

PROPOSAL

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FINAL ACTION

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Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 10 LABORATORIES

Notice of Proposed Action

[25-092-P]

The Acting Secretary of Health proposes to:

- (1) Amend Regulation .03 under COMAR 10.10.01 General;
- (2) Amend Regulation .01 under COMAR 10.10.02 Medical Laboratories—General;
- (3) Amend Regulations .02 and .04 under COMAR 10.10.03 Medical Laboratories—Licenses;
- (4) Repeal existing Regulations .01 and .02 under COMAR 10.10.04 Medical Laboratories;
- (5) Amend Regulations .02, .04, and .05 under COMAR 10.10.05 Medical Laboratories—Proficiency Testing;
- (6) Amend Regulations .02, .07, .08, .12, and .13 and repeal existing Regulation .06 under COMAR 10.10.06 Medical Laboratories—Quality Assurance;
- (7) Amend Regulation .07 under COMAR 10.10.07 Medical Laboratories—Personnel;
- (8) Amend Regulation .02 under COMAR 10.10.08 Medical Laboratories—Sanctions; and
- (9) Amend Regulations .02, .04, and .07 under COMAR 10.10.12 Medical Laboratories—Public Health HIV Testing Programs.

Statement of Purpose

The purpose of this action is to amend COMAR 10.10.01—10.10.08, and 10.10.12 to protect the public and individual health by requiring medical laboratories to employ qualified personnel, operate under reliable procedures, have in place effective quality control and quality assurance programs, and have qualified supervision. This is accomplished by setting minimum, reasonable standards in regulation for the licensing of laboratories in Maryland.

The updated regulations will:

- (1) Reflect current Maryland law;
- (2) Delete obsolete terminology;
- (3) Address concerns brought forth by the industry;
- (4) Align with regulations from the Department of Health and Human Services, Clinical Laboratory Improvement Amendments (CLIA), where appropriate; and
- (5) Reflect current quality and safety standards of medical laboratories.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Jordan Fisher Blotter, Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 534 Baltimore, Maryland 21201, or call 410-767-0938, or email to mdh.regs@maryland.gov. Comments will be accepted through June 30, 2025. A public hearing has not been scheduled.

10.10.01 General

Authority: Courts and Judicial Proceedings Article, §10-1001; Health General Article, §§17-201, 17-202, 17-205, 17-214, and 17-501; Annotated Code of Maryland

.03 Definitions.

- A. (text unchanged)

B. Terms Defined.

(1)—(12) (text unchanged)

(12-1) “CLIA waived test” means a test system, assay, or examination that the federal Department of Health and Human Services has determined meets the Clinical Laboratory Improvement Amendments (CLIA) statutory criteria as specified for waiver under the federal CLIA Amendments of 1988 in Section 353 of the Public Health Service Act of 42 U.S.C. §263a.

(13)—(23) (text unchanged)

(24) “Excepted test” means a medical laboratory test[, as set forth in COMAR 10.10.03.02B, that is authorized by the Secretary to be offered or performed by a laboratory operating under a letter of exception] that is a CLIA waived test.

(25)—(70) (text unchanged)

[(71)] “Single-use test device for forensic testing” means the reagent-containing unit of a test system that:

- (a) Is in the form of a sealed container or cartridge possessing a validity check;
- (b) Possesses a nonresealable closure or an evidentiary tape to ensure detection of tampering;
- (c) Is self-contained and individually packaged;
- (d) Is discarded after each test; and
- (e) Does not allow any test component or constituent of a test system to interact from test to test.

(72) “Single-use test device for nonforensic testing” means the reagent-containing unit of a test system in the form of a cartridge, test pack, or other container that:

- (a) Includes a validity check;
- (b) Is self-contained and individually packaged;
- (c) Is discarded after each test; and
- (d) Does not allow any test component or constituent of a test system to interact from test to test.]

