Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2011677	05/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Elite Pediatric And Adolescent Medicine, Llc	201 Lakeview Dr, Suite A, Somerville, TN	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the Laboratory Personnel Report (CLIA) Form (CMS-209), the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and staff interview, the laboratory failed to ensure that testing person (TP) two participated in the Hematology/Coagulation PT (four of four events reviewed) in 2024 and 2025 for the complete blood count with automated differential (CBC w/Diff) analytes. The findings include 1. A review of the CMS-209 completed for the recertification survey on 05/29/2025 revealed three TP that performed CBC w/Diff patient testing. 2. A review of the laboratory's API PT Hematology/Coagulation attestation records revealed TP two had not participated in the 2024 Event One, 2024 Event Two, 2024 Event Three, or 2025 Event One. 3. A telephone interview with the laboratory's technical consultant on 06/03/2025 at 9:22 a.m. confirmed the survey findings. Word Key: CLIA- Clinical Laboratory Improvement Amendments
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 laboratory's American Proficiency Institute (API)

	proficiency testing (PT) records and staff interview, the laboratory failed to document review and evaluation for the 2024 Hematology/Coagulation event two (one of four events reviewed) for the complete blood count with automated differential (CBC w /Diff) analytes. The findings include 1. A review of the laboratory's API PT records revealed that the 2024 Event Two performance evaluation (print date 08/16/2024) did not have documentation of review on the survey date (05/29/2025). 2. A telephone interview with the laboratory's technical consultant on 06/03/2025 at 9:22 a.m. confirmed the survey findings.
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 laboratory's American Proficiency Institute (API) proficiency testing (PT) records, lack of records, and staff interviews, the laboratory failed to document corrective action for unsatisfactory scores received for two of two Hematology/Coagulation events in 2024 for the complete blood count with automated differential (CBC w/Diff) analytes. The findings include 1. A review of the laboratory's API PT Hematology/Coagulation records revealed the following: 2024 Event One: Unacceptable results for sample HEM-05 for the Monocytes/Mids % analyte. The Performance evaluation review dated 05/01/2024 stated, "Sample Five is repeated." Documentation of the repeat analysis or corrective action was not available on the survey date (05/29/2025). 2024 Event Three: Unacceptable results for sample HEM-14 for the Platelet Count analyte. The Performance evaluation review dated 12 /12/2024 stated, "No corrective actions required." 2. A telephone interview with the laboratory's technical consultant on 06/03/2025 at 9:22 a.m. confirmed the survey findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure, manufacturer's operator's manual, patient test records, and staff interview, the laboratory procedure for the complete blood count with automated differential (CBC w /Diff) performed on the Cell Dyn Emerald instrument did not include procedures for corrective actions to take for unacceptable quality controls, panic/critical result values, or procedures to follow for flagged CBC w/Diff results in 2024 and 2025. The findings include 1. An observation of the laboratory on 05/29/2025 at 10:15 a.m. revealed the Abbott Cell-Dyn Emerald (Serial Number 030921-010876) used for CBC w/Diff patient testing (new since the previous survey 03/05/2024). 2. A review of the laboratory procedure titled "Cell-DYN Emerald" (SOP: #003) revealed that the procedure did not contain corrective action steps for unacceptable quality control results, panic/critical result values, or procedures to follow for flagged CBC w/Diff patient results. 