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 and must complete this application.

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

Per WAC 246-338-050, all licensed medical test sites, excluding those granted a certificate of waiver, must enroll in procificency testing for all CMS regulated analytes.

In order to process your request:

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

Department of Health
P.O. Box 1099
Olympia, WA 98507-1099

Contact Us:
360-236-4985

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

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 categorized license applications received during the first year of the state biennium (7/01/2023 through 6/30/2024) are required to submit the full fee. Applications received during the second year of the state biennium (7/01/2024 through 6/30/2025) are required to submit half of the full fee. The license categories and corresponding fees are:

Category	Fee – Applies to applications submitted during the first year of the biennium 7/01/23 – 6/30/24	Fee – Applies to applications submitted during the 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 - Choose this option if the facility has never been issued an MTS license.
- Change of ownership - Choose this option if the facility was previously issued an MTS license and is now under new ownership and/or has a new UBI number.
- Change of license type - Choose this option if the facility has previously been issued a different type of MTS license, such as a Provider Performed Microscopic Procedure (PPMP) MTS license, a waived MTS license, or an accredited MTS license.

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

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

Federal Employer ID Number (FEIN): Enter your FEIN, 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 Employer ID Number (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 Employer ID Number (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. First name, Last name, and Washington State professional license number, if applicable. (See Section 5. Personnel Qualification Requirements)
2. Email address

Lab Contact: Enter the lab contact's:

1. First name, Last name, and Washington State professional license number, if applicable.
2. Email address

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

☐ **Section 4. Additional Information:**

Waived Tests: Fill in the test system and test manufacturer in the provided table for each test your lab performs. Refer to the CLIA waived test list provided by the FDA to verify the test you are using is approved for waived use.

PPMP Tests: Next to each test, provide an annual estimate of the volume of testing to be performed. The microscopic prodedures can only be performed in your facility by a Washington State licensed MD, DO, DPM, ARNP, PA, 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, provide an estimate of the annual number of tests to be 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 separate tests.

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 CLIA-CME Course for Physician Lab Directors of Moderate Complexity Laboratories: https://cme.medicine.uiowa.edu/
- COLA's Laboratory Director CME Certification Course: https://education.lms.cola.org/catalog/info/id:133
- COLA's Annual Laboratory Enrichment Forum: https://education.cola.org/2024-laboratory-enrichment-forum
- LabUniversity Laboratory Director CME Program: https://labuniversity.org/lab-director-cme-program/

These courses are designed to meet the CLIA requirement at 493.1405(b)(2)(ii)(B).

☐ **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:**
The legal owner or authorized representative must sign and date the application. Print the name and title of the legal owner or authorized representative.

You will receive a renewal notice for this license approximately 60 days before the expiration date. The renewal will be mailed to the facility mailing address on file.

Please contact Facilities 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/mts**.

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.

Categorized Medical Test Sites must enroll in PT for all regulated analytes listed on the next page. Most programs are offered as five-sample modules shipped in three separate test events annually. A list of the currently approved PT programs and their phone numbers can also be found on the next page. Call the program or check their website for a free copy of their PT brochure.

Information needed to enroll:

- The name of your MTS exactly as it appears on your MTS license,
- Address,
- CLIA ID number, and;
- MTS license number.

Select the appropriate program(s) for your laboratory. When enrolling in the PT program(s), you must indicate that a copy of your PT results be sent to the Washington Medical Test Site Program. **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). Some PT providers offer two-sample programs that can be used for biannual verification of 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 enroll in a PT program for the test by 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 notify your PT provider and/or choose the code “test not performed” on the PT answer sheet.

If you have other questions, email MTS@doh.wa.gov for assistance.

Additional information is available at our website in the proficiency testing section.