[(73)] (71)—[(88)] (86) (text unchanged)

(87) “Test System” means the instructions, instrumentation, equipment, and reagents necessary to perform an assay or examination that generates test results.

[(89)] (88) “Validity check” means a procedural, testing process, or analytical verification of proper performance of one or more analytical steps performed by the test system operator, built into a [single-use test device,] test system, and carried out by a [single-use test device] test system to detect environmental damage or interfering substances that may have affected the device or the results of the testing process.

10.10.02 Medical Laboratories—General

Authority: Courts and Judicial Proceedings Article, §10-1001; Health General Article, §§17-201, 17-202, 17-205, 17-214, and 17-501, Annotated Code of Maryland

.01 Responsibilities of the Department.

A.—B. (text unchanged)

C. Issuance of Licensing Documents. The OHCQ shall:

- (1) (text unchanged)
- (2) Issue a license that includes the:
 - (a) (text unchanged)
 - (b) Name of the licensee or laboratory director; and
 - (c) Name of the laboratory owner[; and].
 - [(d) Expiration date of the license; and]
- (3) (text unchanged)

D. Administration and Information Management. The OHCQ shall:

- (1)—(2) (text unchanged)
- (3) Monitor the proficiency testing performance of a laboratory required to participate in proficiency testing; and
- [(4) Conduct a cytology proficiency testing program for each cytotechnologist and pathologist who performs gynecological examinations;
- (5) Set and collect fees as set forth in COMAR 10.10.04.]
- [(6)] (4) [Impose] For tests that are not CLIA waived, impose alternative sanctions and initiate actions leading to imposition of principal sanctions against a laboratory under the appropriate provisions of this subtitle.

E. Recommending Excepted Test Status.

- [(1)] (text unchanged)
- [(2)] The Laboratory Advisory Committee's responsibilities shall include making a recommendation to the Secretary in favor of or against granting a test excepted status.

(3) The Laboratory Advisory Committee shall consider a test for excepted test status and make a recommendation to the Secretary if:

- (a) The Laboratory Advisory Committee is requested in writing by:
 - (i) The Secretary;
 - (ii) A Maryland chapter of a specialty medical society; or
 - (iii) The Medical and Chirurgical Faculty of Maryland;

(b) The test on which the request is based is waived under CLIA, by the CDC, or by the federal Food and Drug Administration;

(c) The test employs a directly collected specimen not subjected to post-collection manipulation or processing; and

(d) The test is a manual test or is a test system employing a single use test device for nonforensic testing that tests for one or more analytes in a single specimen.

(4) The Laboratory Advisory Committee shall make a recommendation to the Secretary concerning excepted test status based on:

(a) Immediate patient need for the test in order to:

(i) Provide rapid patient follow-up;

(ii) Order additional tests; or

(iii) Make an immediate diagnostic or therapeutic decision;

(b) Whether the test is core to a physician's practice, based on:

(i) Physician specialty;

(ii) Usefulness of the test in the specialty; and

(iii) Who actually performs the test;

(c) Access, applicability, and ease of performance by personnel in a POL and POC setting;

(d) Whether all analytes testable on a multi-test, single-use test device are recommended for excepted status;

(e) Consideration of the known benefits and risks of the test or test system, especially those involving an infectious disease;

and

(f) The potential harm to a patient if the test:

(i) Is performed incorrectly; or

(ii) Produces a false positive or false negative test result.

(5) In recommending a test for excepted status, the Laboratory Advisory Committee may specify certain conditions to be met based on factors set forth in §E(4) of this regulation.

F. Authorizing Excepted Test Status.

(1) The Secretary may authorize a test for excepted status if:

(a) The test is recommended for excepted test status by the Laboratory Advisory Committee; or

(b) The Secretary:

(i) Determines that the test meets the criteria of §E(3)(b)—(d) of this regulation; and

(ii) Bases the authorization for excepted status on the factors set forth in §E(4) of this regulation.

(2) In authorizing a test for excepted status, the Secretary may specify certain requirements to be met based on factors set forth in §E(4) of this regulation.]

