Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0649525	05/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Maine Health & Environmental Testing Lab	47 Independence Drive, 12 State House Station, Augusta, ME	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on technical supervisor and testing personnel interviews and bacteriology quality control policies and procedures record review, the laboratory failed to have a procedure manual that included the specific bacteria quality control organisms that must be used and how bacteria quality control organisms must be maintained to perform media quality control procedures. Findings included: a. In the bacteriology section, pursuant to 42 CFR 493.1256(e)(4), it was the practice of the laboratory to

	perform media quality control procedures using quality control bacteria organisms. According to testing personnel on May 13, 2025 at 01:50 pm, to maintain viable quality control bacteria organisms, the laboratory cultured quality control bacteria organisms from a frozen aliquot semi-annually and subsequently subcultured the organisms from the frozen aliquot culture monthly. b. According to the technical supervisor, the laboratory maintained no written procedures detailing the specific quality control bacteria organisms (e.g., the specific ATCC bacteria organisms) to be used for media quality control procedures, and no written procedures detailing the maintenance of viable quality control bacteria organisms described by the testing personnel on May 13, 2025 at 01:50 pm. c. For example, for the media quality control protocol for blood agar plates (BAP), which were used to culture bacteria from patient specimens, laboratory records indicated that Streptococcus pyogenes and Streptococcus mitis were the quality control organisms used. The technical supervisor confirmed that the laboratory maintained no written policies and procedures indicating what strain of Streptococcus pyogenes and Streptococcus mitis quality control organisms should be used and how these quality control were to be maintain as viable quality control organisms. d. According to laboratory documents, the laboratory received and cultured approximately 9,069 patient bacteriology specimens annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and preanalytic and postanalytic policies and procedures record review, the laboratory failed to maintain documentation to indicate that patient specimen processing and patient test results reporting procedures had been approved, signed, and dated by the current laboratory director before use. Findings included: a. It was the practice of the laboratory to process most patient specimens received for testing centrally. Once processed, patient specimens were distributed throughout the laboratory for analysis. b. It was the practice of the laboratory to enter patient test requisition information into the laboratory's informations system, STARLIMS, upon receipt of the patient specimens. This data entry process was required before patient test results could be reported. c. Although the laboratory maintained written protocols for the patient specimen processing and patient test results reporting procedures described, laboratory personnel confirmed on May 13, 2025 at 10:10 am and 11:30 am that the laboratory maintained no documentation to indicate that these written protocols had been approved, signed, and dated by the current laboratory director before use. d. According to laboratory documents, the laboratory received, performed tests, and reported test results for approximately 32,861 patient specimens annually.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on technical supervisor and testing personnel interviews and bacteriology catalase reagent quality control records review, the laboratory failed to perform catalase reagent quality control procedures following the manufacturer's instructions. Findings included: a. In the bacteriology section, for patient testing, it was the practice of the laboratory to use catalase reagents purchased from a manufacturer for determining the presence of catalase produced by bacteria. b. According to the manufacturer's instructions, catalase reagent quality control procedures should include the use of Staphylococcus aureus, ATCC 25923, and Streptococcus pyogenes, ATCC 19615. b. On May 13, 2025 at 02:00 pm, the technical supervisor and testing personnel could not confirm whether the laboratory used Staphylococcus aureus, ATCC 25923, and Streptococcus pyogenes, ATCC 19615 to perform catalase reagent quality control procedures. c. According to laboratory documents, the laboratory received and cultured approximately 9,069 patient bacteriology specimens annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and interview with Technical Supervisor (TS) for Virology, the laboratory failed to label Enterovirus PCR, Herpes Simplex Virus PCR, Varicella-Zoster Virus PCR, Neisseria meningitidis RT-PCR, Mumps RT-PCR, and Measles RT-PCR Primer/Probe Mix vials with corresponding expiration dates. Findings included: a. On May 13, 2025, at approximately 1:00 p.m., during a tour of the BSL-3 Virology Section (Room 432), a refrigerator (ID #912205257742PW-2304) was observed. Inside the refrigerator were vials labeled as Enterovirus PCR, Herpes Simplex Virus PCR, Varicella-Zoster Virus PCR, Neisseria meningitidis RT-PCR, Mumps RT-PCR, and Measles RT-PCR Primer/Probe Mix. Each vial was labeled with the reagent name, lot number, volume, and the date it was removed from the freezer and placed in the refrigerator for use. However, the vials were not labeled with expiration dates. b. On May 13, 2025, at approximately 1:10 p.m., an interview with the Virology TS confirmed that the Primer/Probe Mix vials were not labeled with expiration dates. The TS stated that expiration is determined based on mix performance and not routinely documented on the vials. c. The laboratory reports performing approximately 63 tests per year for Enterovirus PCR, 34 tests per year for Herpes Simplex Virus PCR, 49 tests per year for Varicella-Zoster Virus PCR, 33 tests per year for Neisseria meningitidis RT-PCR, 5 tests per year for Mumps RT-PCR, and 11 tests per year for Measles RT-PCR.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) (d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively;