Approved Proficiency Testing Providers

Accutest	800-665-2575	College of American Pathologists (CAP)	847-832-7000
Amer. Assoc. of Bioanalysts - MLE	800-234-5315	WSLH	800-462-5261
American Proficiency Institute (API)	800-333-0958		

Regulated Analytes: Each laboratory must enroll in a PT program for the following tests:

Chemistry

ALT/SGPT
Albumin
Alkaline phosphatase
Amylase
AST/SGOT
B-natriuretic peptide (BNP)
Bilirubin, total (or neonat.)
Blood gas p02, pC02, pH
Calcium, total
Cancer antigen (CA) 125
Carbon dioxide
Carginoembryonic antigen
Chloride
Cholesterol, total
LDL cholesterol, direct
HDL cholesterol
Creatine kinase
Creatine kinase isoenzymes
Creatinine
Ferritin
GGT
Glucose
Hemoglobin A1c
Iron, total
Total iron binding capacity, direct
LDH
LDH isoenzymes
Magnesium
Phosphorus
Potassium
ProBNP
Prostate specific antigen
Sodium
Total protein
Triglycerides
Troponin I
Troponin T
Urea nitrogen
Uric acid

Endocrinology

Cortisol
Estradiol
Free thyroxine
Folate, serum
FSH
Serum pregnancy (HCG) (qualitative or quantitative)
Luteinizing hormone
Parathyroid hormone
Progesterone
Prolactin
Testosterone
T3 uptake
Triiodothyromine
TSH -Thyroxine
Vitamin B12

Toxicology

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

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
Anti-HCV
ASO
C-reactive protein (high sensitivity)
HIV
Complement C3, C4

Immunology (cont.)

HBsAg, Anti–HBc, HBeAg, Anti-HBs, 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

P.O. Box 1099
Olympia, WA 98507-1099
360-236-4700
http://www.doh.wa.gov/mts

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 Employer ID Number (FEIN)	
Legal Owner/Operator Entity Name (as it appears on the UBI/Master Business License)			
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 Employer ID Number (FEIN) (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.

First Name	Last Name	WA State Professional License number

Email Address

Does the director of this laboratory serve as director for any other laboratories that are separately licensed in Washington or another state? ☐ Yes ☐ No

If yes, provide the name of the laboratory and CLIA number:

_____

Lab Contact Person

First Name	Last Name	WA State Professional License number

Email Address

Section 4. Additional Information—Waived Tests

Complete the table below for waived tests performed by the laboratory. Refer to the Application Instructions Checklist, Section 4, if you need assistance completing this table.

Test Name	Test System (e.g. One Step Glucose)	Test Manufacturer (e.g. ACME)
Adenovirus		
Aerobic/Anaerobic Organisms - Vaginal		
Alanine Aminotransferase (ALT) (SGPT)		
Albumin		
Albumin, Urinary		
Alcohol, Saliva		
Alkaline Phosphatase (ALP)		
Amines		
Amphetamines		
Amylase		
Aspartate Aminotransferase (AST) (SGOT)		
Bacteria Associated With Bacterial Vaginosis		
Barbiturates		
Benzodiazepines		
Bilirubin, Total		
Bladder Tumor Associated Antigen		
B-Type Natriuretic Peptide (BNP)		
Buprenorphine		
Calcium, Ionized		
Calcium, Total		
Cannabinoids (THC)		
Carbon Dioxide, Total (CO2)		
Catalase, Urine		
Chlamydia		
Chloride		
Cholesterol		
Cocaine Metabolites		
Collagen Type I Crosslink, N-Telopeptides (NTX)		
Cotinine		
Creatine Kinase (CK)		
Creatinine		
Eddp (Methadone Metabolite)		
Erythrocyte Sedimentation Rate (ESR), Nonautomated		
Estrone-3 Glucuronide		
Ethanol (Alcohol)		
Fecal Occult Blood		
Fentanyl		
Fern Test, Saliva		