10.10.03 Medical Laboratories—Licenses

Authority: Environment Article, §6-303; Health-General Article, §§2-104(b), 17-202, 17-205—17-210, 17-212, 17-502, 17-503, 17-505, [17-508], and 17-510, Annotated Code of Maryland

.02 Letters of Exception.

A. (text unchanged)

B. Excepted Tests. A POL or POCL operating under a letter of exception may perform one or more [of the following excepted tests or types of tests:

(1) Whole blood glucose by glucose monitoring devices cleared by the FDA for home use or a CLIA waived analyzer;

(2) Dermatophyte screen;

(3) Dipstick glucose;

(4) Dipstick urinalysis using reagent test pads affixed to plastic strips that detect one or a combination of any of the following urine characteristics or constituents:

(a) Glucose;

(b) Bilirubin;

(c) Ketones detected in the form of acetoacetic acid;

(d) Specific gravity;

(e) Red blood cells or hemoglobin;

(f) pH;

(g) Protein;

(h) Urobilinogen;

(i) Nitrites; and

(j) Leukocytes;

(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) Sickie-cell screen;
 - (16) *H. pylori* test with a single-use test device for nonforensic testing, using a whole-blood specimen;
 - (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 using a direct nasal or throat swab specimen;
 - (23) Hemoglobin A1c test using a whole blood specimen;
 - (24) Qualitative test for bladder cancer markers in voided urine including a test to detect:
 - (a) Human complement factor H-related protein; or
 - (b) Nuclear mitotic apparatus protein (NMP);
 - (25) Brain natriuretic peptide (BNP) test using a whole blood specimen to detect:
 - (a) Heart disease; or
 - (b) The response of treatment for heart failure;
 - (26) Fern test for qualitative detection of:
 - (a) Amniotic fluid crystallization; or
 - (b) Estrogenic activity;
 - (27) Qualitative semen analysis, limited to detecting:
 - (a) The presence or absence of sperm; or
 - (b) Sperm motility;
 - (28) Nitrazine vaginal pH test using phenolphthazine reagent paper strips;
 - (29) Qualitative immunochromatographic test to detect the presence of adenovirus antigens directly from eye fluid;
 - (30) Microalbumin-creatinine urinalysis test utilizing an instrument based dip-and-read reagent test strip for determining urine albumin and creatinine levels, including the urinary albumin-to-creatinine ratio (UACR) in a random urine specimen;
 - (31) Screening tests for urine or saliva performed on FDA-cleared for home use or FDA approved single-use test devices for the presence of alcohol and drugs of abuse solely for the purpose of directing patient counseling;
 - (32) Qualitative enzyme activity test using a chromogenic substrate of bacterial sialidase for use in the detection of bacterial vaginosis directly from vaginal fluid specimens;
 - (33) Qualitative immunochromatographic test to detect the presence of *Trichomonas vaginalis* antigens directly from a vaginal swab;
 - (34) CLIA-waived Prothrombin Time/International Normalized Ratio (PT/INR) with the additional requirements that:
 - (a) The licensee shall enroll into a Proficiency Testing program offered by an entity that has been approved by the Centers for Medicare and Medicaid Services (CMS) to ensure validation of all measurement capabilities for the instrument used to perform the test; and
 - (b) When the numerical score is less than 80 percent, the licensee shall submit the official proficiency test results to the Office of Health Care Quality for review and monitoring with evidence of documented remedial actions taken;
 - (35) CLIA waived blood lipid analysis for cholesterol, HDL, LDL, and triglycerides;
 - (36) Whole blood lead testing on a CLIA waived analyzer with the additional requirements:
 - (a) The licensee shall enroll into a Proficiency Testing program offered by an entity that has been approved by the Centers for Medicare and Medicaid Services to ensure validation of all measurement capabilities for the instrument used to perform the test;
 - (b) When the numerical score is less than 80 percent, the licensee shall submit the official proficiency test result to the Office of Health Care Quality for review and monitoring with evidence of documented remedial actions taken;
 - (c) All staff involved in testing shall undergo training on the testing device and testing techniques with annual competencies;
 - (d) Records of training and competencies for staff shall be:
 - (i) Maintained by the laboratory; and
 - (ii) Made available for review by the Department; and
 - (e) Reporting requirements stated in §C of this regulation shall be followed; and
 - (37) CLIA Waived Urine Drug Screens with the following additional requirements:
 - (a) The licensee shall enroll into a proficiency testing program offered by an entity that has been approved by the Centers for Medicare and Medicaid Services; and
 - (b) When the numerical score is less than 80 percent, the licensee shall submit the official proficiency test result to the Office of Health Care Quality for review and monitoring with evidence of documented remedial actions taken] *CLIA waived tests.*
- C.—D. (text unchanged)

