

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  20D0649525	<b>(X3) Date Survey Completed</b>  05/24/2023
<b>Name of Provider or Supplier</b>  Maine Health & Environmental Testing Lab	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2010</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review of Blood Lead proficiency testing (PT) records, worksheets, instrument printouts, and interviews with the testing personnel (TP#1) and general supervisor (GS#1), the laboratory failed to process, 5 of 6 Blood Lead PT events in 2021 and 2022 Blood Lead PT events in the same manner as patient samples. Findings include: 1. Record review conducted on 05/22/2023 of 2021 and 2022 of WSLH Blood Lead proficiency testing (PT) records and Graphite Furnaces Atomic Absorption (GFAA) worksheets, and instrument printouts, revealed the laboratory tested 5 of 6 WSLH PT event samples separately from patient samples. The review revealed WSLH PT events samples from 2022 Events 1, 2, &amp; 3 and 2021 Events 1&amp;2 were tested separately from routine patient samples. 2. Record review conducted on 05/22/2023 of Blood Lead worksheets and instrument printouts and patient test records revealed that patient samples were tested the same day as the PT event samples, but tested separately from PT samples on 03/26/2021, 06/24/2021, 03/24/2022, 06/28/2022, and 11/18/2022. 3. Interview with the GS#1 and TP#1 on 05/23/2023 at 11:45 AM confirmed the above findings.</p>
<b>D5311</b>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when</p>

appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on record review and staff interviews the laboratory failed to establish and follow written policies and procedures for handling and transporting specimens submitted for Venereal Disease Research (VDRL) testing. Findings include: 1. Record review conducted on 05/23/2023 of the BD BBL VDRL Antigen package insert revealed the following under specimen collection and storage instructions: "Store serum specimens at room temperature for up to 4 hours; after 4 hours, store at 2-8 C." 2. Record review conducted on 05/23/2023 of the laboratory's Directory of Clinical Testing Services manual revised 04/06/2023 revealed the following "Unacceptable Conditions" for VDRL CSF screen, "specimen not refrigerated or not frozen". 3. Surveyor observation on 05/23/2023 at 10:50 AM revealed that the State Postal Courier Service delivering patient samples from Maine General in Augusta did not transport specimens in a cooler with an ice pack coolant to ensure specimens remain at 2-8 C and avoid temperature extremes during transport. 4. Surveyor interview on 05/23/2023 at 10:30 AM with the courier from State Postal Courier Service confirmed the above observational finding above. 5. Record review conducted on 05/23/2023 of a report listing samples received from Maine General in Augusta for the period of December 2022- May 2023, listed VDRL 17 patient CSF samples received for VDRL testing. 6. Staff interview with the General Supervisor (GS#2) on 05/23/2023 at 11:15 AM confirmed the above findings.

**D5401**

PROCEDURE MANUAL  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

A. Based on record review, standard operating procedure (SOP), and interview with General Supervisor #1 (GS#1), the laboratory failed to follow their Clostridium difficile SOP for two of two patient reports. Findings include: 1. Interview on 05/22/2023 at 01:30 PM, GS #1 confirmed the laboratory performed Clostridium difficile testing using the ABI 7500 DX Fast Real-Time Polymerase Chain Reaction (RT PCR) platform. 2. On 05/22/2023, a review of the laboratory's SOP titled, "Traditional Bacteriology" under "Sample Collection and Rejection Criteria" stated, "Raw stool specimens for Clostridium difficile, sent at room temperature, must arrive within 2 hours of collection. Spores remain viable for several days if stool has been refrigerated and is sent at 4C." 3. On 05/22/2023, a review of Clostridium difficile patient requisitions and patient reports performed between 01/27/2022 through 05/12/2023 revealed no evidence specimens were sent at 4C for two of two patients: a. Patient M01055475 - specimen collected 01/24/2023, received 01/26/2023, and reported 01/27/2023. b. Patient M01173501- specimen collected on 05/01/2023, received 05/04/2023, and reported 05/12/2023. 4. Interview with GS#1 on 05/22/2023 at 02:30 PM confirmed the findings. 5. The laboratory performed 2 Clostridium difficile patient tests in 2022 B. Based on record review, standard operating procedure

