Certificate of Waiver 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.

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
Revenue Section
P.O. Box 1099
Olympia, WA 98507-1099

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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
- 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 two 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
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:**
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.

If you perform any tests other than the waived tests listed, do not complete this application. See the LQA website: http://www.doh.wa.gov/lqa.htm to help you determine your correct license category or call the Department of Health at 360-236-4985.

☐ **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:**
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.

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Washington State Department of HEALTH

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

Revenue: 0420030000

Fee
☐ April 1, 2023 – June 30, 2025.....$260.00

Date Stamp Here

Certificate of Waiver 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 _____
___ 23 Prison
___ 24 Public Health Lab
___ 25 Rural Health Clinic
___ 26 Student Health Service
___ 27 Skilled Nursing Facility
___ 28 Tissue Bank/Repository
___ 29 Drug Treatment
___ 30 Clinic
___ 31 Adult Family Home

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 Waived Director)

Name

Washington State Professional License (if applicable)

Email Address

MTS Contact Person

Name

Washington State Professional License (if applicable)

Email Address

Note: **If your test kit doesn't appear on the FDA-approved waived test list, do not complete this application**. See the FDA website to check that your test kits are for waived use and to determine the correct license category for your site based on the test kit you intend to use.

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. (Acme Brand Rapid Strep, Acme Home Glucose Monitor, etc...)

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 (Hemoglobin A1C) _____

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 _____

_____

_____

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

Physical Address

City	State	Zip Code

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