

Medical Test Site License Pre-Renewal Verification Instructions for Categorized and Accredited (Non-Waived, Non-PPMP) Laboratories

Response Deadline: February 20, 2009

Current Medical Test Site (MTS) licenses will expire on **June 30, 2009**. The MTS rules require licensees to submit a completed renewal application form and fee 30 days prior to the expiration date of the license. A two-step process is required.

- Complete this pre-renewal verification form now.
- Pay the fee (based upon the information you provide on this pre-renewal verification form). A fee statement will be mailed in early April.

It is essential that the information on the pre-printed renewal verification form be checked closely for accuracy. The information on the renewal form is entered into the MTS computer system and the Centers for Medicare & Medicaid Services (CMS) computer system. The information in the CMS database is accessed by government reimbursement agencies, such as Medicare and Medicaid, who use the information to reimburse medical claims to providers.

Pre-Printed Information: The demographic information contained in the MTS database is pre-printed on the first page of the pre-renewal verification form. **It is critical that you review this information and modify it to reflect your current information.** If any information is incorrect or missing, write in the correct information. The pre-printed information includes:

- **Name of Facility:** The name listed on the pre-renewal verification form should be the name you routinely use to identify your facility.
- **Federal Tax ID Number (EIN):** This should be the number used for tax reporting purposes. When a facility originally applies to an insurance company to be eligible to obtain reimbursement, the Tax ID Number is required information.
- **Telephone Number:** Be sure that the area code and phone number are correct.
- **Fax Number:** Add the fax number if it is not listed.
- **Accredited License:** If your facility is **accredited and inspected** by an approved accreditation organization, you qualify for an accredited license. (This should appear on the pre-printed renewal information for your facility.)

Note: If you are only participating in proficiency testing, but are **Not Inspected** by the organization, **You Are Not Accredited.**

- **Address Information:**
 - **Site Address:** This is the physical location of the facility
 - **Mailing Address:** If mail **cannot** be delivered to the site address, list a mailing address.
- **Multiple Sites:** If your facility is already licensed as a Multiple Site, attach the name and address for each separate site on a separate piece of paper

To be eligible for a multiple-site license, you must qualify as a Not-For-Profit or state or local government facility that performs Limited Public Health Testing (a total of 15 or less different waived or moderate complexity tests) at different locations. If your facility qualifies for a multiple-site license and you want to consolidate sites under one license, you must submit the following with your renewal application:

- A copy of your federal 501(c)(3) tax determination letter from the Internal Revenue Service (IRS) if you are not a state or local government facility. If this is already on file with the LQA Office, you do not have to resubmit.
- Include a list of the name and address of each site that will be consolidated under one license and a list of the tests performed at each site (including waived tests). Include the MTS and CLIA numbers of each separate site if they are currently licensed separately.
- On pages 7-8 of the application form, check all the tests and record the total number of tests **performed by all the sites** on the line next to the appropriate specialty or subspecialty.

Only one license will be issued for a multiple-site facility. **It is the responsibility of the medical test site to make copies of the license for each separate site under that license.**

Note: If you are performing testing at more than one location **on a single campus or complex**, you are not subject to the above requirements for a multiple site license. You do not need to list each site separately.

- **Personnel:** Verify that the information for the following categories
 - Owner: name of the legal owner of the MTS license
 - Lab Director: director the laboratory. If there is a new director, complete the “Change in Director” form found under the “Supplemental Material” listing on the LQA website (<http://www.doh.wa.gov/lqa.htm>).
 - Lab Contact: person that we contact to verify information about the facility, to schedule on-site inspections, and discuss problems.
 - Microbiology Contact: supervisor of the microbiology department
 - Cytology Contact: supervisor of the cytology department

The following are optional categories and will not apply to all facilities.

- Lab Consultant: name of the laboratory consultant, if applicable
 - Lab Administrative Contact: name of other administrative staff, if applicable
- **E-Mail Address:** Please list an e-mail address, if available, for the personnel categories listed above.
 - **Owner Signature:** The pre-renewal verification form **must be signed (on page 2) by the owner or authorized representative** of the medical test site. Unsigned forms will be returned for signature and will delay the relicensing process.

Waived and PPMP Testing (pages 3-6)

- **Waived Tests:** If your facility performs any tests classified as waived, check the specific waived test system/kit you perform using the list on pages 3-6 of this application.

Note: Recently, several of the Abbott iSTAT test cartridges were classified as waived tests by the Food and Drug Administration (FDA). Several of the reagent discs for the Abaxis Piccolo analyzer were also classified as waived tests by the FDA when using whole blood. Refer to the list of waived tests on pages 3-6 of the pre-renewal form for information about specific waived tests, waived analyzers, and specimen types.

- **Provider-Performed Microscopic Procedures - PPMP Tests:** Check all microscopic tests listed on page 6 that are performed in your office **by a provider** (MD, DO, DPM, ARNP, Nurse Midwife, PA, Naturopath, or Dentist). If these microscopic tests are performed by other personnel in your office, complete the information on page 7 under Microscopic Procedures.

Moderate and High Complexity Testing - By Specialty (pages 7-8)

Pages 7 and 8 of the pre-renewal verification form list specific moderate and high complexity tests, according to test specialties and subspecialties. Place a check mark by each of the tests you perform at your medical test site. **If you perform any tests not listed, write the name of the tests under the appropriate specialty or subspecialty area or attach a list (including total volume) of these tests to the form.**

Write the total number of tests performed annually on the line next to the specialty or subspecialty as indicated. When counting the total volume of tests:

- Count each test in a chemistry profile as an individual test.
- **Count the measured parameters as separate tests for CBCs.** Example: A RBC, WBC, Hemoglobin, MCV, Platelet Count and Automated differential are separate parameters measured by your hematology analyzer; the test count would be 6 separate tests. If a manual differential is performed, count it as a separate test.

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Review the test listing carefully to assure that all tests you perform are included.
The following are some commonly missed tests:

- Glycohemoglobin (A1C) (non-waived test) is found under Chemistry
- Infectious mononucleosis (non-waived test) is found under General Immunology
- Influenza (non-waived test) is found under Virology (viral antigen detection)
- Rapid Strep Screen (non-waived test) is found under Bacteriology
- Serum pregnancy test (HCG, serum) is found under Endocrinology
- Urinalysis (performed by a non-waived instrument) is found under Urinalysis

Note: Contact the LQA Office at (206) 418-5600 if:

- You no longer perform any moderate or high complexity testing.
- You no longer need a MTS license (no longer perform any high complexity, moderate complexity, PPMP, or waived tests).
- Your accreditation status has changed.

Washington Department of Health Questionnaire (pages 9-10)

In an effort to reduce the number of separate requests for information from various divisions of the Department of Health (DOH), we are asking you to fill out pages 9 and 10 of the renewal application. Please list information only for tests you perform on-site. Write your MTS number at the top of the form.

Fees: Once we receive and process your completed pre-renewal verification form we will send you a fee statement in April for a two-year MTS license. A list of fees for the various MTS license categories is found on the LQA website (<http://www.doh.wa.gov/lqa.htm>).

Remember:

- **The owner or an authorized representative must sign your completed pre-renewal verification form.**
- The deadline for returning your completed pre-renewal verification form is **February 20, 2009**.
- **Do not send payment** with your completed pre-renewal verification form. We will bill you in April after reviewing and processing your pre-renewal verification form.

Questions?

Please call at (206) 418-5600 us with any questions you have regarding the license renewal process or completing the renewal application form. It is better to call than provide incorrect information.