.04 Letter of Exception and Permit — Administrative Procedures.

A. Application — Filing.

(1)—(5) (text unchanged)

[(6) A person shall submit with the application the nonrefundable partial licensing fee set forth in COMAR 10.10.04.02C.]

B.—D. (text unchanged)

E. Amending a Permit. Except as prescribed in §D of this regulation, a licensee holding an unexpired permit who wishes to amend it shall:

(1) (text unchanged)

[(23)] (2) (text unchanged)

[F. Expiration and Renewal.

(1) A letter of exception or permit expires on the date shown on the license.

(2) The OHCQ shall mail a renewal application to a laboratory not less than 30 days before the expiration date shown on the license.

(3) A licensee shall file an application to renew a license using forms provided by the OHCQ and following the same procedures prescribed in §§A and B of this regulation.

(4) A licensee who fails to submit a completed renewal application before the expiration date may not operate the laboratory after its letter of exception or permit has expired.]

[G.] F. (text unchanged)

G. Letter of Exception. A person applying for a letter of exception for a POL or POCL shall submit an initial application.

H. Letter of Exception — Limited Testing for Rare Diseases. A person applying for a letter of exception—limited testing for rare diseases for a laboratory shall submit an initial application.

10.10.05 Medical Laboratories—Proficiency Testing

Authority: Health General Article, §§17-202 and 17-211, Annotated Code of Maryland

.02 Discipline, Specialty, and Subspecialty.

A. (text unchanged)

B. Discipline Standards.

(1) (text unchanged)

(2) Gynecologic Cytology. A licensee operating under a permit to perform gynecologic cytology shall ensure that the laboratory enrolls and maintains successful participation in[:

(a) A cytology PT program operated by the Secretary if the laboratory is located inside this State; or

(b) A] a cytology PT program approved by CMS [if the laboratory is located outside this State].

(3) (text unchanged)

.04 Cytology—Departmental Requirements.

A. The Secretary may not issue a license to operate a laboratory that examines gynecologic cytology specimens if the laboratory does not enroll and participate satisfactorily in a cytology PT program [operated or approved by the Secretary] *approved by CMS.*

[B. The OHCQ shall conduct annual PT for each pathologist and cytotechnologist who examines gynecological cytology slides acquired in the State.

C. The OHCQ or an agent of the Department shall hand carry test materials for first-event testing in a PT cycle to a laboratory and shall conduct and supervise all testing.

D. The OHCQ shall:

(1) Conduct announced and unannounced on-site testing for individuals during an annual PT cycle; and

(2) Schedule and conduct a retesting event for an individual who has failed the annual PT testing event not more than 45 days after receipt of the notification of the PT testing event failure by the:

(a) Individual who failed the annual PT testing event; and

(b) Laboratory director of the individual who failed the annual PT testing event.

E. The OHCQ may conduct unannounced PT at any time during normal laboratory working hours when the testing is conducted as part of routine PT, a complaint investigation, a follow-up certification, or a regulatory compliance survey.

