

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0304806	(X3) Date Survey Completed 06/26/2018
Name of Provider or Supplier Southeastern Pediatric Associates Pa	Street Address, City, State 364 Honeysuckle Road, Dothan, 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
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 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 reviews of the Medonic M Series Hematology analyzer quality control (QC) records, patient test records, and an interview with the General Supervisor, the surveyor determined the laboratory failed to ensure at least two levels of Hematology QC were within acceptable limits before patient testing began. This was noted on two days of patient CBC (Complete Blood Count) testing in June 2017. The findings include: 1. A review of the Hematology cumulative QC report revealed the following days when patient samples were tested and resulted without at least two levels of QC within acceptable ranges: A) 6/14/2017: No QC was run in the MC (Microtainer) mode; one patient CBC was performed in the MC mode. B) 6/16/2017: No QC performed; 14 patient CBCs were tested. 2. During an interview and review of the QC and patient records on 6/26/2018 at 4:00 PM, the General Supervisor was asked if the manufacturer required QC to be run in both the OT (Open Tube) and MC modes each day of patient testing. The Supervisor answered, "Yes", and confirmed the Testing Personnel performing testing on the above dates had not followed the laboratory's QC policies. Thus the above noted findings were confirmed. SURVEYOR:Laura T. Williams, BS, MT (ASCP)Licensure and Certification Surveyor</p>