Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0220037	(X3) Date Survey Completed 03/23/2023
Name of Provider or Supplier Children's Medical Group Laboratory	**Street Address, City, State** 500 Greene St, Cumberland, MD	
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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory manager (LM), the laboratory was not in compliance with the Code of Maryland Regulations (COMAR) 10.10.06.06B(6)(b) for performing quality control (QC) testing on a qualitative test system. Findings: 1. The laboratory performed serum human chorionic gonadotropin (hCG) testing which is categorized by the Food and Drug Administration as moderate complexity and by COMAR as a single-use test device. 2. The COMAR section 10.10.06.06B(6)(b) for quality control of single-use test devices states that a licensed laboratory "shall ensure that quality control testing for a qualitative test system is performed and documented using known positive and negative control materials before patient testing: (i) On each lot of single-use test device received in a shipment; (ii) At least weekly for each lot of a single-use test device used for patient testing; (iii) After a single-use test device is exposed to an environment or condition that could affect the accuracy or reliability of test results; and (iv) Each day of use during test system validation." 3. Records of hCG QC testing from 04/2021 through 12/2022 were reviewed and showed that QC was being tested with each new kit lot number (04/15/2021, 06/16/2021, 08/06/2021, 09/17/2021, 06/08/2022, 07/24/2022, 08/26/2022, 10/20/2022, and 12/20/2022). 4. During a call on 03/23/2023 at 10:25 AM, the LM confirmed that hCG QC was run with each new kit lot number and not weekly as required by COMAR 10.10.06.06B(6)(b).
D3011	FACILITIES CFR(s): 493.1101(d)

	Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of the manufacturer's product insert (PI) and interview with the laboratory manager (LM), the laboratory failed to test the functionality of the eyewash fountain on a weekly basis as stated in the PI. Findings: 1. The laboratory used an emergency eyewash fountain that was hooked up to the sink faucet. 2. The PI stated to "Test unit on a regular weekly basis to verify compliance with ANSI [American National Standards Institute] requirements." 3. There was no documentation showing that the eyewash fountain was tested on a weekly basis. 4. During the survey on 03/15/2023 at 3:30 PM, the LM confirmed that the laboratory was not testing the functionality of emergency eyewash fountain on a weekly basis.
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 review of the manufacturer's reference manual and temperature records and interview with the laboratory manager (LM), the laboratory failed to monitor the humidity in the space where the hematology analyzer was used. Findings: 1. The laboratory used a Beckman Coulter AcT diff 2 hematology analyzer. 2. The manufacturer's addendum to the reference manual, PN 4237498GC November 2019, stated to "Keep room temperature between 16C and 35C (61F and 95F) and humidity at 20-85% without condensation" for the operation of the analyzer. 3. Review of the temperature records showed that laboratory humidity was not being monitored. 4. During the survey on 03/15/2023 at 3:30 PM, the LM confirmed that the laboratory was not monitoring the humidity in the space where the hematology analyzer was used.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on review of the manufacturer's certificate of accuracy, the manufacturer's calibration statement, and the laboratory's procedure and interview with the laboratory manager (LM), the laboratory failed to verify the accuracy of the thermometers placed in the incubators used for throat cultures. Findings: 1. The laboratory used two incubators each monitored with a Streck thermometer. 2. The Streck Temp-Chex thermometer certificate of accuracy for lot number 20550269 showed a date of certification of 09/08/2011 and the laboratory began using the thermometer on 08/22 /2012. 3. The Streck website included a document titled "Temp-Chex thermometer calibration statement" which stated "Due to use in diverse applications and handling, there is no precise way to predict how long calibration will be maintained. As with any thermometer, drift is a possibility and accuracy can be affected by shock, aging, temperature and contamination through daily use. Periodic recalibration or verification should be scheduled by each laboratory in accordance with its accrediting agency and/or established procedure. At a minimum, annual recalibration or verification from the date the thermometer is put "in use" is good lab practice." 4. The laboratory did not have a procedure defining the frequency with which to verify the accuracy of the Streck Temp-Chex thermometers. 5. During the survey on 03/15/2023 at 3:30 PM, the LM confirmed that the two Streck Temp-Chex thermometers used in the incubators have not been recalibrated/verified since put into use in 2012 and the laboratory did not have a procedure for verifying the accuracy of the thermometers.