F. The OHCQ shall conduct announced retesting within an annual PT cycle at a site selected by the Department.

G. The OHCQ shall schedule an individual who misses a laboratory's annual PT event to make up the missed test.]

[H.] B. (text unchanged)

.05 Cytology—Laboratory and Individual Standards.

A. Primary Standard. A pathologist or cytotechnologist who examines gynecological cytology specimens from individuals in this State shall participate satisfactorily in an annual cytology PT program approved by [the Secretary] *CMS.*

B. Laboratory Standards.

(1) A licensee operating under a permit to examine gynecologic cytology specimens shall ensure that each pathologist and cytotechnologist who examines gynecologic cytology specimens participates in a cytology PT program conducted by the Department or approved by [the Secretary] *CMS.*

[(2) An in-State laboratory shall participate in the Department's PT program.

(3) An out-of-State laboratory shall participate in either the Department's PT program or another equivalently rigorous cytology PT program approved by the Secretary].

[(4)] (2) A licensee employing an individual who has failed a second testing event in an annual PT cycle shall:

(a) (text unchanged)

(b) Document the individual's completion of education and training [using a form provided by the OHCQ].

[(5)] (3) (text unchanged)

C. (text unchanged)

10.10.06 Medical Laboratories — Quality Assurance

Authority: Health-General Article, §§17-202, 17-202.1, 17-214, and 17-504, Annotated Code of Maryland

.02 Authorization to Request Laboratory Tests.

A. (text unchanged)

B. Other Authorized Persons. Other persons authorized to order laboratory tests include:

(1)—(5) (text unchanged)

(6) Clinical staff who:

(a)—(b) (text unchanged)

(c) Is authorized to order tests to detect the presence of controlled dangerous substances on patients enrolled in the substance abuse treatment program; [and]

(7) A pharmacist, for tests that qualify for a letter of exception under COMAR 10.10.03.02B and for glucose, A1c, lipids (including total cholesterol, HDL, LDL, and triglycerides), AST, and ALT[.]; and

(8) *A naturopathic physician consistent with Health Occupations Article, §14–5F–01 through §14–5F–32, Annotated Code of Maryland and COMAR 10.32.21.*

C. (text unchanged)

.07 Quality Control—Specialty and Subspecialty.

A. (text unchanged)

B. Standards.

(1) General. A licensee shall ensure that the laboratory meets the applicable quality control requirements for each specialty and subspecialty under:

(a) (text unchanged)

(b) Regulations .07—[.16] .15 of this chapter.

(2) (text unchanged)

.08 Quality Control—Job-Related Alcohol and Drug Testing.

A. Primary Standard. A licensee shall ensure that a laboratory has in place a quality assurance program designed to monitor and evaluate all phases of the testing process including but not limited to:

(1)—(6) (text unchanged)

[(7)] Single-use test devices;

[(8)](7) — [(9)](8) (text unchanged)

B. Standards.

(1)—(7) (text unchanged)

(8) Cutoff Levels.

(a) (text unchanged)

(b) Urine. A laboratory testing urine shall use the cutoff levels set forth in [49 CFR §40.87] 49 CFR §40.85.

(c)—(d) (text unchanged)

[(9)] Single-Use Test Devices. A laboratory that performs screening tests using single-use test devices, as defined in COMAR 10.10.01.03B, may meet the quality assurance and quality control standards set forth in Regulation .06 of this chapter instead of the standards set forth at §B(1) of this regulation.]

[(10)](9) —[(11)](10) (text unchanged)

.12 Quality Control—Temporary and Mobile Laboratories: General.

A. (text unchanged)

B. Standards.

(1)—(9) (text unchanged)

(10) Disposal of Special Medical Waste. A licensee operating a temporary or mobile laboratory shall dispose of special medical waste as required in [COMAR 10.06.06] *COMAR 10.06.06.01—10.06.06.07.*

.13 Quality Control — Temporary and Mobile Laboratories: Personnel Training.

