Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1071931	03/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Auburn Pediatric And Adult Medicine	2353 Bent Creek Road Suite 110, Auburn, AL	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to ensure the Laboratory Director signed the attestation statements for six of fifteen events reviewed in 2020 through 2023. The findings include: 1. A review of the API PT records revealed the no signature by the Laboratory Director (or designee) on attestation statements for the following surveys: a) 2020 Microbiology 3rd Event. b) 2020 Hematology 3rd Event. c) 2022 Hematology 1st Event. d) 2022 Hematology 2nd Event. e) 2022 Hematology 3rd Event. f) 2022 Microbiology 1st Event. 2. During an interview on March 28, 2023, at 11:12 PM, Testing Personnel #1 confirmed the above findings.
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 a review of the refrigerator and freezer temperature records, the Cell Dyn 18+ Quality Control (QC) package insert, the Filmarray Biofire QC package insert, and an interview with Testing Personnel #1, the Laboratory failed to ensure QC material was stored within the manufacturer's acceptable limits. Refrigerator temperatures were below acceptable ranges for six out of twelve months in 2022, and freezer temperatures were higher than acceptable ranges since the previous survey on 2/5/2020 to the current survey on 3/28/2023. The findings include: 1. A review of the temperature records revealed the refrigerator in which the Cell Dyn+ Hematology Controls were stored were below the manufacturer's acceptable limits (less than 2 degrees Celsius) from April through September 2022. 2. A review of the Cell Dyn 18+ Control package insert revealed, "Cell Dyn 18+ controls should be tightly capped and stored at 2-10 degrees Celsius." 3. A review of the freezer temperature records revealed: a) Temperatures for the freezer in which the Filmarray Biofire Gastrointestinal (GI) controls were stored were above the manufacturer's acceptable limits since the previous survey on 2/5/2020 to the current survey on 3/28/2023. b) The laboratory's "acceptable ranges" of 3-8 degrees Fahrenheit do not reflect manufacturer's storage requirements for the Filmarray GI control Panel. 4. A review of the Filmarray Biofire GI controls package insert revealed, "Filmarray GI control Panel M238 should be stored frozen (-25 degrees Celsius to -15 degrees Celsius)". 5. During an interview on March 28th, 2023, at 1:03 PM, Testing Personnel #1 confirmed the above findings.
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 a review of the refrigerator and freezer temperature records and an interview with Testing Personnel #1, the Laboratory failed to implement and document corrective actions when refrigerator and freezer temperatures were outside the manufacturers' storage parameters for items therein. The surveyor noted refrigerator temperature were below acceptable ranges for six of twelve months in 2022 and the freezer temperatures were higher than acceptable ranges since the previous survey on 2/5/2020 to the current survey on 3/28/2023 with no documentation of corrective action. The findings include: 1. A review of environmental records revealed refrigerator and freezer temperatures were outside the manufacturers' storage parameters for the Quality Controls stored therein. (Refer to D5413.) There was no documentation of corrective action. 2. During an interview on March 28th, 2023, at 1:03 PM, Testing Personnel #1 confirmed the above findings.