Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0214058	11/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Annapolis Pediatrics	1655 Crofton Blvd Suite 301, Crofton, 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
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 surveyor observation and interview with the technical consultant (TC), the laboratory did not ensure that an eye wash station was located in the laboratory area where testing occurs. Findings: 1. During a tour of the laboratory, it was observed that there was no eye wash station available in the laboratory where hematology testing is performed. Laboratory staff stated that the eyewash had been moved to a room next to the laboratory where waived testing kits were located. 2. During an interview on 11/1 /19 at 12:45 PM, the TC confirmed that there was no eye wash station located in the room where laboratory testing is performed.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant (TC), the laboratory did not ensure that hematology controls were labeled with the date that they expire.

	Findings: 1. During a tour of the laboratory at 9:15 AM, it was observed that the opened and in use "Cell-Dyn 18 Plus" hematology controls in the laboratory refrigerator were labeled with the date that they were put in to use but were not labeled with the expiration date. A review of manufacturer instructions showed that the hematology controls expire 8 days after opening. 2. During an interview on 11/1 /19 at 12:45 PM, the TC stated that the controls are replaced weekly and confirmed that the in-use hematology controls were not labeled with the expiration date.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on temperature log record review and interview with the technical consultant (TC), the laboratory failed to document corrective action when incubator temperatures were out of range. Findings: 1. The temperature range for the laboratory incubator is 35 - 37 degrees Celsius. 2. A review of temperature logs from January to October, 2019 showed that the incubator temperature was out of range 7 out of 211 times recorded; and 3. The temperature was not recorded 3 out of 211 times. 4. There were no corrective actions documented for these dates. 5. During an interview on 11/1/19 at 12:45 PM, the TC confirmed that there were no corrective actions documented for the days that the incubator temperatures were out of range.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the procedure manual, final patient reports in the laboratory information system (LIS), and interview with the technical consultant (TC), the laboratory failed to ensure that the final test report included the correct name and address of the laboratory where throat cultures were interpreted. Findings: 1. A review of the laboratory procedure manual shows that throat culture specimens which are collected on Thursdays and Fridays are transported to their Annapolis office to be

	interpreted because the laboratory is not open over the weekend. 2. Random review of the final reports of patients whose cultures were sent to the Annapolis office on Thursdays and Fridays showed that 2 of 3 patients' final reports stated that the final interpretation was performed at the Crofton office, not the Annapolis office. 3. During an interview on 11/1/19 at 12:45 PM, the TC confirmed that the name and address of the laboratory where throat cultures were interpreted was not correctly documented on patient final reports.
D6073	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(4) Each individual performing moderate complexity testing must follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. This STANDARD is not met as evidenced by: Based on laboratory procedure manual and quality control (QC) record review and interview with the technical consultant (TC), the testing personnel did not follow the laboratory's procedure for documenting out of range QC and the corrective actions taken for the hematology analyzer. Findings: 1. The procedure, "Quality Control" states that "Corrective action for control values that exceed the defined tolerance limits is documented in the 'Troubleshooting Log.'" 2. A review of documentation on "Abbott Emerald Hematology Analyzer" troubleshooting logs from 9/11/18 to 11/30 /18 showed that on 19 days out of 63, actions taken for out of range QC was not documented; and 3. One day out of 63 the problem documented did not accurately reflect the QC which was run on that day. 4. During an interview on 11/1/19 at 12:45 PM, the TC confirmed that testing personnel did not follow the laboratory's established corrective action policy for out of range hematology QC.