Waived Tests (continued)		
Follicle Stimulating Hormone (FSH)		
Fructosamine		
Gamma Glutamyl Transferase (GGT)		
Gastric Occult Blood		
Gastric pH		
Glucose		
Glycated Hemoglobin, Total		
Glycosylated Hemoglobin (HGB A1C)		
hCG, Urine		
HDL Cholesterol		
Helicobacter Pylori		
Helicobacter Pylori Antibodies		
Hematocrit		
Hemoglobin		
Hemoglobin By Copper Sulfate, Nonautomated		
Hepatitis C Virus Antibody		
Herpes Simplex I And/Or II Antibodies		
HIV-1 And HIV-2 Antibodies		
HIV-1 And HIV-2 Antigens		
Infectious Mononucleosis Antibodies (Mono)		
Influenza (A/B)		
Ketone, Blood		
Ketone, Urine		
Lactic Acid (Lactate)		
LDL Cholesterol		
Lead, Blood		
Leukocyte Esterase, Urinary		
Lithium		
Luteinizing Hormone (LH)		
Lyme Disease Antibodies (Borrelia Burgdorferi Abs)		
Matrix Metalloproteinases-9 (MMP-9)		
Methadone		
Methadone Metabolite (EDDP)		
Methamphetamine		
Methylenedioxymethamphetamine (MDMA)		
Microalbumin		
Morphine		
Neisseria Gonorrhoeae		
Neutrophil Percentage (Neut%)		
Nicotine And/Or Metabolites		
Nitrite, Urine		
Norfentanyl		
Nortriptyline		

Waived Tests (continued)		
Opiates		
Osmolality, Tears		
Ovulation Test (LH) By Visual Color Comparison		
Oxazepam		
Oxycodone		
pH		
pH, Urine		
Phencyclidine (PCP)		
Phenobarbital		
Phosphorus		
Platelet Aggregation		
Platelet Count		
Potassium		
Pregnanediol Glucuronide		
Propoxyphene		
Protein, Total		
Prothrombin Time (PT)		
Red Blood Cell Count (Erythrocyte Count) (RBC)		
Respiratory Bacterial Pathogens		
Respiratory Syncytial Virus		
Respiratory Viruses		
SARS-CoV-2		
SARS-CoV-2 And Other Respiratory Viruses		
Secobarbital		
Semen		
Sodium		
Spun Microhematocrit		
Streptococcus, Group A		
Thyroid Stimulating Hormone (TSH)		
Tramadol		
Treponema Pallidum (Syphilis) Antibodies		
Trichomonas		
Tricyclic Antidepressants		
Triglyceride		
Urea (BUN)		
Uric Acid		
Urinary Protein, Qualitative		
Urine Dipstick Or Tablet Analytes, Nonautomated		
Urine hCG By Visual Color Comparison Tests		
Urinalysis		
Vaginal pH		

Waived Tests (continued)		
White Blood Cell Count (Leukocyte Count) (WBC)		
White Blood Cell Differential (WBC Diff)		
Whole Blood Qualitative Dipstick Glucose		
Yeast, Candida Only		
Other Waived Test(S) Not Listed		

Provide an estimated total annual test volume for all waived tests performed: _____

Provider-Performed Microscopic Procedures (PPMP)

Next to each microscopic procedure, provide an annual estimate of the volume of testing to be performed by a state licensed MD, DO, DPM, ARNP, PA or dentist. Refer to the Application Instructions Checklist, Section 4, if you need assistance completing this table.

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 Testing (attach additional sheets if needed)

Place a checkmark by all the non–waived and non–PPMP tests that are performed at your medical test site. Refer to the Application Instructions Checklist, Section 4, if you need assistance completing this table. All analytes listed in bold print are regulated and must be covered by proficiency testing.

Microbiology

Microscopic Procedures

Total Volume: _____

NOTE: If the following microscopic tests are ONLY done by a licensed provider, DO NOT complete this section

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

Bacteriology

Total Volume: _____

___ Affirm VP (TV, GV, YST)
___ Antibiotic Sensitivities
___ Bacterial Antigens
  ___ Clostridium difficile
  ___ Group A Strep) rapid test - nonwaived kits)
  ___ Group B Strep
___ Bacterial Toxin Detection
___ Blood Culture
___ Chlamidia
___ CSF Culture
___ Gram Stain
___ GC
___ Throat Culture
___ Urine Culture
___ Urine Colony Count
___ Other Culture/ID:_____

