Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1048892	04/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Etowah Pediatrics	170 Independent Drive, Rainbow City, 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) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation during the laboratory tour, a review of the Complete Blood Count (CBC) Quality Control (QC) package insert, and an interview with the Technical Consultant (TC) and Testing Personnel 1 (TP1), the laboratory failed to write the new expiration dates on QC vials after opening. The surveyor noted three of the three levels of QC currently in use had no open expiration dates recorded. The findings include: 1. During the laboratory tour on 4-14-2026 at approximately 9:08 AM the surveyor observed TP had not recorded the new expiration date on the CBC QC vials after opening for the following controls. A) Abnormal Low, Lot 352618311, Expires 06-05-2026 B) Normal, Lot 362618312, Expires 06-05-2026 C) Abnormal High, Lot 372618313, Expires 06-05-2026 2. A review of the DxH 500 Series Control package insert revealed the manufacturer's open-vial stability of 16 days. 3. During an interview with TP1 on 04-14-2026 at 9:16 AM, TP1 stated the laboratory opens a new vial of controls every first and fifteen of the month but had no documentation of the process.
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 reviews of the 2025 Hematology quality control (QC) records for the Beckman Coulter (BC) DxH 520 analyzer, the patient daily lab journal, and interviews with the Technical Consultant (TC) and Testing Personnel (TP), the laboratory failed to ensure at least two levels of quality control were performed and acceptable, prior to analyzing patient specimens and reporting the results. The surveyor noted three of the five months reviewed from July 2024 through March 2026 were missing the QC performance documentation. The findings include: 1. A review of the BC DxH 520 QC records revealed no documentation of the three levels of QC performed prior to patient testing for the following months. A) July 2024, 19 days B) April 2025, 22 days C) October 2025, 14 days 2. A review of the patient daily lab journal revealed 355 patients were performed and results reported when QC was not documented prior to analyzing patient specimens. 3. The TC and TP confirmed the above findings during the exit conference on 04-15-2026 at 1:13 PM.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on a review of the personnel records listed on the CMS 209 Form (Laboratory Personnel Report), and an interview with the Technical Consultant, the TC failed to ensure competency assessments for Testing Personnel (TP) performing moderate complexity analysis in Hematology included the six minimal CLIA regulatory requirements. The surveyor noted four of the four TP competency assessments were missing the six requirements. The findings include: 1. A review of the 2024-2026 personnel records revealed TP competency assessments for TP1-4 in the Hematology specialty had no documentation of the six minimal CLIA regulatory requirements which are as follows: (1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing. (2) Monitoring the recording and reporting of test results. (3) Review of intermediate test results of worksheets, quality control records, proficiency testing results, and preventive maintenance results. (4) Direct observation of performance of instrument maintenance and function checks. (5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. (6) Assessment of problem-solving skills. 2. TC confirmed the above findings during the exit conference on 04-15-2026 at 1:13 PM.