(SOP), and interview with General Supervisor #1 (GS#1), the laboratory failed to follow their identification of Bacillus species SOP for one of two patient reports. Findings include: 1. Interview on 05/22/2023 at 02:35 PM, GS #1 confirmed the laboratory identified Bacillus species from clinical samples or isolates using conventional media, biochemical methods, and molecular methods. 2. On 05/22/2023, a review of the laboratory's SOP titled, "Traditional Bacteriology" under "2. Procedure for identification of Bacillus species" stated, "If the sample is an isolate, also sub to Egg yolk agar, TSI slant, and Motility tube". 3. On 05/22/2023, a review of Bacillus species identification patient requisitions and patient reports performed on 05/24/2021 and 08/04/2021 revealed no evidence an isolate was sub-cultured to the TSI (Triple Sugar Iron) slant for one of two patients: a. Patient M00832917 - specimen collected 05/10/2021, received 05/24/2021, and reported 06/10/2021. 4. Interview with GS#1 on 05/22/2023 at 02:42 PM confirmed the findings. C. Based on record review, standard operating procedure (SOP), and interview with General Supervisor #1 (GS#1), the laboratory failed to follow their identification of Haemophilus species SOP for one of three patient reports. Findings include: 1. Interview on 05/23/2023 at 09:30 AM, GS #1 confirmed the laboratory identified Haemophilus species from clinical samples or isolates using conventional media and biochemical methods. 2. On 05/23/2023, a review of the laboratory's SOP titled, "Traditional Bacteriology" under "XIV. Identification of Haemophilus Species" section titled, "2. Perform gram stain, oxidase, catalase, spot indole, Moeller's ornithine, Urea" stated, "i. If spot indole is negative, perform Erlich's tube indole". 3. On 05/23/2023, a review of Haemophilus identification patient requisitions and patient reports performed on 08/10/2022, 11/21/2022, and 03/29/2023 revealed no evidence of the Erlich tube indole test when the spot indole test was negative for one of three patients: a. Patient M01160802 - specimen collected 11/15/2022, received 11/21/2022, and reported 11/28/2022. 4. Interview with GS#1 on 05/23/2023 at 09:54 AM confirmed the findings. 5. The laboratory performed 31 Haemophilus Species identification patient tests in 2022. As of 05/23/2023, the laboratory performed 14 Haemophilus Species identification patient tests in 2023 D. Based on record review, standard operating procedure (SOP), and interview with the microbiology supervisor and General Supervisor #1 (GS#1), the laboratory failed to document the appropriate quality control (QC) microorganism for one of two microorganisms. Findings include: 1. Interview on 05/23/2023 at 11:30 AM, GS #1 confirmed the Motility Test Medium was performed in the laboratory for the detection of motility of enteric organisms. 2. On 05/23/2023, a review of the laboratory's SOP titled, "Traditional Bacteriology" under "XXX. Motility" section titled, "Reagents and Supplies" stated: a. "1. QC Organisms:" b. "a. E. Coli = positive growth throughout media" c. "b. S epidermidis = negative growth along stab line" 3. On 05/23/2023, a review of the "QUALITY CONTROL RECORD MEDIA MOTILITY (AEROBIC) WITH TCC" revealed the QC microorganisms did not match the laboratory's SOP for one of two QC microorganisms: a. The negative QC microorganism was documented as "K.pneumoniae" 4. Interview with the microbiology supervisor on 05/23/2023 at 12:15 PM confirmed the findings. 5. The laboratory performed 2 enteric patient screening tests in 2022. As of 05/23/2023, the laboratory performed 8 enteric patient screening tests in 2023. E. Based on record review, standard operating procedure (SOP), and interview with General Supervisor #3 (GS#3), the laboratory failed to follow their Mycobacterium SOP for four of four patient reports. Findings include: 1. Interview on 05/24/2023 at 10:00 am, confirmed the laboratory performed Mycobacterium testing from blood, bone, bone marrow, bronchial brush, bronchoalveolar lavage, bronchial washings, endotracheal aspirates, and transtracheal aspirates. 2. On 05/24/2023, a review of the laboratory's SOP titled, "Mycobacterium" under "Collection" stated, "Specimens are transported to the HETL as soon as possible to avoid overgrowth of contaminating bacterial and fungi.

Specimens must be refrigerated prior to and during transportation." 3. On 05/24/2023, a review of Mycobacterium patient requisitions and patient reports performed on 01/25/2023, 03/15/2023, 04/07/2023, 04/10/2023 revealed no evidence specimens were refrigerated prior to and during transportation. a. M01166043 - specimen collected 01/23/2023, received 01/25/2023, and reported 02/02/2023. b. M91169469 - specimen collected 03/13/2023, received 03/13/2023, and reported 03/15/2023. c. M01171241 - specimen collected 04/05/2023, received 04/07/2023, reported 04/07/2023. d. M01171434 - specimen collected 04/07/2023, received on 04/10/2023, reported on 04/10/2023. 4. Interview with GS#3 on 05/24/2023 at 11:00 AM confirmed the findings. 5. As of 05/24/2023, the laboratory performed 727 acid-fast bacilli patient tests in 2023

