

## IQCP Is Coming January 2016

The educational phase for Individualized Quality Control Plans (IQCP) for non-waived laboratory testing ends January 1, 2016, with full implementation to follow.

IQCP replaces Equivalent Quality Control (E-QC). The Medical Test Site (MTS) Program has deemed that testing currently approved to use E-QC is eligible for the new IQCP regulation. IQCP allows laboratories to customize quality control (QC) plans for their specific environment and offers flexibility in achieving QC compliance. IQCP strengthens manufacturer and laboratory partnerships and formalizes risk management decisions.

IQCP is a new quality control option, based on risk management for laboratories performing non-waived testing. IQCP is voluntary. The laboratory can choose to return to performing two levels of external QC each day of patient testing instead of implementing IQCP.

Laboratories that perform tests categorized and approved by FDA as waived tests must continue to follow manufacturer's instructions for these tests. This requirement will not change.

Implementation of IQCP is about six months away. Laboratories should use this remaining time to learn about IQCP, and to write their QC policies and procedures for IQCP. The IQCP educational phase started January 1, 2014 and concludes December 31, 2015. Laboratories may continue to perform E-QC until January 1, 2016. The laboratory director retains overall responsibility for ensuring that QC programs are established and maintained to assure the

quality of laboratory test results.

CMS has provided educational IQCP materials at the [CLIA website](#).

A free tool developed by the Centers for Disease Control and Prevention (CDC), Division of Laboratory Systems in conjunction with Centers for Medicare & Medicaid Services (CMS), Division of Laboratory Service is now available. This step-by-step instructional workbook is designed to assist laboratories that choose to develop an IQCP for tests they perform. It describes how laboratories can perform a risk assessment to evaluate and record their current quality activities on an IQCP worksheet, create a QC plan from the risk assessment information, and establish a quality assessment for the test system being evaluated for an IQCP. The approach outlined in this workbook is not mandatory nor is it the only example that can be used. Laboratories can develop their own format that meets their needs. "[Developing an IQCP; A Step-By-Step Guide](#)" is available online through the CDC's website.

If you are an accredited laboratory, contact your accreditor continued on page 4

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### Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the [LQA website](#).

Acute Diarrhea	Lipid Screening
Anemia	PAP Smear Referral
ANA	Point-of-Care Testing
Bioterrorism Event Mgmt	PSA
Bleeding Disorders	Rash Illness
Chlamydia	Red Cell Transfusion
Diabetes	Renal Disease
Group A Strep Pharyngitis	STD
Group B Streptococcus	Thyroid
Hepatitis	Tuberculosis
HIV	Urinalysis
Infectious Diarrhea	Wellness
Intestinal Parasites	

# Provider Performed Microscopic Procedures (PPMP) MTS Requirements

**What is a PPMP license?** It is one of four licenses that are available under the Medical Test Site (MTS) licensure program. Facilities performing only tests indicated as “waived” and moderate complexity tests listed below and under WAC 246-338-020(2)(b)(i) through (x) called “provider performed microscopy procedures” (PPMP), which are performed in conjunction with a patient visit and performed by a licensed professional meeting the qualifications of a provider under WAC 246-338-020(a)(i) through (vi), require a PPMP license.

These facilities must apply for a MTS license before beginning any patient testing and must meet the minimum requirements listed below. If the facility is performing tests that are not waived or are not on the PPMP approved list, the facility must apply for a MTSC (Categorized) or MTSA (Accredited) license. Performance of PPMP tests by testing personnel other than those indicated below also requires applying for a MTSC or MTSA license as a moderate complexity laboratory.

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Secretary, DOH: John Weisman, DrPH, MPH  
Health Officer: Kathy Lofy, MD  
Director, PHL: Romesh Gautam, PhD  
Program Manager, LQA: Susan Walker  
Editor: Leonard Kargacin  
Circulation: Leonard Kargacin

Comments, letters to the editor, information for publication, and requests for subscription can be directed to:

*ELABORATIONS*  
1610 NE 150th St  
Shoreline, WA 98155

e-mail address: leonard.kargacin@doh.wa.gov

NOTE: Letters to the editor may be published unless specified otherwise by the author.

