

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0304806	<b>(X3) Date Survey Completed</b>  03/22/2023
<b>Name of Provider or Supplier</b>  Southeastern Pediatric Associates Pa	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on a review of CAP (College of American Pathologists) Proficiency Testing (PT) records, and an interview with General Supervisor #1, the laboratory failed to implement a mechanism to ensure all PT results were submitted and received by the PT provider. The surveyor noted results for one of three 2022 Urine Culture surveys were not submitted to CAP. The findings include: 1. A review of the Routine Microbiology Combination (RMC)-Event C survey results revealed scores for the Throat Culture survey, however there were no scores for the Urine Culture survey. The surveyor requested the scores from General Supervisor #1 who stated the laboratory missed printing the pages with the Urine Culture Scores, and she needed to check the CAP website. 2. During an interview on 3/22/2023 at 11:48 AM, General Supervisor #1 stated there were no results for the 2022 RMC-C Urine Culture survey, however she had confirmed it was performed. General Supervisor #1 believed the results may not have been submitted on line correctly. The surveyor then asked if the laboratory had Quality Assurance reviews to ensure accurate and complete results were submitted to CAP; the Supervisor confirmed this was not usually done. .</p>
<b>D5441</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The</p>

laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the Medonic M Series Hematology Quality Control (QC) records, and an interview with General Supervisor #1, the laboratory failed to ensure data from each day of QC was included on Levy Jennings (L-J) charts or the Interlaboratory Quality Assurance Program (IQAP) reports to track for shifts and trends over time. The laboratory failed to include 59 days of QC data from August 2021 through March 2022. The findings include: 1. A review of the Medonic M Series Hematology QC records revealed the laboratory printed cumulative monthly reports with the daily QC data, and the L-J charts attached. However, the surveyor noted six months with a total of 59 days of missing QC results, as follows: A) 8/1--8/9/2021 (9 days) B) 8/26--8/31/2021 (5 days) C) 10/26--11/9/2021 (15 days) D) 12/1--12/11/2021 (11 days) E) 2/1--2/7/2022 (7 days) F) 3/1--3/12/2022 (12 days) 2. A further review of the CDS (Clinical Diagnostic Solution) IQAP data revealed QC from the above dates in 2021 were not included in the laboratory's monthly statistics reports. 3. During an interview on 3/22/2023 at 3:00 PM, the surveyor asked General Supervisor #1 about the the process for printing the cumulative monthly QC from the Medonic, and submitting the data to CDS for inclusion in the IQAP statistics. The Supervisor explained the problems were occurring when they implemented a new lot # (number) of QC in the middle of a month. Staff sometimes forgot to print the cumulative data and L-J charts from the previous lot number of QC, or they forgot to print and submit the end of the month QC for the new lot # to the CDS IQAP. SURVEYOR ID# 32558  
Licensure and Certification Surveyor