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(b)**

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
 A. Based on record review of the manufacturer's instructions, surveyor observation, and interview with Testing Personnel (TP#2), the laboratory failed to ensure the humidity and room temperature were maintained as required by the manufacturer for the SeqStudio Genetic Analyzer for the period of February 2023 through May 2023. Findings include: 1. Record review of quality control records conducted on 05/24/2023 revealed that the laboratory failed to document the humidity and room temperature of Room 151 where the SeqStudio Genetic Analyzer was used to perform the ID of Bacteria by 16S Ribosomal DNA Sequencing for the period of February 2023 through May 2023. 2. Surveyor observation on 05/24/2023 at 10:29 AM of the laboratory testing area in Room 151 revealed a humidity reading of 12.0% and a room temperature of 26.9 C. 3. Record review conducted on 05/24/2023 of the SeqStudio Genetic Analyzer Instrument, Environmental Requirements, Appendix G stated the "Operation Humidity from 20%- 80%" and "Operation Temperature: 15 C to 30 C." 4. Staff interview with TP#2 on 05/24/2023 at 10:29 AM confirmed the findings above. 5. The laboratory tested 21 patient samples using ID of Bacteria by 16S Ribosomal DNA Sequencing patient in 2023. 47272 B. Based on record review, manufacturer's instructions, and interview with Technical Supervisor #1 (TS#1), the laboratory failed to ensure the humidity was maintained as required by the manufacturer for the Hologic Panther analyzer for 12 of 12 months. Findings include: 1. Record review conducted on 05/22/2023 revealed that the laboratory failed to document the humidity where the Hologic Panther was used to perform Chlamydia trachomatis/Neisseria gonorrhoeae testing during 2022. 2. Review of the Operator's Manual stated under Environmental Requirements "Relative humidity: 20%- 85%". 3. Interview with TS#1 on 05/22/2023 at 10:42 AM confirmed the laboratory failed to ensure humidity was maintained as required by the manufacturer as indicated above. 5. The laboratory performed 3,850 Chlamydia trachomatis/Neisseria gonorrhoeae, patient tests in 2022

**D5449**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

A. Based on record review of the Identification of Bacteria by 16S Ribosomal DNA Sequencing procedures, 16S quality control (QC) records, and interview with the Testing Personnel (TP#2), the laboratory failed to include a positive control at least once each day patient samples was were tested using 16S Sequencing. Findings include: 1. Record review on 05/24/2023 of the Identification of Bacteria by 16S Ribosomal DNA Sequencing procedure (Document number SOP-CM-029, 02/09/2023) stated the following under Section XI. Quality Assurance, "The positive control should be performed whenever possible, but not required on every run due to the internal quality parameters for each sample." 2. Record review on 05/24/2023 of 16S Ribosomal DNA Sequencing Worksheets for the period of 10/22/2022 through 05/09/2023 revealed that 7 of 7 daily runs did not include a positive control sample. The record review also revealed that patient samples were included in each of the 7 daily runs. 3. Staff interview with (TP#2) at 10:15 AM confirmed the findings above. 47272  
B. Based on record review, standard operating procedure (SOP), and interview with General Supervisor #3 (GS#1), the laboratory failed to perform negative and positive control material for one of three patients reviewed. Findings include: 1. Interview on 05/24/2023 at 10:00 am, confirmed the laboratory performed Kinyoun Carbol fuchsin staining in the detection of acid-fast bacilli. 2. On 05/24/2023, a review of the laboratory's SOP titled, "Mycobacterium" under "Quality Control" stated, "A positive /negative control slide is included with each staining run." 3. On 05/24/2023, a review of Mycobacterium patient requisitions and patient reports performed on 01/25/2023, 03/15/2023, and 04/07/2023 revealed no evidence of a positive and negative control slide for one of three patients. a. M01166043 - specimen collected 01/23/2023, received 01/25/2023, and reported 02/02/2023. 4. Interview with GS#3 on 05/24/2023 at 10:30 AM confirmed the findings. 5. As of 05/24/2023, the laboratory performed 727 acid-fast bacilli patient tests in 2023

**D5821**

**TEST REPORT**  
CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on record review and staff interview with the General Supervisor (GS#2), the laboratory failed to indicate SARS-CoV-2 RT-PCR patient reports as "corrected". Findings include: 1. Record review on 05/24/2023 of a laboratory information system (LIS) generated report listing corrected results reported by the laboratory in 2021 and

2022 revealed 14 SARS- CoV-2 RT-PCR results noted as "Corrected" in the LIS. The review further revealed that the results were generated on 06/27/2022. 2. Record review conducted on 05/24/2023 of original and corrected reports for samples M01129691, M01129693, M01129696, M01129700, M1129702, M01129708, and M01129713 revealed the reports reissued by the laboratory on 06/27/2022 had changes to the patient's first names, but the 06/27/2022 reports did not indicate that the reports were corrected. 3. Staff interview with the General Supervisor (GS#2) confirmed the findings above.