Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0655844	07/27/2023
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
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: Based on the procedure and record review and interview with the Quality Assurance supervisor, the laboratory failed to establish acceptable criteria for humidity in 2 of 2 procedures and 4 of 4 Room Temperature and Humidity Records. Findings include: 1. Review of QA procedure 51793.1130 "Laboratory Environmental Monitoring" and procedure NBS-18 SCID/SMA (TREC/SMNI), showed no established range for humidity defined. 2. Review of room temperature and humidity records, document 51793.847 for the calendar year 2022 for Section TB, Room 105B, Section Molecular Room 141, Section Microbiology Room 156, and for the calendar year 2021 for Section Molecular Room 141 showed no acceptable range for humidity defined. 3. On 7/27/2023 at 11:00 am, the Quality Assurance supervisor confirmed the above findings.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to check and document for 10 of 72 weeks, the positive and negative reactivity of control organisms using gram stains each week of use in the specialty of Bacteriology. Findings: 1. Review of the "Gram Stain" test log revealed the following statement: "QC (quality control) frequency: Each Week of Use". 2. Review of the Gram stain QC log sheets from the year of 2022 and January through July of 2023 documented the following gaps in QC dates: 02/07/2022 - 02/25/2022 = 18 days 03/14/2022 - 03/29/2022 = 15 days 09/01 /2022 - 09/12/2022 = 10 days 10/11/2022 - 10/27/2022 = 16 days 12/01/2022 - 12/16 /2022 = 15 days 12/28/2022 - 01/13/2023 = 16 days 03/06/2023 - 03/21/2023 = 15 days 04/18/2023 - 05/02/2023 = 15 days 05/17/2023 - 06/06/2023 = 19 days 06/28 /2023 - 07/10/2023 = 12 days 3. Further review of the QC documents failed to show any evidence of review by the technical/general supervisor. 4. On July 27, 2023 at 2: 35 PM, the Quality Assurance supervisor and laboratory personnel confirmed the above findings.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on the review of procedures and interviews with the new laboratory director and quality assurance supervisor, the new laboratory director failed to approve 16 of 16 laboratory procedures. Findings include: 1. Review of 16 procedures in the electronic document control system showed the new laboratory director did not approve 16 of 16 documents. These included: NBS-1,9,11,10,16,12,14, 7,8,19,17,18,20, and 21 51793.107 Appendix C-Cut off and Panic Values 51793.1130 laboratory Environmental Monitoring 2. On 7/27/2023 at 1:15 pm the Laboratory Director confirmed the documents were only reviewed and not approved. 3. On 7/27 /2023 at 10:00 am the Quality Assurance Supervisor confirmed the above findings and the laboratory director's start date as April 1, 2023.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on the review of preventative maintenance records and interviews with the quality assurance supervisor and general supervisor, the technical supervisor failed to review 6 f 6 maintenance records and 12 of 12 equipment temperature records. Findings include: 1. Review of completed preventative maintenance records showed no review by the technical supervisor or designee for the following records: a. GSP Maintenance Log, October 2022 b. Dailey Preventative Maintenance Log, Instrument ID TQD1, November 2021 c. Weekly Maintenance Log, Instrument ID TQD2, 2021 d. Instrument Quality Control and Preventive Maintenance Record, ABI #3 2022 e.

	Instrument Quality Control and Preventive Maintenance Record, ABI #4 2022 f. Instrument Quality Control and Preventive Maintenance Record, ABI #5 2022 2. Review of 12 equipment temperature records for water baths, freezers, and refrigerators showed no review by the technical supervisor or designee for the following: a. Micro room 143 -20C freezer b. Micro room 143 VWR fridge 9558560 c. NBS Isotemp Y15D-504865 d. Micro East Hall phcbi freezer e. Micro room 143 -20 C freezer f. Micro room 143 VWR fridge 9558560 g. BT room 105 freezer h. BT/TB room 106 refrigerator i. Gen Micro room 116 waterbath j. BT/TB room 106 refrigerator k. Micro -20 freezer l. Gen Micro room 148 Revco Isotemp low freezer 3. No delegation of duties was available at the time of the survey. 4. Review of the general supervisor's annual competency form for newborn screening did not show any responsibility for the review of preventative maintenance records. 5. On 7/27/2023 at 11:00 am the Quality Assurance supervisor confirmed the above findings. 6. On 7/27 /2023 at 1:00 pm the general supervisor #1 confirmed the above findings.