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## PPMP Laboratory Requirements

**They are exempt from** routine onsite surveys.

**They are subject to:**

- An MTS license that authorizes the facility to perform only waived and PPMP tests (listed below) for a period not to exceed two years.
  - Direct wet mounts including preparations of vaginal, cervical or skin specimens
  - Fecal leukocyte examination
  - Fern tests
  - KOH (potassium hydroxide) preparation
  - Nasal smears for granulocytes
  - Pinworm examination
  - Post-coital direct, qualitative exams of vaginal or cervical mucus
  - Qualitative semen analysis (limited to presence or absence of sperm and motility)
  - Urine sediment examinations
- Inspections for complaints and to validate that only waived and PPMP tests are performed and all other applicable requirements are met.
- Maintain a copy of the test order for two years per MTS regulations (five and six years for Medicare and Medicaid respectively)
- Meet requirements for testing personnel: tests classified as PPMP may be performed by a MD, DO, Podiatrist, Dentist, Advanced Registered Nurse Practitioner, Midwife licensed under 18.50 RCW, Naturopath or Physician Assistant.
- Provide written procedures for waived and PPMP test performance, which have been approved by the laboratory director, and made readily available to testing personnel
- Meet director qualifications as listed below
- Meet record and report requirements (see below)
- Meet quality assurance requirements (see below)
- Perform and document biannual verification or proficiency testing for the PPMP tests performed
- Meet the department standards for safety and disposal of hazardous and infectious waste
- Inform the Washington State Department of Health, Laboratory Quality Assurance Section of changes in laboratory name, director(s), or location within 30-days of any change
- Apply for MTSC or MTSA license and meet additional requirements prior to performing or reporting any test not specified on the waived or PPMP lists.

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# PPMP MTS Requirements, cont'd from page 2

**Director Qualifications:** The director of a PPMP laboratory is legally liable and responsible for all aspects of testing. The director must meet one of the following requirements and must be licensed by the appropriate board and the State of Washington:

- Physician or podiatrist
- Dentist
- Nurse practitioner or nurse midwife
- Physician assistant
- Naturopath.

**Record and Report Requirements** (Maintain records of the following for two years)

- Training and experience of personnel performing PPMP tests.
- Each specimen examined including:
  - o Name of person tested (two identifiers)
  - o Name of authorized person who is requesting the test (written or electronic)
  - o Date and time of specimen collection and test report
  - o Type of test performed
  - o Test result
  - o Signature or identification of person performing the test
  - o Other information that may be needed to aid in interpretation of the result, and
  - o Name and location of laboratory where the test was performed.

**Quality Assurance Requirements:** The laboratory must establish and follow written policies and procedures for a comprehensive quality assurance (QA) program. It must be designed to monitor and evaluate the ongoing and overall quality of the total testing process including pre-analytic, analytic, and post-analytic. The laboratory's QA plan must evaluate the effectiveness of its policies and procedures; identify and correct problems; ensure the accurate, reliable and prompt reporting of tests results; and ensure the adequacy and competency of staff members. All QA activities and corrective action must be documented and discussed with pertinent staff members.

The laboratory must monitor, evaluate, and revise, if necessary, the following:

- Criteria for patient preparation, specimen collection, specimen rejection, labeling, preservation and transportation of specimens.
- Completeness and accuracy of test requisitions, results, and other information for interpretation of test results.
- Accuracy and reliability of test reporting systems, storage of records, and retrieval of results.
- Remedial action for problems.
- Policies and procedures for documenting competency of testing personnel at least every six months for the first year of employment and annually thereafter.
- Policies and procedures for documenting initial training for testing personnel upon hire and before performance of testing.
- Complaints and complaint policy.

## Referral of Specimens

- Refer specimens only to laboratories operating in compliance with the Clinical Laboratory Improvement Amendments (CLIA).
- The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.

Meeting the above requirements, at a minimum, will help the laboratory provide accurate and reliable results for its patients. Please contact the Washington State Department of Health Laboratory Quality Assurance section at (253) 395-6745 if you want further information.

