Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1048892	05/16/2024
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on a review of the 2022-2023 API (American Proficiency Institute) PT (Proficiency Testing) records and an interview with the Laboratory Director, the laboratory failed to ensure the Laboratory Director signed the attestation statements for three of five survey events. The findings include: 1. A review of the API PT records revealed no signature by the Laboratory Director (or designee) on attestation statements for the following surveys: a) 2022 Hematology 3rd Event. b) 2023 Hematology 1st Event. c) 2023 Hematology 2nd Event. 2. During an interview on 5/16 /24, at 9:53 AM, the Laboratory Director confirmed the above findings.
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 2022-2023 API (American Proficiency Institute) PT (Proficiency Testing) records and an interview with the Laboratory Director, the laboratory failed to document review for two of five survey events. The findings include: 1. A review of the API PT records revealed no documentation of review by the Laboratory Director, or designee, for the following surveys: a) 2022 Hematology

	2nd Event. b) 2023 Hematology 1st Event. 2. During an interview on 5/16/2024, at 9: 53 AM, the Laboratory Director confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on reviews of the Policy and Procedures manual, validation records, calibration records, QC (Quality Control) records, QA (Quality Assessment) records, and interviews with the Laboratory Director, the laboratory failed to ensure: A) Policies and procedures for the Hematology analyzer were updated and approved by the Laboratory Director. (Refer to D5407.) B) An acceptable calibration was performed by the Beckman Coulter Service Engineer during the validation of the AcT Diff 2 Hematology analyzer and approved by the Laboratory Director. (Refer to D5421.) C) Calibrations on the BC (Beckman Coulter) AcT Diff 2 and DxH 520 Hematology analyzers were performed every six months. (Refer to D5437.) D) A mechanism was implemented to monitor for shifts and trends in Hematology QC. (Refer to D5441.) E) The QA (Quality Assessment) program was maintained to assure the quality of laboratory services provided. (Refer to D5791.)
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Policy and Procedure Manual and an interview with the Laboratory Director, the laboratory failed to ensure policies and procedures for the Hematology analyzer were updated and approved by the Laboratory Director. This was noted from the implementation date of the new Beckman Coulter DxH 520 Hematology analyzer on 5/24/2023, to the date of the current survey, 5/16/2024. The findings include: 1. A review of the Policy and Procedure manual revealed the discontinued Hematology AcT Diff 2 analyzer policy was still active. There was no evidence of the Laboratory Director's approval of the new DxH 520 Hematology analyzer user manual procedures. 2. During an interview on 5/16/2024 at 10:00 AM, the Laboratory Director confirmed the policies and procedures were not updated and approved when the new Hematology analyzer was implemented.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it

	can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the Hematology validation calibration records, a review of the Beckman Coulter (BC) DxH 520 user manual, and an interview with the LD (Laboratory Director), the laboratory failed to ensure an acceptable calibration was performed by the Beckman Coulter Service Engineer during the validation of the BC DxH 520 Hematology analyzer, prior to patient testing. This was noted for one of one instruments, the DxH 520, implemented on 5/24/2023. The findings include: 1. A review of the calibration performed during the validation of the BC DxH 520 Hematology analyzer revealed calibration for WBC (White Blood Cell) was "needed"; there was no evidence of an acceptable calibration of the WBC parameter performed during the installation and validation by the Beckman Coulter Service Engineer. The Laboratory Director also failed to document review and approval of the validation. 2. A review of the BC DxH 520 user manual on page 52 under "CALIBRATION / REPRODUCIBILITY" revealed, "Verify PASSED for all parameters." 3. During an interview on 5/16/2024, at 11:03 AM, the Laboratory Director confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Hematology calibration records, a review of the QA (Quality Assessment) program, and an interview with the LD (Laboratory Director), the laboratory failed to perform acceptable calibrations on the BC (Beckman Coulter) AcT Diff 2 and DxH 520 Hematology analyzers every six months as per the laboratory QA policy. This was noted for two of five calibrations reviewed in 2022 through 2024. The findings include: 1. A review of the Hematology calibration records revealed the following: a) The BC AcT Diff 2 was last calibrated on 4/21/2023. No evidence of documentation that another calibration was performed on the AcT Diff 2 for the second half of 2023. b) The new BC DxH 520 Hematology analyzer was implemented and calibrated on 5/24/2023, however this calibration was invalid. (Refer to D5421.) c) Ten and a half months later the BC DxH 520 was