Mycobateriology

Total Volume: _____

___ AFB Smear/Stain
___ AFB Antibiotic Sensitivities
___ AFB Culture & ID

Mycology

Total Volume: _____

___ DTM Only
___ Direct fungal antigen detection
___ Fungus Culture
  ___ Growth/No Growth
  ___ Culture and ID
___ Yeast Culture
  ___ Growth/No Growth
  ___ Culture and ID

Parasitology

Total Volume: _____

___ Direct Smear
___ Concentrate/Stain
___ Parasitic Antigens

Virology

Total Volume: _____

___ Herpes Antigen
___ Herpes Culture
___ Other Viral Culture
___ Viral Antigen Detection
  ___ Human Papillomavirus (HPV)
  ___ Influenza (nonwaived kits)
  ___ RSV (nonwaived kits)
___ SARS-CoV-2 (nonwaived kits)
___ Other (list): _____

Moderate and High Complexity Testing Performed in your facility (attach additional sheets if needed)

Diagnostic Immunology

Syphilis Serology

Total Volume: _____

___ **RPR**

___ **VDRL**

___ **MHA-TP (TP-PA)**

___ **FTA**

General Immunology

Total Volume: _____

___ Allergy Testing (count individual allergens tested)

___ **Alpha-1 Antitrypsin**

___ **AFP/Tumor**

___ **AFP/Other**

___ **ANA**

___ **ASO**

___ **Anti-HCV**

___ **HIV**

___ **C3**

___ **C4**

___ C-reactive protein

___ **C-reactive protein (high sensitivity)**

___ **HBsAg**

___ **Anti-HBc**

___ **Anti-HBs**

___ **HBeAg**

___ **HCV**

___ **IgA**

___ **IgG**

___ **IgE**

___ **IgM**

___ **Infectious Mononucleosis (nonwaived kit)**

___ **Rheumatoid Factor**

___ H. pylori (nonwaived kits)

___ COVID-19 Serology

___ **Rubella Antibody**

___ Other (list): _____

Histocompatibility

Histocompatibility

Total Volume: _____

___ Transplant

___ Nontransplant (list specific tests): _____

Pathology

Pathology

Total Volume: _____

___ Histopathology _____/year

___ Dermatopathology _____/year

___ Oral Pathology _____/year

___ Gyn Cytology _____/year

___ Non-gyn Cytology _____/year

Radiobioassay

Radiobioassay

Total Volume: _____

_____

(list in vitro tests, i.e. blood volume by Cr 51, Schilling test, etc.)

Do NOT include routine RIA tests

Moderate and High Complexity Testing Performed in your facility (attach additional sheets if needed)

Chemistry

Routine Chemistry

Total Volume: _____

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

___ **ALT/SGPT**
___ **Albumin**
___ **Alkaline Phosphatase**
___ **Amylase**
___ **AST/SGOT**
___ **Bilirubin, Total/Neonatal**
___ **B-natriuretic peptide (BNP)**
___ **pH (blood gas)**
___ **pO2 (blood gas)**
___ **Calcium, Total**
___ **Cancer antigen (CA) 125**
___ **Carbon Dioxide**
___ **Carcinoembryonic antigen (CEA)**
___ **Chloride**
___ **Cholesterol, Total**
___ Cholinesterase: RBC methodology: _____
plasma/serum methodology: _____
___ **HDL Cholesterol**
___ **LDL-Direct Cholesterol**
___ **Creatine Kinase**
___ **CK Isoenzymes**
___ **Creatinine**
___ **Ferritin**
___ **GGT**
___ **Glucose**
___ **Hemoglobin A1C**
___ **Iron, Total**
___ **LDH**
___ LDH Isoenzymes
___ **Magnesium**
___ Myoglobin
___ **Phosphorus**
___ **Potassium**
___ **ProBNP**
___ **PSA (Prostate specific antigen, total)**
___ **Sodium**
___ **Total iron binding capacity (TIBC), direct**
___ **Total Protein**
___ **Triglycerides**
___ **Troponin I**
___ **Troponin T**
___ **Urea Nitrogen (BUN)**
___ **Uric Acid**
___ Ammonia
___ Bilirubin, direct
___ C-peptide
___ CA 19-9
___ CA 15-3
___ Ceruloplasmin
___ FFN (Fetal Fibronectin)
___ Free PSA
___ Haptoglobin
___ Homocysteine
___ Lactic Acid
___ Lipase
___ Ketones, serum
___ Osmolality
___ Protein Electrophoresis
___ Prealbumin
___ ROM (Rupture of Membranes)
___ Transferrin, direct
___ Vitamin D
___ Other (list): _____

