| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 20D0649525 | 03/07/2019 |
| **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 |
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| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory director (LD) or technical supervisor (TS) failed to sign attestation statements documenting that proficiency testing (PT) samples were tested in the same manner as patient samples. Findings include: 1. Record review conducted on 03/06/2019 of 2018 PT records revealed the following: College of American Pathologists (CAP) 2018 Syphilis Serology PT attestation statements: a) GA 2018- LD signature section signed by the General Supervisor (GS1) b) GB 2018- LD signature missing, not signed c) GC 2018- LD signature missing, not signed American Proficiency Institute (API) 2018 Microbiology PT attestation statements: a) 2018 Event 1- LD signature missing, not signed b) 2018 Event 2- LD signature missing, not signed CAP 2018 Bacteriology PT attestation statements: a) DA 2018- LD signature section signed by the General Supervisor (GS2) b) DB 2018- LD signature section signed by the General Supervisor (GS1) 2. Interview with the Quality Assurance Officer (QA) on 03/06/2019 at 4:00 PM confirmed the above findings. |

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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to establish and follow written policies to assess competency of the technical supervisor (TS) and general supervisors (GS) according their position responsibilities listed in Subpart M for high complexity testing personnel. Findings include: 1. Record review conducted on 03/05/2019 of 2017 and 2018 employee competency records revealed that the annual competency assessment for individuals listed on the CMS Form 209 as GS and TS only included the six required procedures and not the GS and TS position responsibilities and duties listed under Subpart M, 493.1451 and 493.1463. 2. Record review conducted on 03/05/2019 of the Clinical Microbiology Quality Assurance Control Policy, Revision 06, approved 11/30/2018, Section XIII. Competencies, only included the six procedures for all personnel performing laboratory testing and not an assessment of the TS and GS position responsibilities listed under Subpart M. 3. Interview with the Quality Assurance Officer (QA) and the technical supervisor (TS) on 03/05/2019 at 10:30 AM confirmed the above findings. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on record review and staff interview with the general supervisor (GS1), the laboratory failed to monitor and document the temperature of the Cole- Parmer heat block used by the molecular laboratories. Findings include: 1. Record review of the Cole-Parmer Heat Block (Room 157D) maintenance records on 03/06/2019 revealed no temperature monitoring or thermometer calibration documentation. 2. Record review conducted on 03/06/2019 of the procedure Detection of Plasmodium by PCR, Revision 2, approved November 13, 2018, page 8, under QIAamp DNA Blood Minikit stated "Incubate in 56C heat block for 10 min." 3. Record review conducted on 03/06/2019 of the procedure Parainfluenza virus 1-4 in Human Specimens by rtRT-PCR assay, Revision 02, approved 12/10/2018, Section IX.9 states, " Incubate in heat block at 56C for a minimum of 15 minutes. Lysis tubes may now be safely removed from biological safety cabinet. Specimens are considered to be non-infectious after this step." 4. Interview conducted on 03/06/2019 at 3:30 PM with the GS1 confirmed the above findings above. B. Based on record review and staff interview with the general supervisor (GS2), the laboratory failed to monitor and document the temperature of the Eppendorf ThemoMixer used by the Molecular Laboratories. |

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| | Findings include: 1. Record review of the Eppendorf ThemoMixer (room 155A) maintenance records on 03/06/2019 revealed no temperature monitoring or thermometer calibration documentation. 2. Record review conducted on 03/06/2019 of the procedure Detection of Carbapenem Resistance Enterobacteriaceae (CRE) Genes by RT-PCR, Revision 01, approved 12/23/2018, Section IX. 3, stated "Place in 99C heat block for 20 minutes". 3. Interview on 03/06/2019 at 12:30 PM with GS2 confirmed the above findings. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview conducted on 03/06/2019, the laboratory failed to verify the accuracy of the final report interpretation for Carbapenem Resistant Enterobacteriaceae (CRE) by RT-PCR in the laboratory information system (LIS) after updating the CRE RT-PCR procedure. Findings include: 1. Record review of the CRE Multiplex REAL-Time PCR worksheet Run # 01-28-19-01 for HELTL# M00349612 revealed the following gene target results: Klebsiella pneumoniae Carbapenemase (KPC): 15.2546 New Delhi metallo-B-lactamase (NDM): Undet. Oxacillin hydrolyzing B-lactamase (OXA): Undet. Verona integron metallo-B-lactamase (VIM): Undet. 2. Record review of Carbapenemase positive resistance genes detected by PCR test report for HELTL# M00349612 completed and reported on 01/28/2019 revealed the following gene target results: KPC (Klebsiella pneumoniae Carbapenemase) gene: Detected NDM (New Delhi metallo-B-lactamase) gene: NOT Detected GES (Guiana extended spectrum) gene: NOT Detected OXA (Oxacillin hydrolyzing B-lactamase) gene: NOT Detected VIM (Verona integron metallo-B-lactamase) gene: NOT Detected 3. Interview with the general supervisor (GS) and the technical supervisor (TS) on 03/06/2019 at 12:30 PM confirmed that IMP-1: Undet and IMP-2: Undet. results were tested and not reported, and the GES (Guiana extended spectrum) gene: NOT Detected result was not tested, but reported. The GS further revealed that the CRE PCR procedure was modified on 01/23/2019, but the LIS report template was not changed when the updated procedure was implemented for patient testing. 4. Record review of Carbapenemase positive results from specimens received from 10/15/2018 to 03/05/2019 that revealed one (1) of seven (7) patient specimens was reported after the CRE PCR procedure was modified on 01/23/2019. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that |

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| | perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to document corrective actions when the temperature of the Blue M Incubator fell outside of its established operational temperature range. Findings include: 1. Record review conducted on 03/06/2019 of the temperature chart recordings of the Blue M Incubator from 01/01/2019 to 03/05/2019 revealed an established operating temperature range of 42 C  2C. The review revealed a temperature recording of 48C on 02/28/2019 with no documented corrective action associated with the out-of-range temperature. 2. Interview on 03/06/2019 at 10:50 AM with the testing personnel (TP1) and the general supervisor (GS) confirmed the findings above, and further revealed that the incubator was used for the Campylobacter testing. |