	calibrated on 4/4/2024. 2. A review of the QA Program revealed, "Calibration is performed and documented at least every 6 months." 3. During an interview on 5/16 /2024, at 11:21 AM, the LD confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (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 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 BC (Beckman Coulter) DxH 520 Hematology Quality Control (QC) records and an interview with the Laboratory Director, the laboratory failed to implement a mechanism monitoring the accuracy and precision of test performance over time. The findings include: 1. A review of BC DxH 520 QC records revealed only raw data from the instrument. No evidence of Levy-Jennings charts or peer group data was available for review during the survey. 2. During an interview on 5/16/2024 at 12:50 PM, the Surveyor inquired about the review of Levy-Jennings charts for the DxH 520 Hematology analyzer. The Laboratory Director confirmed the laboratory was not reviewing Levy-Jennings charts, and had not implemented another mechanism to monitor for shifts or trends in that testing system.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the Policies and Procedures and an interview with the Laboratory Director, the laboratory failed to maintain a QA (Quality Assessment) program to assure the quality of laboratory services provided. This was noted from the date of the previous survey on 7/12/2022 to the date of the current survey on 5/16 /2024. The findings include: 1. A review of Policies and Procedures revealed no evidence of documentation on the QA plan for the facility. 2. During an interview on 5 /16/2024 at 1:40 PM, the Laboratory Director confirmed he stopped using the monthly QA checklist.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on reviews of the BC (Beckman Coulter) DxH 520 validation records, QA (Quality Assessment) records, Policy and Procedure Manual, and interviews with the Laboratory Director, the Laboratory Director: 1) Failed to document review and approval of the validation procedures for the BC DxH 520. (Refer to D6013.) 2) Failed to maintain a QA program to assure the quality of laboratory services provided. (Refer to D6021.) 3) Failed to document approval of the new Beckman Coulter DxH 520 Hematology analyzer user manual. (Refer to D6031.)
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the validation records for the Beckman Coulter DxH 520 Hematology analyzer and an interview with the Laboratory Director, the Laboratory Director failed to document review and approval of the validation procedures prior to instrument use for patient testing. This was noted for one of one instruments, the DxH 520, implemented on 5/24/2023. The findings include: 1. A review of the Beckman Coulter DxH 520 validation records revealed no evidence of the Laboratory Director's review and approval (as evidenced by signature and date) before the instrument was utilized for patient testing on 5/24/2023. 2. During an interview on 5/16/2024 at 10:30 AM, the Laboratory Director confirmed the above findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the Policies and Procedures and an interview with the Laboratory Director, the Laboratory Director failed to maintain a QA (Quality Assessment) program to assure the quality of laboratory services provided. This was noted from the date of the previous survey on 7/12/2022 to the date of the current

	survey on 5/16/2024. The findings include: 1. A review of Policies and Procedures revealed no evidence of documentation on the QA plan for the facility. 2. During an interview on 5/16/2024 at 1:40 PM, the Laboratory Director confirmed he stopped using the monthly QA checklist.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of the Policy and Procedure Manual and an interview with the Laboratory Director, the Laboratory Director failed to document approval of the new Beckman Coulter DxH 520 Hematology analyzer user manual prior to patient testing. This was noted from the implementation date of the DxH 520 on 5/24/2023, to the date of the current survey, 5/16/2024. The findings include: 1. A review of the Policies and Procedures manual revealed no evidence of the Laboratory Director's approval on the DxH 520 user manual. 2. During an interview on 5/16/2024 at 10:00 AM, the Laboratory Director confirmed the above findings.