Moderate and High Complexity Testing Performed in your facility (attach additional sheets if needed)

Chemistry (continued)

Urinalysis

Total Volume: _____

___ Strip by nonwaived instrument

Endocrinology

Total Volume: _____

___ **Cortisol**

___ **Estradiol**

___ **Folate, serum**

___ **FSH**

___ FT3 (Free Triiodothyronine)

___ **FT4 (Free Thyroxine)**

___ **HCG (Serum Pregnancy or nonwaived urine HCG)**

___ **Luteinizing hormone (LH)**

___ **Parathyroid hormone (PTH)**

___ **Progesterone**

___ **Prolactin**

___ **Testosterone**

___ **T3 Uptake**

___ **T3 (Triiodothyronine)**

___ **TSH**

___ **T4 (Thyroxine)**

___ **Vitamin B12**

___ ACTH (Adrenocorticotropic hormone)

___ DHEA-S

___ Insulin

___ Procalcitonin

___ Other (list): _____

Toxicology

Total Volume: _____

___ **Acetaminophen, serum**

___ **Alcohol, Blood**

___ **Carbamazepine**

___ **Digoxin**

___ Ethosuximide

___ **Gentamicin**

___ **Lead, Blood**

___ **Lithium**

___ **Phenobarbital**

___ **Phenytoin**

___ Primidone

___ Procainamide/metabolites

___ Quinidine

___ **Salicylate**

___ **Theophylline**

___ **Tobramycin**

___ **Valproic Acid**

___ **Vancomycin**

___ Drugs of Abuse (urine):

___# of Panels **X** ___# of Analytes = ____Total

___ Fentanyl

___ Tacrolimus

___ Other (list): _____

Moderate and High Complexity Testing Performed in your facility (attach additional sheets if needed)

Hematology

Hematology

Total Volume: _____

___ Cell Identification/Manual Differential

CBC (Complete Blood Count):	Note: Each measured parameter (automated differential, RBC, hematocrit(or MCV), hemoglobin, WBC, platelets) must be counted as a separate test.
___ Auto WBC Differential	
___ RBC	
___ Hematocrit	
___ Hemoglobin	
___ WBC	
___ Platelet Count	

___ Reticulocyte Count

___ Hemoglobin Electrophoresis

___ Flow Cytometry

___ ESR (Erythrocyte Sedimentation Rate)

___ Other (list): _____

Coagulation

Total Volume: _____

___ Fibrinogen

___ PTT

___ Prothrombin Time

___ Thrombin Time

___ Factor Assays

___ Activated Clotting Time

___ D-dimer

___ Other (list): _____

Immunohematology

Immunohematology

Total Volume: _____

___ ABO Group_____/year

___ D (Rh) Typing_____/year

___ Antibody Detection (Screen) _____/year

___ Antibody Identification_____/year

___ Compatibility Test (Crossmatch) _____/year

___ Other (list): _____

Genetics

Genetic Testing

Total Volume: _____

____Biochemical Genetic Tests (list tests):

_____

____Cytogenetic Tests (list tests):

_____

____Molecular Genetic Tests (list tests):

_____

NOTE: add HPV testing under Virology, add Chlamydia and/or GC testing under Bacteriology

Section 5. Personnel Qualification Requirements

Determine if your lab performs moderate or high complexity testing. Only complete the section that is appropriate for the complexity level of your MTS.

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, what is the country of origin for the foregn entity?: _____

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