Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0650270	01/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Massachusetts Department Of Public Health	305 South St, Jamaica Plain, MA	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a record review of CAP Blood Lead 2021 and 2022 proficiency testing (PT) records and interviews with the Childhood Blood Lead Technical Supervisor (TS#1), Childhood Blood Lead Testing Personnel (TP#1), and Quality Manager (QAM), the laboratory failed to test proficiency testing (PT) samples in the same manner as patient specimens. Findings include: 1. Record review conducted on 01/24/2023 of 2021 and 2022 CAP Blood Lead (BL) PT records revealed that all CAP samples from CAP 2021 BL-B, 2021 BL-C, and all 2022 BL Events were all run on GFAA instrument #1. 2. Record review of test worksheets and patient test records on 01/24 /2023 generated in 2021 and 2022 revealed that patient samples were tested on all 4 GFAAs and not just on GFAA instrument #1. 3. Interview on 01/24/2023 at 2:45 PM with TS#1, TP#1, and the QAM confirmed these findings. The interviews further revealed that the practice of running all CAP PT event samples on GFAA instrument #1 resulted from a corrective action (21-BL-002) implemented in March 2021.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)

	(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. This STANDARD is not met as evidenced by: Based on a review of records and interview with Technical Supervisor (TS #7), the laboratory director or designee or testing person failed to sign a proficiency testing attestation statement for two of nine events. Findings include: 1. The surveyor reviewed 2021 and 2022 proficiency testing records on 01/25/2023 and identified the following for two of nine events: a. First 2021 Mycobacteriology (E-A) Event - The attestation statement was not signed by the testing person. b. First 2022 Mycobacteriology (E-A) Event - The attestation statement was not signed by the laboratory director or designee. 2. Staff interview conducted with TS #7 on 01/25 /2023 at 11:57 AM confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and interview with Technical Supervisor (TS#7), the laboratory failed to perform quality control as stated in their IQCP (Individualized Quality Control Plan) for two of 12 months. Findings include: 1. On 01/26/2023 at 01: 30 PM, (TS#7) stated the laboratory performed NAAT (Nucleic Acid Amplification Test) using on the GeneXpert analyzer. IQCP had been developed for the test system. 2. On 01/26/2023 a record review of the IQCP for NAAT testing revealed that two levels of QC (quality control) materials were tested monthly, on new lots or shipments of cartridges. 3. A review of QC records for the NAAT testing from 01/01/2022 through 12/31/2022 identified that QC testing was not performed in April 2022 and July 2022. 4. Staff interview conducted with TS#7 on 01/26/2023 at 02:00 PM confirmed the findings above.
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: Based on record review and interview with Technical Supervisor (TS#7), the laboratory failed to test a negative and positive control material for Fluorochrome Staining for one of five days of patient testing. Findings include: 1. On 01/25/2023 at 02:00 PM, (TS#7) stated the following: a. The Fluorochrome Stain was used to stain patient smear samples to visualize Acid-Fast Bacilli (AFB). b. Negative and positive QC (quality control) materials were performed each day of patient testing. 2. On 01/25 /2023, a review of QC and patient testing records from June 3, 2022 through June 09, 2022, revealed negative and positive QC materials was not documented as being performed each day of patient testing for one of five days of testing. The specific day was 06/06/2022. 3. Staff interview conducted with (TS#7) on 01/25/2023 at 02:44 PM confirmed the findings.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with the Clinical Microbiology Technical Supervisor (TS#2), the laboratory failed to check each batch of media for sterility, the ability to support and/or inhibit growth, and produce a biochemical response. Findings include: 1. Record review on 01/26/2023 of 2022 quality control (QC) records of Chocolate Agar (Lot #600922 expiration: 03/02/2023) and TSA Blood agar (Lot #609721 expiration 03/13/2023) plates in use, revealed that media batches were not checked for sterility and the ability to support and/or inhibit growth. 2. TS#2 confirmed the findings above during an interview on 01/26/2023 at 2:45 PM and further revealed that certain commercially prepared media was only visually inspected.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on a lack of documentation and staff interview with Technical Supervisor (TS#8), the laboratory failed to evaluate the relationship between the test performance of five ABI instruments used to perform molecular testing during the review period of January 2022 through December 2022. Findings include: 1. On 01/26/2023 at 01:30 PM, (TS#8) stated the laboratory performed the following molecular testing: a. Influenza, Measles, Mumps, Orthopox, SARS Coronavirus, and West Nile Virus testing using five ABI instruments (ABI#1 serial number 275010560, ABI#2 serial number 275010648, ABI#3 serial number 275010870, ABI#4 serial number 275011283, ABI#7 serial number 275030154). 2. On 01/26/2023, record review conducted of the ABI instruments revealed no documentation that the laboratory evaluated the test performance of five ABI instruments during the review period of January 2022 through December 2022. 3. Staff interview conducted with (TS#8) on 01 /26/2034 at 02:40 PM confirmed the findings.