Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0655844	06/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ohio Department Of Health Laboratory	8995 East Main Street, Bldg 22, Reynoldsburg, OH	

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
D0000	A federal jurisdictional recertification survey was conducted on 6/10/2025 to 6/12 /2025. Standard level deficiencies were cited.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of emails, and interview with Quality Officer, the laboratory failed to have a system in place to ensure document all complaints and conduct investigation of complaints in 2024 and 2025 as evidenced by: 1. In review the laboratory's policy, "Corrective Action" under 2. Document NCE states, "Once a problem or potential problem is identified, the significance and type of problem is evaluated by the Laboratory Director and the section supervisor to determine of the corrective action process is required.... If the problem or potential problem is considered significant, the NCE will be documented in Media Labs. Refer to Document IGQ-CAPA system 2.0 Medial Non-Conforming events." 2. In review of the following two emails, they were not entered into Media labs as per the policy. A. May 1 ,2025 Subject: Practice getting repeated "Immediate Action" notifications B. May 30, 205 Subject: Need assistance on a live abscess Case [Sic] 3. In an interview with the Quality Officer on 6/11/2025 at 1020 he stated that these emails may be significant and should have been entered into media labs as per SOP. 4. The laboratory has not entered any "significant issues" into their Medialab system for 2024 or 2025.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	(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 direct observation, review of the laboratory's Chemical Hygiene Plan, and an interview with General Supervisor #2 (GS #2), the laboratory failed to follow its policy requiring received and open dates to be written on chemicals used in TB testing and failed to follow its policy for discarding chemicals that had exceeded the laboratory's assigned expiration period. Findings: 1. During a tour of TB Room #106 on June 11, 2025, at approximately 8:00 AM, the following items were observed inside a biological safety cabinet: -Remel TB Auramine O Stain Kit - no received, or open date. -Remel TB Kinyoun Carbolfuchsin Stain Kit - no received, or open date. -Hardy Diagnostics Gram Stain Kit - no received, or open date. Additional chemical containers stored in open bins on shelves were observed: -Citric Acid Trisodium Salt Dihydrate, Lot #22G1856100 - no open date. -Potassium Hydroxide, Lot #BO152936 - no open date. -Potassium Phosphate Monobasic, Lot #230499 - no open date. -Sodium Chloride, Lot #222879 - handwritten open date: 12/22/2023. -Potassium Bicarbonate, Lot #216165 - handwritten open date: 4/3/2024. 2. Review of the laboratory's Chemical Hygiene Plan revealed the following applicable policies: Section 9.6.1.2: "Chemicals or commercial reagents that have been open for 1 year; unless documentation can be obtained by the laboratory section that the chemical has not deteriorated. Complete Appendix J and submit to the Laboratory Director for chemical storage period extension approval." Section 11.2.3: "Received and open dates are required on all chemical containers; including the individual containers inside a kit and the kit box." 3. In an interview conducted on June 12, 2025, at approximately 9:00 AM, GS #2 confirmed that stains and other chemicals used for TB testing were not consistently labeled with received, open, or expiration dates, and that chemicals were not discarded after one year as required by laboratory policy, nor were chemical storage extensions requested. 4. The laboratory reports performing approximately 1,675 Mycobacterium species smears, cultures, identifications, and PCR tests, and approximately 175 Mycobacterium tuberculosis antimicrobial susceptibility tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: I. Based on direct observation, review of room temperature records, and an interview with General Supervisor #2 (GS #2), the laboratory failed to define and maintain room

temperature conditions consistent with the manufacturer's storage instructions for reagents used in TB Room #106, where Mycobacterium smear testing is performed. Findings: 1. During a laboratory tour on June 11, 2025, at approximately 8:00 AM, a Remel TB Kinyoun Carbolfuchsin Stain Kit was observed stored inside a biosafety cabinet in TB Room #106. The product label specified a required storage temperature of 20-25C. 2. Review of room temperature logs for TB Room #106 covering the years 2024 and 2025 showed that the laboratory had defined an acceptable temperature range of 15-30C, handwritten on the logs. The recorded temperatures fell below the manufacturer ' s specified range on multiple occasions, including: -June 2024: 19C for 15 days; 18C for 1 day -July 2024: 19C for 12 days -August 2024: 19C for 10 days -November 2024: 19C for 18 days -December 2024: 19C for 10 days 3. In an interview conducted on June 11, 2025, at 2:30 PM, GS #2 confirmed that the laboratory had not established a room temperature range based on the manufacturer's storage requirements for reagents stored in TB Room #106. 