A. (text unchanged)

B. Standards.

(1) All Personnel. A licensee shall ensure that all personnel are trained to:

(a)—(c) (text unchanged)

- (d) Dispose of special medical waste as set forth in [COMAR 10.06.06.] *COMAR 10.06.06.01—10.06.06.07*.
(2)—(4) (text unchanged)

10.10.07 Medical Laboratories — Personnel

Authority: Health General Article, §§17-202, 17-203, 17-206, Annotated Code of Maryland

.07 Permitted Laboratory Other than POL or POCL—Testing Personnel.

- A. (text unchanged)
B. Standards — General.
(1) Personnel Qualifications. An individual performing one or more laboratory tests shall meet the applicable qualifications set forth in [42 CFR §493.1489] *42 CFR §493.1423*.
(2) Responsibilities. Testing personnel shall carry out the responsibilities set forth in [42 CFR §493.1495] *42 CFR §493.1425*.
C.—D. (text unchanged)

10.10.08 Medical Laboratories—Sanctions

Authority: Health General Article, §§17-202, 17-206, 17-210, 17-211, and 17-509, Annotated Code of Maryland

.02 Departmental Actions—General.

- A. (text unchanged)
B. Deficiency Not Posing Immediate Jeopardy.
(1)—(2) (text unchanged)
(3) [Unsuccessful] *Unsatisfactory* Proficiency Testing. If a laboratory exhibits [unsuccessful] *unsatisfactory* proficiency testing *performance*, as set forth in COMAR 10.10.01.03B, the Secretary may impose the training and technical assistance requirements set forth in Regulation .04 of this chapter as a directed plan of correction, as well as any other sanction.
(4) (text unchanged)
C.—D. (text unchanged)

10.10.12 Medical Laboratories—Public Health HIV Testing Programs

Authority: Health-General Article, Annotated Code of Maryland

Regulation	Sections
.01 Scope	17-202
.02 Definitions	17-202
.03 Incorporation by Reference	17-201, 17-202
.04 Public Health Testing License, for Rapid HIV Antibody Testing	17-202, [17-204,] 17-205, 17-206, 17-207, 17-208, [17-209,] 17-210
.05 Quality Assessment Plan and Quality Control Requirements	17-202, 17-206
.06 Personnel Training and Competency	17-202, 17-206
.07 Standard Operating Procedures Manual	17-202
.08 Public Health Testing Program Director	17-203, 17-206
.09 Manufacturer's Requirements	17-202
.10 Confirmatory Test	17-202

.02 Definitions.

- A. (text unchanged)
B. Terms Defined.
(1)—(8) (text unchanged)
(8-1) “Rapid hepatitis C virus test” means a public health hepatitis test that:
 [(a) Is a single-use test device as defined in COMAR 10.10.01.03B;]
 [(b)] (a) — [(d)] (c) (text unchanged)
(9) “Rapid HIV antibody test” means a public health HIV test that:
 [(a) Is a single-use test device as defined in COMAR 10.10.01.03B;]
 [(b)] (a) — [(d)] (c) (text unchanged)
(10) (text unchanged)

.04 Public Health Testing License for Rapid HIV Antibody Testing and HCV Testing.

- A.—C. (text unchanged)
D. The Department shall issue a public health testing license that:
 [(1) Is valid for a period of not more than 2 years;]

[(2)](1) —[(3)](2) (text unchanged)

E.—G. (text unchanged)

.07 Standard Operating Procedures Manual.

A. (text unchanged)

B. A person seeking or holding a public health testing license shall ensure that the SOPM includes the step-by-step instructions for the operations, tasks, and techniques occurring before, during, and after testing, including:

(1)—(8) (text unchanged)

(9) How to refer an individual who has been tested for HIV antibodies or hepatitis C antibodies, or both, for services as prescribed in COMAR 10.18.08.10C [and 10.18.09.07].

RYAN B. MORAN, DRPH, MHSA
Acting Secretary of Health