Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2117879	09/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Eastern Shore Children's Clinic	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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the College of American Pathologists (CAP) Proficiency Testing (PT) records, and an interview with Testing Personnel (TP) #1, the Laboratory Director (LD), or designee, failed to review the failing PT test score for Hematocrit. This was noted for one of two reviewed in 2026. The findings include: 1. A review of the CAP PT records revealed no documentation of a review from the Laboratory Director, or designee, for the 2026 FH2-B Hematology event, Hematocrit 60%. 2. TP #1 confirmed the above findings during an interview on 9/24/26, at 12:00pm.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the College of American Pathologists (CAP) Proficiency Testing (PT) records, and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure investigation and documentation of corrective actions (CA) by the Laboratory Director, or designee, for Hematocrit. This was noted for one of two reviewed in 2026. The findings include: 1. A review of the CAP PT records revealed no

	documentation of corrective actions for the 2026 FH2-B Hematology event, Hematocrit 60%. 2. TP #1 confirmed the above findings during an interview on 9/24 /26, at 12:00pm.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers 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 2025 Medonic quality control (QC) records, a review of patient testing logs, and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure at least two levels of QC were acceptable, prior to analyzing patient specimens and reporting the results. This was noted for 1 out of 31 days reviewed in May 2025. The findings include: 1. A review of the QC records for the Medonic Hematology analyzer revealed the following QC levels were outside acceptable limits prior to patient testing on May 5, 2025. a. Low Level (L1) Lot#: 2241231 Expiration date: 5/15/25 b. Normal Level (L2) Lot#: 2241232 Expiration date: 5/15/25 2. A review of patient testing logs revealed that 3 patients were performed when the QC was outside the acceptable limits. 3. TP #1 confirmed the above findings during the exit interview on 9/24/26 at 12:00pm.