4. The laboratory reports performing approximately 1,675 Mycobacterium species smears annually. 47272 II. Based on observation, manufacturer's instructions, and interview with the quality assurance manager, the laboratory failed to store Revvity NeoLSD MSMS Kits according to the manufacturer's instructions for 16 of 16 kits. Findings include: 1. Observation on 06/10/25 at 09:30 am of the laboratory's warehouse revealed 16 boxes of Revvity NeoLSD MSMS Kits (Lot#761174) with a manufacturer's storage requirement of 2-30C. 2. On 06/10/25 at 09:40 am, the quality assessment manager confirmed the laboratory used the Revvity NeoLSD MSMS Kits for newborn screening. 3. Interview on 06/10/25 at 09:45 am with the quality assurance manager confirmed the laboratory failed to monitor room temperatures in the laboratory's warehouse. III. Based on laboratory's written policy and procedure, review of freezer temperature records, and interview with testing person #16 (TP #16) and testing person #17 (TP #17), the laboratory failed to store patient specimens according to the laboratory's policy and procedure for 26 of 26 days reviewed. Findings include: 1. Review of the laboratory's written policy and procedure titled, "(version 4.0) NBS 10-Tgal" section, "14. Specimen Retention" stated, "14.2 Abnormal specimens that have been confirmed diagnostically as "true positive" specimens are pulled from regular storage and stored at -80C to preserve the specimen for future Quality Control use indefinitely." 2. Review of the April 2025 NBS-4 freezer temperature records revealed the laboratory failed to store positive patient specimens according to the laboratory's written policy and procedure for 26 of 26 days as follows: a. 04/01/25 temperature documented at -10C b. 04/02/25 temperature documented at -11C c. 04/03/25 temperature documented at -6C d. 04/04/25 temperature documented at -14C e. 04/05 /25 temperature documented at -10C f. 04/06/25 temperature documented at -14C g. 04/08/25 temperature documented at -12C h. 04/09/25 temperature documented at -15 C i. 04/10/25 temperature documented at -12C j. 04/11/25 temperature documented at -15C k. 04/12/25 temperature documented at -6C l. 04/13/25 temperature documented at -15C m. 04/15/25 temperature documented at -13C n. 04/16/25 temperature documented at -11C o. 04/17/25 temperature documented at -3C p. 04/18/25 temperature documented at -13C q. 04/19/25 temperature documented at -7C r. 04/20 /25 temperature documented at -11C s. 04/22/25 temperature documented at -12C t. 04 /23/25 temperature documented at -15C u. 04/24/25 temperature documented at -11C v. 04/25/25 temperature documented at -15C w. 04/26/25 temperature documented at -9C x. 04/27/25 temperature documented at -15C y. 04/28/25 temperature documented at -15C z. 04/29/25 temperature documented at -10C aa. 04/20/25 temperature documented at -10C 3. Interview on 06/11/25 at 03:10 pm with TP #16 and TP #17 confirmed the findings above. IV. Based on observation, manufacturer's instructions, freezer temperature records, and interview with testing person #15 (TP #15), the laboratory failed to store Revvity Iduronate 2-sulfatase S&IS reagent boxes according

	to the manufacturer's instructions for six of eight days. Findings include: 1. On 06/10 /25, TP #15 confirmed the laboratory used the Revvity Iduronate 2-sulfatase S&IS reagent for newborn screening. 2. Observation on 06/10/25 at 02:45 pm of freezer NBS F9 revealed 15 boxes of Revvity Iduronate 2-sulfatase S&IS with a manufacturer's storage requirement of -16 to -30C. 3. Review of the NBS F9 freezer temperature records from 06/02/25 through 06/10/25 revealed temperatures colder than -30C for six of eight days as follows: a. 06/04/25 temperatures documented at -31 C b. 06/05/25 temperatures documented at -31C c. 06/06/25 temperatures documented at -31C d. 06/07/25 temperatures documented at -31C e. 06/09/25 temperatures documented at -31C f. 06/10/25 temperatures documented at -31C 3. Interview on 06 /10/25 at 02:50 pm with TP #15 confirmed the findings above. V. Based on observation, manufacturer's instructions, freezer temperature records, and interview with testing person #15 (TP #15), the laboratory failed to store Revvity Lyso PC Internal Standard reagent boxes according to the manufacturer's instructions for nine of 22 days. Findings include: 1. On 06/10/25, TP #15 confirmed the laboratory used the Revvity Lyso PC Internal Standard reagent for newborn screening. 2. Observation on 06/10/25 at 02:35 pm of the freezer NBS RAD-2 freezer revealed 15 boxes of Revvity Iduronate 2-sulfatase S&IS with a manufacturer's storage requirement of -16 to -30C. 3. Review of the NBS RAD-2 freezer temperature records from 04/01/25 through 04/30/25 revealed temperatures warmer than -16C for nine of 22 days as follows: a. 04/15/25 temperature documented at -10.4C b. 04/16/25 temperature documented at -10.4C c. 04/17/25 temperature documented at -10.3C d. 04/22/25 temperature documented at -9.9C e. 04/23/25 temperature documented at -10.1C f. 04 /28/25 temperature documented at -10.1C g. 04/29/25 temperature documented at -10.1C h. 04/30/25 temperature documented at -10.1C 3. Interview on 06/10/25 at 02: 40 pm with TP #15 confirmed the findings above.
