



Certificate of Waiver Medical Test Site (MTS) Application Packet

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Important Information:

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

If the application you are submitting is handwritten, please ensure the information is written clearly, accurately, and legibly in order to ensure there is no delay in processing.

In order to process your request:

Return Completed Application (original copy) and fee in the form of check or money order (made out to Department of Health) to:

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

Fee Information

Certificate of waiver MTS 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 corresponding fees are:

	Fee - Applies to applications submitted during the first year of the biennium 7/01/2023-6/30/2024	Fee - Applies to applications submitted during the second year of the biennium 7/01/2024-6/30/2025
Certificate of waiver Medical Test Site License Application	\$260	\$130

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 civil.rights@doh.wa.gov.

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Certificate of Waiver 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 categorized 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 two 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 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.
2. Email address.
3. If the director of this laboratory serves as the director for any separately licensed laboratory, provide the name and CLIA number of the laboratory. Include laboratories licensed in other states.

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. Please verify the waived status of your test system at <https://www.accessdata.fda.gov>.

If you perform any non-waived tests, do not complete this application. See the [MTS website](#) to help you determine your correct license category or email the MTS Program at MTS@doh.wa.gov.

Section 5. 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 new license type.

Change of Ownership Information: If applicable, list the previous 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 6. Foreign Ownership: Complete if facility is owned fully or partially by 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: <https://doh.wa.gov/mts>.

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

Date
Stamp
Here

Revenue: 0420030000

Certificate of Waiver Medical Test Site License Application

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

Check One

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

Section 1. Demographic Information

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

Mailing Address

City	State	Zip Code	County
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Phone (enter 10 digit #)	Fax (enter 10 digit #)
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Email Address	Web Address
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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
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Facility Phone (enter 10 digit #)	Facility Fax (enter 10 digit #)
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Mailing Address (if different than physical address)

City	State	Zip Code	County
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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 Drug Treatment |
| <input type="checkbox"/> 8 End Stage Renal Disease Dialysis | <input type="checkbox"/> 19 Mobile Lab | <input type="checkbox"/> 30 Clinic |
| <input type="checkbox"/> 9 Federally Qualified Health Center | <input type="checkbox"/> 20 Pharmacy | <input type="checkbox"/> 31 Adult Family Home |
| <input type="checkbox"/> 10 Health Fair | <input type="checkbox"/> 21 Physician Office | |
| <input type="checkbox"/> 11 Health Main. Organization | <input type="checkbox"/> 22 Other _____ | |

Hours of Testing

List days and times during which **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. - if applicable. A professional license is not required to be a director for a waived MTS license)

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:

MTS 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: _____

Section 5. 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 the facility 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
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Physical Address

City	State	Zip Code
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If changing ownership, do you want the facility to keep the already assigned CLIA number? Yes No

If yes, provide the CLIA number: _____

Section 6. 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? _____

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