	This STANDARD is not met as evidenced by: Based on review of Rapid Plasma Reagin (RPR) quality control records, the manufacturer's instructions, and interview with the Technical Supervisor (TS) for Serology, the laboratory failed to include a control material with tiered reactivity in its RPR card test procedure. Findings included: a. On May 13, 2025, at approximately 12: 40 p.m., review of the RPR quality control worksheets showed that the laboratory performed testing using reactive, minimally reactive, and nonreactive controls. However, no titer (graded reactivity) control was used. b. On May 13, 2025, a review of the manufacturer ' s instructions for the BD RPR Card Antigen Suspension (used in BD Macro-Vue RPR Card Tests) indicated: "Control sera with established patterns of graded reactivity should be included in each day's testing to confirm optimal reactivity of the antigen suspension." c. On May 13, 2025, at approximately 12:45 p.m., an interview with the Serology TS confirmed that the laboratory did not include a titer control. The TS stated that BD Macro-Vue RPR dehydrated test control cards were used, which did not include graded reactivity controls. d. The laboratory reports performing approximatey 1,762 RPR syphilis screening tests per year.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on technical supervisor and testing personnel interviews and gram stain quality control records review, the laboratory failed to have documentation to indicate that the statistical parameters for unassayed gram stain quality control materials had been established over time by the laboratory through concurrent testing of gram stain quality control materials having previously determined statistical parameters. Findings included: a. In the bacteriology section, for patient testing, it was the practice of the laboratory to use unassayed quality control slides to monitor patient gram stain testing. The unassayed gram stain quality control slides were made by the laboratory using their quality control bacteria organisms. b. According to the technical supervisor and testing personnel on May 13, 2025 at 01:50 pm, the laboratory maintained no documentation to indicate that the statistical parameters (i.e., gram positive/gram negative) of the unassayed gram stain quality control slides used to monitor patient gram stain testing had been established over time through concurrent testing gram stain quality control materials having previously determine statistical parameters. c. According to laboratory documents, the laboratory received and cultured approximately 9,069 patient bacteriology specimens annually.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)

	(e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on technical supervisor and testing personnel interviews and bacteriology media quality control records review, the laboratory failed to document the physical charateristics of Campy CVA media obtained from a manufacturer to culture bacteria from patient specimens. Findings included: a. In the bacteriology section, it was the practice of the laboratory to use Campy CVA media obtained from a manufacturer to culture bacteria from patient specimens. b. On May 13, 2025 at 01:45 pm, the technical supervisor and testing personnel confirmed that the laboratory maintained no documentation to indicate that the laboratory had noted the physical charateristics of the Campy CVA media available for use (shipment date May 5, 2025) to culture patient specimens. c. According to laboratory documents, the laboratory received and cultured approximately 9,069 patient bacteriology specimens annually.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on technical supervisor and testing personnel interviews and bacteriology media quality control records review, the laboratory failed to ensure that it had a record system that documented the results of all media quality control procedures performed had met the laboratory's criteria for acceptability before reporting patient culture test results. Findings included: a. In the bacteriology section, for patient testing, it was the practice of the laboratory to use blood agar plates (BAP) for the growth of bacteria from patient specimens. Pursuant to 42 CFR 493.1256(e)(4), laboratory records indicated that each lot of BAP culture media made by the laboratory had met the laboratory's criteria for acceptability. b. On May 13, 2025 at 01: 30 pm, the technical supervisor and testing personnel confirmed that, although each lot of BAP culture media had met the laboratory's quality control criteria for acceptability, laboratory records did not indicate which lot of BAP culture media was used to culture bacteria from a patient specimen. c. For example, BAP lot numbers W104, W105, W106, and W107 were available for patient testing as of April 18, 2025. During the period of time these BAP lots were available for use, laboratory records did not indicate which specific BAP lot was used to culture bacteria from any specific patient specimen. d. According to laboratory documents, the laboratory received and cultured approximately 9,069 patient bacteriology specimens annually.