Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2117879	(X3) Date Survey Completed 12/05/2024
Name of Provider or Supplier Eastern Shore Children's Clinic	**Street Address, City, State** 9603 Stagecoach Commercial Park Circle, Spanish Fort, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, a review of the Complete Blood Count (CBC) Boule Quality Control (QC) manufacturer's instructions, and an interview with the Clinical Manager (CM), the laboratory failed to label three of the three open vials of QC material with the revised expiration date. The findings include: 1. During the laboratory tour on 12/05/2024 at approximately 8:48 AM, the surveyor observed the three levels of CBC QC, Lot 22409 Expiration date 2-10-2025, currently in use were labeled with the open date, "12/5/2024", however the testing personnel had not recorded the new expiration date upon opening on the vials. 2. A review of the Boule QC manufacturer's instructions under Storage and Stability revealed the following statement, " Open vial stability 14 days after opening when returned to refrigerator after each use". 3. During the exit conference at 2:47 PM on 12-05-2024, the CM confirmed the laboratory failed to label vials with open expiration dates.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the Clinical Manager (CM), the Technical Consultant failed to ensure 27 of the 27 Testing Personnel (TP) had competency assessments for the moderate complexity testing which included the six CLIA minimal regulatory requirements. The surveyor noted four of the six requirements were missing on annual and semi-annual competencies. The findings include: 1. A review of the 2022 through 2024 personnel records for 27 TP (listed on the CMS-209) who performed moderate complexity testing revealed TP competency assessments for Bacteriology and Hematology specialties had no documentation on four of the six CLIA regulatory requirements. The surveyor noted the missing four requirements were as follows: (1) Review of intermediate test results of worksheets, quality control records, proficiency testing results, and preventive maintenance results. (2) Direct observation of performance of instrument maintenance and function checks. (3) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. (4) Assessment of problem-solving skills. 2. The CM confirmed the above findings during the exit conference on 12/05/2024 at 2:47 PM.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the Clinical Manager (CM), the Technical Consultant (TC) failed to ensure 27 of the 27 Testing Personnel (TP) listed on the CMS-209 (Laboratory Personnel Report) who performed moderate complexity testing had semi-annual competency assessments during the first year of patient testing. The findings include: 1. A review of the personnel records revealed all TP performing Bacteriology interpretations did not have semi-annual competency assessment documentations from 2022-2024. 2. A further review of the personnel records revealed all TP performing Hematology testing had no semi-annual competency assessment documentations from 2022-2024. 3. The surveyor noted 8 of the 27 TP had no Bacteriology documentation of semi-annual competency assessments, and 19 of the 27 TP had no Hematology documentation of semi-annual competency assessments. 4. During the exit conference on 12/05/2024 at 2:47 PM, the CM confirmed the above findings.
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 personnel records and an interview with the Clinical

	Manager (CM), the Technical Consultant (TC) failed to ensure 27 of the 27 Testing Personnel (TP) listed on the CMS-209 (Laboratory Personnel Report) who performed moderate complexity testing had annual competency assessments. The findings include: 1. A review of the personnel records revealed all TP performing Bacteriology interpretations did not have annual competency assessment documentation from 2022-2024. 2. A review of the personnel records also revealed all TP performing Hematology testing had no annual competency assessment documentation from 2022-2024. 3. The surveyor noted 8 of the 27 TP had no Bacteriology documentation of annual competency assessments, and 19 of the 27 TP had no Hematology documentation of annual competency assessments. 2. During the exit conference at 2: 47 PM on 12/05/2024, the CM confirmed the above findings.