cytotechnology

__ 6. Prior to 9/1/94:

- 2 yrs of FT experience under supervision of a TS in cytology in US in past 5 yrs; and by 9/1/95 graduate from an accredited school or be certified by an approved agency

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

If changing license type, do you want to keep the already assigned CLIA number? ☐ Yes ☐ No
If yes, provide the CLIA number: _____

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

If changing ownership, do you want to keep the already assigned CLIA number? ☐ Yes ☐ No
If yes, provide the CLIA number: _____

Section 7. Foreign Ownership

Does this facility have partial or full ownership by a foreign entity or foreign government? ☐ Yes ☐ No
If yes, provide the CLIA number: _____

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