

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0857452	(X3) Date Survey Completed 10/07/2022
Name of Provider or Supplier Alabama Pediatrics	Street Address, City, State 2815 Independence Drive, Birmingham, 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 Chemistry QC (Quality Control) records, the Piccolo IQCP (Individualized Quality Control Plan), and an interview with Testing Personnel #1, the Laboratory failed to ensure testing personnel performed the Piccolo QC every 30 days as per the IQCP. The surveyor noted four out of eighteen months in 2021 and 2022 when QC was not performed as required by the IQCP. The findings include: 1. A review of the Piccolo Chemistry IQCP revealed, "Perform external Quality Control at least every 30 days." 2. A review of the Piccolo records revealed the laboratory exceeded the 30-day requirements for external serum Bilirubin QC, as follows: a) 4/7 /2021 to 5/13/2021; 6 days overdue. b) 7/7/2021 to 8/10/2021; 3 days overdue. c) 6/3 /2022 to 7/14/2022; 11 days overdue. d) 9/1/2022 to 10/4/2022; 3 days overdue. 3. During an interview on October 7, 2022, at 12:38 PM, Testing Personnel #1 confirmed the above findings.</p>
D5481	<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</p>

manufacturer's 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 a review of the Hematology Quality Control (QC) records and an interview with Testing Personnel #1, the laboratory failed to ensure the Medonic Hematology QC was within the manufacturer's acceptable ranges before patient testing began one day in 2021. The findings include: 1. A review of the Medonic Hematology QC records revealed two levels of QC failed on October 2, 2021. One patient CBC (Complete Blood Count) was run on this date. 2. During an interview on October 7, 2022, at 12:38 PM, Testing Personnel #1 confirmed the above findings.