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ing agency for their requirements.

Contact your Washington State Department of Health, Laboratory Quality Assurance (LQA) surveyor if you have questions or need assistance. The surveyors have shared information at the end of MTS surveys when IQCP will affect the laboratory. Refer to the CMS brochures and handouts left by the LQA surveyors.

## Measles RT-PCR Replaces Culture at WAPHL

Beginning June 1, 2015, the Virology Laboratory at the Washington State Public Health Laboratories (WAPHL) no longer offers measles culture as a routine diagnostic test. Traditionally, the WAPHL has performed measles culture on all specimens submitted for RT-PCR. However, upon performance evaluation of the measles real-time RT-PCR assay test, the WAPHL has determined that the results obtained through this test alone are sufficient to support patient management and epidemiological follow-up without the need for culture confirmation.

As a reminder, requirements and limitations of the measles RT-PCR test are as follows:

- Preferred specimens are collected through the use of a nasopharyngeal swab.
- Validated specimens also include: urine, oropharyngeal swab, dual nasopharyngeal/throat swab, nasal wash, and culture isolates.
- Improper specimen types/collection/handling; the presence of inhibitors in the sample; or the presence of measles viral RNA in concentrations below the level of detection by the assay may result in sub-optimal sensitivity.
- Prolonged specimen storage and shipment can affect the quality of results.
- Specimens collected within 72 hours of rash onset yield the best results.

For additional laboratory-specific guidance on this test and any other tests, please refer to the updated [Directory of Services](#). The measles culture test menu was updated in the Directory of Services on June 1, 2015. Contact WA State Virology Laboratory at 206-418-5458 with any questions.

## HIV Testing Protocol Changes at WAPHL

Starting July 1, 2015, the WAPHL, HIV unit will change its testing protocol. These changes are in response to the availability of new FDA approved 4th generation test kits and serve to bring our HIV testing services into alignment with recently released HIV diagnostic testing practices.

Our new algorithm will proceed as follows:

### **Screening - Oral fluids, Serum, Plasma:**

- All specimens will initially be tested with the 4th generation “GS HIV Combo Ag/Ab EIA” manufactured by Bio-Rad. This new test has the added ability to detect HIV p24 antigen in addition to patient antibodies (IgM/IgG). This allows for earlier detection of HIV in patient samples. Specimens that are negative by this assay will be reported as such and no further testing will be performed.

### **Confirmation - Serum, Plasma:**

- HIV-positive specimens will be confirmed and differentiated (HIV-1 and HIV-2) using the Multispot test also produced by Bio-Rad. Indeterminate results may necessitate specimen recollection after four weeks or sending to the CDC for a Nucleic Acid Amplification test (NAAT) for confirmation.

### **Confirmation - Oral fluids:**

- Oral fluids will be confirmed using the Western Blot. Indeterminate results will necessitate specimen recollection, preferably serum/plasma.

Because of the nature of the new screening test, there will be a change in the specimen shipping requirements. Serum and plasma must be shipped cold to maximize test sensitivity, as well as to facilitate PCR testing in the event of an indeterminate result. All other aspects of specimen collection remain the same. If you have any questions about the change please contact [Craig Colombel](#)

# Budget Impasse

Due to the ongoing Washington State budget impasse, the DOH WAPHL and LQA are preparing for a temporary shutdown beginning July 1, 2015.

**LQA:** offices will be closed

**WAPHL:**

- Newborn Screening – Services will not be interrupted
- Rabies Testing - Services will not be interrupted
- Emergency Response - Services will not be interrupted
- All other laboratory services will be temporarily suspended.

If the budget is passed the service interruptions will not occur.

## Calendar of Events

**Training Classes:**

[2015 Northwest Medical Laboratory Symposium](#)

October 14-17, 2015      Seattle

[22nd Annual Clinical Laboratory Conference](#)

November 9, 2015      Tukwila

[2016 ASCLS-WA Spring Meeting](#)

April 21-23, 2016      Vancouver, WA

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

For persons with disabilities, this document is available upon request in other formats. To submit a request, please call 1-800-525-0127 (TTY/TDD 1-800-833-6388).

