Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303491	01/15/2026
Name of Provider or Supplier	**Street Address, City, State**	
Gadsden Pediatric Clinic Pa	501 Bay Street, Gadsden, 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
D2121	HEMATOLOGY CFR(s): 493.851(a) (a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) records and interviews with the Administrator and Testing Personnel 1 (TP1), the laboratory received failing scores for the Basophils in the White Blood Cell (WBC) Differential, a non-regulated test. The surveyor noted the laboratory failed in three consecutive PT events out of the six events reviewed in 2024-2025. The findings include: 1. A review of the API PT records revealed the laboratory received unsatisfactory scores for the WBC Differential on Basophils for the following PT events. A) 2024 Hematology/Coagulation 2nd Event 60 percent B) 2024 Hematology /Coagulation 3rd Event 40 percent C) 2025 Hematology/Coagulation 1st Event 40 percent 2. The Aadministrator and TP1 confirmed the above findings during the exit conference on 01-15-2026 at 1:30 PM.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by:

	Based on interviews with the Administrator and the Testing Personnel 1 (TP1) during the laboratory tour, the Policy and Procedure (P&P) manual, the laboratory failed to ensure a patient specimen identifier was entered on the analyzer before testing. The surveyor noted the missing entry to identify the patient specimens from the Complete Blood Count (CBC) analyzer occurred from the date of the last survey (04-25-2024) to the date of the current survey (01-15-2026). Findings include: 1. During the laboratory tour, interviews with the Administrator and TP1 revealed the staff did not enter any specimen identifier in the CBC analyzer before testing. 2. A review of the P&P manual revealed there was no written instructions on the process of patient specimen identity preservation from collection to testing to reporting of results. 3. The Administrator and TP1 confirmed the above findings during the exit conference on 01-15-2026 at 1:30 PM.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on reviews of the Hematology Quality Control (QC) records and the Hematology analyzer maintenance logs, the laboratory failed to provide the required QC and maintenance documentation prior to patient testing and reporting of test results. Refer to D5429, D5447, D5481.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on reviews of the Beckman Coulter (BC) DxH 500 Hematology analyzer maintenance records and an interview with the Administrator and the Testing Personnel 1 (TP1), the laboratory failed to perform the annual maintenance, as per the manufacturer's instructions. The surveyor noted there was no documentation of annual maintenance from 2024-2025. The findings include: 1. A review of the BC DxH 500 Hematology analyzer maintenance records revealed the BC DxH 500 analyzer had no documentation of the annual maintenance in 2024 and 2025. 2. A further review of the BC DxH 500 Hematology analyzer maintenance log form revealed the following annual requirements. A) Yearly (Lubricating Pistons) B) Yearly or every 18,000 cycles (Replace Rinsing Head O-Ring) 3. The Administrator and TP1 confirmed these findings during the exit conference on 01-15-2026 at 1:30 PM.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)

	(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter (BC) DxH 500 Hematology Quality Control (QC) records and interviews with the Administrator and the Testing Personnel 1 (TP1), the laboratory failed to retain the monthly documentation of Levey Jennings (L-J) charts to monitor shifts and trends of test performance over time. The surveyor noted two of the four months from 2024-2025 were unavailable for review. The findings include: 1. A review of the Beckman Coulter (BC) DxH 500 Hematology QC records revealed missing L-J charts from April 2025 and November 2025. 2. A further review of the L-J charts revealed documentation for the April 2025 L-J charts was accidentally deleted. 3. During the exit conference on 01-15-2026 at 1:30 PM, the Administrator and TP1 confirmed the above findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on reviews of the 2025 Hematology quality control (QC) records for the Beckman Coulter (BC) DxH 550 analyzer, the patient electronic history records, and interviews with the Administrator and Testing Personnel 1 (TP1), the laboratory failed to ensure at least two levels of quality control were performed and acceptable, prior to analyzing patient specimens and reporting the results. The surveyor noted missing documentation of QC for 5 of the 30 days in April 2025. The findings include: 1. A review of the BC DxH 550 QC records revealed no documentation of the three levels of QC performed prior to patient testing from April 21, 2025 through April 25, 2025. 2. An email from the Administrator on 01-23-2026 revealed one patient was performed and results reported during those five days in April 2025 when QC documentation was missing. 3. The Administrator and TP1 confirmed the above findings during the exit conference on 01-15-2026 at 1:30 PM.