

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0902104	(X3) Date Survey Completed 04/27/2022
Name of Provider or Supplier Eastern Shore Children's Clinic	Street Address, City, State 7 Medical Park Drive, Fairhope, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the CAP (College of American Pathologists) proficiency testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to ensure attestation statements for four out of four 2021 - 2022 surveys were physically signed by the Laboratory Director and Testing Personnel. The findings include: 1. A review of the CAP Hematology PT records revealed attestation statements did not include the physical signatures of the Laboratory Director and Testing Personnel on the three surveys performed, or the first survey in 2022. 2. A review of the instructions on the CAP electronic attestation statements revealed, "Retain a signed ["signed" is underlined] copy of this page in your laboratory for your records and inspection purposes.". 3. In an interview on 4/27/2022 at 11:05 AM, the surveyor reviewed the instructions on the CAP attestation statements with Testing Personnel #1, who confirmed the Laboratory Director and Testing Personnel had failed to physically sign the attestation. . .</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p>

This STANDARD is not met as evidenced by:
Based on a review of the testing personnel records and an interview with Testing Personnel #1, the Technical Consultant failed to evaluate the performance of testing personnel at least semiannually during the first year of moderate-complexity patient testing. This was noted on two out of nineteen testing personnel listed on the Form CMS-209 Laboratory Personnel Report (CLIA). The findings include: 1. A review of the testing personnel records revealed no semiannual evaluation was documented for Testing Personnel #9 (due September 2021), and Testing Personnel #12 (due December 2021). 2. During an interview on 04/27/20221 at 11:30 AM, Testing Personnel #1 confirmed the semiannual evaluations were not documented for Testing Personnel #9, and Testing Personnel #12. .

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on a review of the testing personnel records and an interview with Testing Personnel (TP) #1, the Technical Consultant failed to evaluate the performance of testing personnel performing moderate complexity testing at least annually for five out of nineteen testing personnel listed on the Form CMS-209 Laboratory Personnel Report (CLIA). The findings include: 1. A review of the testing personnel records revealed the annual performance was not evaluated or documented for testing personnel as follows: A) TP #2: No annual evaluations in 2020 or 2021 B) TP #3: No annual evaluations in 2021 or 2022 C) TP #4: No annual evaluations in 2020, 2021 or 2022 D) TP #5: No annual evaluations in 2021 E) TP #6: No annual evaluations in 2021 2. During an interview on 04/27/20221 at 11:30 AM, Testing Personnel #1 confirmed the above noted findings. SURVEYOR ID#32558 Licensure and Certification Surveyor