

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0303491	<b>(X3) Date Survey Completed</b>  04/25/2024
<b>Name of Provider or Supplier</b>  Gadsden Pediatric Clinic Pa	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5481</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2022 Hematology quality control (QC) records for the Beckman Coulter AcT Diff 2, the patient result log, and an interview with Testing Personnel #1, the laboratory failed to ensure at least two levels of quality control were run and acceptable, prior to analyzing patient specimens and reporting the results. This was noted one day out of three months reviewed in 2022 by the surveyor. The findings include: 1. A review of the QC records for the AcT Diff 2 Hematology analyzer revealed only the low QC was performed and accepted on 05/10/2022. There was no evidence of documentation for the normal or high QC. 2. A review of the patient log printed from the instrument revealed seven patient CBCs (Complete Blood Count) were performed on 05/10/2022. 3. During an interview on 4/25/24 at 12:40 PM, Testing Personnel #1 confirmed normal and high QC were not documented prior to patient testing.</p>