



MARYLAND ACCREDITATION CRITERIA FOR SINGLE-USE TEST DEVICES

The State of Maryland licenses all clinical laboratories in addition to the federal requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). COLA was approved under Maryland State Law as an accrediting agency on July 17, 2007. Previously, laboratories electing to use COLA for CLIA Accreditation were also subject to an additional inspection by the Maryland Department of Health & Mental Hygiene, Office of Health Care Quality, for compliance with state requirements.

In seeking recognition from the State of Maryland, COLA determined a need to create a state-specific criterion to augment its existing accreditation standards and maintain equivalency to state laboratory requirements.

As a result of Maryland's approval of COLA as an accrediting agency, laboratories seeking COLA accreditation will only need to undergo a single survey by COLA. The COLA surveyor will assess compliance with both CLIA and State requirements.

COLA-accredited laboratories in Maryland are expected to comply with COLA Criteria for Quality Lab Performance as found in Section 3 of the COLA Accreditation Manual (www.cola.org), and comply with the following state-specific criterion regarding quality control (QC) procedures:

MD 1: If the laboratory uses single-use test device(s), regardless of specialty and complexity, it must perform 2 levels of external QC once per week UNLESS the test is included in the list below:

- (1) Blood glucose by glucose monitoring devices cleared by the FDA for home use
- (2) Dermatophyte screen
- (3) Dipstick glucose

**AS A RESULT OF MARYLAND'S
APPROVAL OF COLA AS AN
ACCREDITING AGENCY,
LABORATORIES SEEKING COLA
ACCREDITATION WILL ONLY
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SURVEY BY COLA.**

- (4) Dipstick urinalysis
- (5) Gram stain
- (6) Group A streptococcal screen
- (7) Hematocrit
- (8) Hemoglobin
- (9) Infectious mononucleosis slide or card test
- (10) Microscopic urinalysis
- (11) Occult blood
- (12) Pinworms
- (13) Potassium hydroxide skin preparations
- (14) Rheumatoid factor slide agglutination test
- (15) Sickle cell screen
- (16) H. pylori test with a single-use test device for non-forensic testing, using a whole blood specimen

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- (17) Fructosamine test with a single-use test device for nonforensic testing, using a whole blood specimen
- (18) Heterophile antibodies test with a single-use test device for nonforensic testing, using a whole blood specimen
- (19) Urine bacteria colony count
- (20) Urine pregnancy test
- (21) Wet mounts
- (22) Influenza antigen test with a single-use test device for nonforensic testing, using a direct nasal or throat swab specimen
- (23) Hemoglobin A1C test using a manual or a single-use test device for nonforensic testing, with a whole blood specimen

A single-use test device is a test system that can only be inoculated with a single patient specimen. At the completion of testing, all reagents and the patient specimen are depleted, and the device is no longer viable for additional testing.

Examples of single-use test devices that are NOT on the MD exception list, and therefore require 2 levels of external QC each week are: Serum HCG kits, HIV Kits, Drug screen kits, Coagulation testing (PT and ACT).

The federal CLIA quality control standard is 2 levels of external QC daily, unless the laboratory opts to use Equivalent Quality Control (EQC) for eligible tests. Many single-use test devices have built in controls and could thereby qualify for EQC under CLIA standards and COLA criteria.

The state of MD's requirement is different in a number of ways:

1. They created a requirement specifically for single-use test devices.
2. This requirement applies to a device used for any test, in any specialty, and any complexity (waived, moderate, and high) unless it is on the special exception list shown above.
3. If a lab in MD uses a single-use test device that qualifies for EQC and the test is not on the exception list, the lab will have to perform 2 levels of external QC every week - regardless of successful completion of an EQC study to qualify for a selected EQC option.
4. If a lab in MD performs a waived test using a single-use test device and that test is not on the exception list, the lab will have to perform 2 levels of external QC every week.

Your COLA surveyor will look for any test (regardless of the specialty and complexity) performed on a single-use test device that is NOT on the list, to check whether the laboratory performs and documents 2 levels of external QC each week that patients are tested.

Your laboratory should have a consistent location for documenting the performance of external QC. This may be a written or electronic record. The record must include the date of testing, test results, determination of acceptability, and initials of the individual performing the test.

If your Maryland lab is not already in compliance with this Maryland-specific criterion, update your quality control program to define the number and frequency of external controls to perform for each single-use test device. At a minimum, perform two levels of external controls each week of patient testing, as specified by the State of Maryland.

If COLA, the test manufacturer, or your laboratory-established control procedures require more than two levels of external controls, or require external controls to be performed more frequently than once per week, then follow the most stringent requirement.

Conduct and document training for all personnel who perform testing in the laboratory. Periodically review your quality control records to monitor compliance with this requirement as part of your quality control program.

Additional Resource:

Maryland Department of Health & Mental Hygiene, Office of Health Care Quality web site:
www.dhmd.state.md.us/ohcq/regulated_programs/laboratories.htm