Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D0652812	12/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
New Hampshire Public Health Lab	29 Hazen Dr, Concord, NH	

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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on staff interview and record review of Bacteriology Proficiency Testing (PT) 2021 records, the laboratory failed to review and evaluate an unacceptable score for College of American Pathologists (CAP) PT sample D-12 in the D-B 2021 Bacteriology Survey Event. Findings include: 1. Record review conducted on 12/02 /2022 of CAP Bacteriology PT records revealed an unacceptable morphology score for sample D-12. The review showed that the laboratory submitted an unacceptable result of "Diplococci" for sample D-12 and the CAP PT Program's intended response was "Cocci". 2. Record review conducted on 12/02/2022 of the laboratory's completed "Proficiency Test Review FORM" (Document ID QU-FORM-770) for Bacteriology Survey D-B 2021 revealed," "Review and sign, no further action" checked under the Comment/Course of Action section of the form. 3. Record review conducted on 12/02 /2022 of the laboratory's Proficiency Testing SOP (Document ID: QU-SOP-770) revealed the following under Section 5.8 Proficiency Test Report "Results Investigation needs to be performed by the unit supervisor and/or Program Manager when unacceptable results are obtained in a PT or part of a PT." 4. Staff interview with the Technical Supervisor (TS#6) and the Quality Manager (QAM) conducted on 12/02/2022 at 11:30 AM confirmed that no investigation was conducted by the laboratory for the unacceptable PT result score.
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: Based on the surveyor's review of the laboratory's approved Syphilis Rapid Plasma Reagin (RPR) Qualitative and Quantitative Card Test (Document ID VI-NM-SOP-024) procedure manual, laboratory room temperature charts, and interview with the Technical Supervisor 1 (TS#1), the laboratory failed to follow the manufacturer's room temperature requirements for the Macro-Vue (Trademark) RPR Card Test. Findings include: 1. Record review conducted on 12/01/2022 of the BD Macro-Vue (Trademark) RPR Card Tests manufacturer's package insert revealed the following, "allow the antigen to warm to room temperature (23 to 29 C) before use". 2. Record review conducted on 12/01/2022 of the laboratory's approved Syphilis Rapid Plasma Reagin (RPR) Qualitative and Quantitative Card Test (Document ID VI-NM-SOP-024) procedure, effective 12/18/2019, included the following in the Limitation of the Procedure section, a. "Temperatures less than 25 C of sera, reagents, and testing area, decrease reactivity. Temperatures greater than 29 C increase reactivity." 3. Record review conducted on 12/01/2022 of the room temperature charts for Room 325 where the RPR Testing is conducted revealed an acceptable temperate range of 18C- 30C for the years 2021 and 2022. The review further revealed that only 14 days were within the acceptable RPR testing range of 23 to 29 C in 2021 and only 13 days in 2022. 4. Staff interview on 12/01/2022 at 2:50 PM confirmed the findings above. 5. The laboratory performed 1,044 RPR tests in 2022.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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 staff interview and record review, the MALDI-TOF Mycobacteria Identification (ID CM-T-SOP-018) Standard Operating Procedure (SOP) was not signed and approved by the current laboratory director (LD) before use. Findings include: 1. Record review conducted on 12/02/2022 of the MALDI-TOF Mycobacteria Identification SOP (Document ID: MC-T-SOP-18), Revision 1, found that the procedure was not signed and approved by the current LD prior to use. 2. Record review conducted on 12/02/2022 of the Mycobacteria Brucker MALDI-TOF Validation Report revealed an LD approval date of 06/04/2022. 3. Record review conducted on 12/02/2022 of Mycobacteria MALDI-TOF patient test records for the period of June 2022 to November 2022 revealed reported MALDI-TOF test results. 4. Staff interview with the Technical Supervisor (TS#6) and the Quality Manager (QAM) on 12/02/2022 at 2:37 PM confirmed that the MALDI-TOF Mycobacteria Identification SOP (Document ID: MC-T-SOP-18) was put into use and not signed by the LD.
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 and staff interview, the laboratory failed to define an acceptable temperature range for the Clinical Micro Fisher IsoTemp -20 Freezer in use during 2021 and 2022. Findings include: 1. Record review conducted on 12/02 /2022 of 2021 and 2022 temperature charts for the Clinical Microbiology Fisher IsoTemp -20 C Freezer, serial number 1168488901180323, revealed no acceptable temperature range. 2. Staff interview with the Technical Supervisor (TS#6) at 10:51 AM confirmed that the acceptable range was missing. The TS#6 further revealed that the Fisher IsoTemp -20 C Freezer was used during 2021 and 2022 for patient testing. B. Based on record review and staff interview, the laboratory failed to monitor and document the acceptable range of the MDX Clean Room 328 VWR Upright -20 C Freezer and the IsoTemp Glass Door Refrigerator for 2022. Findings include: 1. Record review conducted on 12/02/2022 of the MDX Clean Lab Room 328, VWR Upright Freezer -20C (serial # T01K-486158-TK) and IsoTemp Glass Door Refrigerator (serial # 0168579601110726) revealed: a. 19 missing temperature recordings in 2022 for the IsoTemp Glass Door Refrigerator (serial # 0168579601110726). b. 23 missing temperature recordings in 2022 for the WR Upright Freezer -20C (serial # T01K-486158-TK). 2. Staff interview with the Technical Supervisor (TS#3) on 12/02/2022 at 10:00 AM confirmed that the temperature recordings were missing. TS#3 further revealed that the VWR Upright Freezer -20C (serial # T01K-486158-TK) and IsoTemp Glass Door Refrigerator (serial # 0168579601110726) were used to store reagents, primers, and probes for molecular clinical testing.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and staff interview, the laboratory failed to follow the manufacturer's instructions for BioFire FilmArray Pouch Loading Station Decontamination procedures for the year 2022. Findings include: 1. Record review conducted on 12/02/2022, revealed no evidence the BioFire FilmArray Pouch Loading Station Decontamination procedure had been performed. 2. Staff interview with the General Supervisor (GS #8) on 12/02/2022 at 01:35 PM confirmed that the BioFire FilmArray Pouch Loading Station Decontamination procedure was not documented as being performed.
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 record review and staff interview, the laboratory failed to evaluate and define the relationship between test results using different analyzers in 2022. Findings include: 1. Record review conducted on 12/02/2022, revealed the laboratory failed to evaluate Volatile Organic Compounds test results between the Agilent 5977 and Agilent 5973 instruments in the year 2022. 2. Staff interview with General Supervisor (GS #4) on 12/02/2022 at 10:30 AM confirmed the findings above.