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. This STANDARD is not met as evidenced by: I. Based on direct observation, review of the laboratory ' s Analytic Systems Policy, and an interview with General Supervisor #5 (GS #5), the laboratory failed to perform the semiannual evaluation of test result comparability for its three QuantStudio PCR instruments in calendar years 2024 and 2025. Findings: 1. During a facility tour on June 11, 2025, three QuantStudio PCR instruments (Serial #: 287880273, 287880275, 287880590) were observed in use in the General Microbiology Room #148. These instruments are utilized for Shiga toxin-producing Escherichia coli (STEC) testing and Laboratory Response Network (LRN) testing, including detection of Brucella spp., Bacillus anthracis, and other multi-agent RT-PCR targets. 2. Review of the laboratory's Analytic Systems Policy revealed the following requirement under Section 7, Comparison of Test Results: 7.1: "If the same test is performed using different methodologies or instruments, the laboratory must have a system in place to evaluate and define the relationship between results from these methods/instruments at least twice per year." 7.1.1: "For instruments more susceptible to variability, testing more frequently than twice per year may be necessary." 7.1.2: "Results of the comparison must be documented and signed by both the Supervisor and the

	Laboratory Director." 3. In an interview conducted on June 11, 2025, at approximately 3:00 PM, GS #5 confirmed that no semiannual comparability evaluations were performed in 2024 or 2025 for the three QuantStudio PCR instruments used for STEC and LRN RT-PCR testing. 4. The laboratory reports performing approximately 0 STEC PCR tests and 24 LRN PCR tests annually. 27814 II. Based on review of the laboratory's procedures, direct observation, and interviews with the Laboratory Director, and with two general supervisors (GS#6 and #7), the laboratory failed to perform the semiannual evaluation of test result comparability for its six ABI 7500 in calendars years 2024 and 2025 as evidenced by: A. Review of the laboratory's Analytic Systems Policy revealed the following requirement under Section 7, Comparison of Test Results: 7.1: "If the same test is performed using different methodologies or instruments, the laboratory must have a system in place to evaluate and define the relationship between results from these methods/instruments at least twice per year." 7.1.1: "For instruments more susceptible to variability, testing more frequently than twice per year may be necessary." 7.1.2: "Results of the comparison must be documented and signed by both the Supervisor and the Laboratory Director." B. In direct observation on 6/10/2025 at 1520 six ABI 7500 Instruments (serial # 275030441, serial #275030177, serial #275030175, serial # 275011800, serial #275030138. Serial #275040138 were used for one of the following testing: Serial #275030441 FLU B/A Typing, Flu B typing, Flu/SC2 CRO Serial #275030175 FLU B/A, Flu B typing, FLU/SC2, CRO Serial #275030177 FLU B/A, trioplex, FLU/SC2, CRO Serial #275011800 FLU B/A, trioplex, FLU/SC2, measles /mumps Serial #275030138 FLU/SC2 Measles/Mumps Serial #275030131 FLU/SC2 C. In an interview on 6/10/2025 at 1525 with the Laboratory Director he state we may have the data but nothing specific for the ABI 7500. D. In an interview on 6/10/2025 at 1525 with both general supervisor (GS) #6 and GS #7 confirmed that they didn't have specific documents for ABI 7500 but they may have Quality Control data between instruments. E. The laboratory performs 1095 FLU B/A, 0 Triplex, 36 Measles and Mumps, 0 FLU/SC2.