3. A review of the Abbott Cell-Dyn Emerald Operator's Manual section three, titled "Measurand Data Flags," revealed the following: Section "WBC Flags" L1: Platelet aggregates, NRBCs, Giant Platelets, Cryoglobulins, Incomplete Lysis of RBC, Small Lymphocytes, Fibrin Clots, Shift in WBC distribution due to EDTA anticoagulant equilibration. L2: Myelocytes, Lymphoblasts, Basophils. L3: Eosinophils, Myelocytes. L5: Large size cells present. Section "WBC Measurand Flags" "An asterisk (*) for count invalidation or (s) suspect measurand flags are displayed with the corresponding results." Table 3.4, titled "WBC Flags," and Table 3.5, titled "Platelet Flags," in the "Action" columns revealed instructions for the flags, which included inspecting specimens for clots, reviewing stained smears, recollection, and retesting. 4. A review of patient test records revealed the following: Patient 6058, reported on 11/19/2024 at 2:43 p.m., was the first patient reported from the Cell-Dyn Emerald. The patient report contained "s" flags for the LYM, MID, GRA, LYM%, MID%, and GRA% analytes and an "L3" flag. Patient 7615 reported on 02/03/2025 at 3:59 p.m. reported from the Cell-Dyn Emerald. The patient report contained "s" flags for the LYM, MID, GRA, LYM%, MID%, and GRA% analytes and an "L3" flag. 5. A telephone interview with the laboratory's technical consultant on 06/03/2025 at 9:22 a.m. confirmed that the laboratory procedure manual did not include quality control corrective action procedures, critical/panic patient ranges, or procedures to follow for flagged CBC w/Diff patient test results. Word Key: WBC- White Blood Cell NRBC- Nucleated Red Blood Cell RBC- Red Blood Cell EDTA- Ethylenediaminetetraacetic acid LYM- Lymphocytes MID- Mid Cells GRA- Granulocytes %- percent
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the laboratory's quality assessment procedure, quality assessment documentation, quality control records, lack of records, and staff interview, the laboratory's quality assessment process did not include reviews of effective corrective action or complete documentation of corrective actions taken for the Cell-Dyn Emerald used for complete blood count with automated

differential (CBC w/Diff) patient testing in 2024 and 2025. The findings include 1. Observation of the laboratory on 05/29/2025 at 10:15 a.m. revealed the Abbott Cell-Dyn Emerald (Serial Number 030921-010876) used for CBC w/Diff patient testing (new since the previous survey 03/05/2024). 2. A review of the laboratory's quality assessment procedure, "Quality Assessment Policy" (SOP: #005), in section 3 b, "Quality Control Assessment," revealed that "Quality control records will be reviewed quarterly by a technical consultant." 3. A review of the laboratory's Quality Assurance Checklist & Tracker records titled "Monthly QC Review" revealed the following: Quality Control lots L4288, N4288, and H4288, used from 11/18/2024 through 01/09 /2025, were reviewed by the technical consultant on 01/13/2025. Section Additional Observations/Notes L4288: "Noted random shifts in PLT QC in November," N4288: "RBC running on the High side of the mean," and H4288: "RBC running on high Side of the mean." Quality Control lot H4316, used from 01/13/2025 through 02/28/2025, was reviewed 03/03/2025 by the technical consultant. Section Additional Observations /Notes "HCT running on the high Side of the mean.-Early calibration may be required to correct performance". The technical consultant reviewed Quality Control lots L5034 and N5034, used from 03/04/2025 through 05/06/2025, on 05/06/2025. Section Additional Observations/Notes L5034: "Noted random shifts in PLT QC in November. Appears to have been corrected". N5034: "Noted random shifts in PLT QC in November. Aperture cleaning may be required". 5. A review of the laboratory's quality control records revealed the following: L4288: Repeat Quality control runs performed for results that were not acceptable for 16 of 28 dates (11/18/2024, 11/26 /2024, 12/03/2024, 12/04/2024, 12/11/2024, 12/18/2024, 12/27/2024, 12/30/2024, 01 /02/2025, 01/03/2025, 01/06/2025, and 01/07/2025) N4288: Repeat Quality control runs performed for results that were not acceptable for 8 of 28 dates (12/10/2024, 12 /11/2024, 12/17/2024, 12/23/2024, 12/27/2024, 01/02/2025, 01/06/2025, 01/09/2025) H4288: Repeat Quality control runs performed for results that were not acceptable for 8 of 28 dates (11/25/2024, 11/27/2024, 12/02/2024, 12/04/2024, 12/11/2024, 12/31 /2024, 01/03/2025, 01/06/2025) H4316: Repeat Quality control runs performed for results that were not acceptable for 12 of 33 dates (01/15/2025, 01/16/2025, 01/17 /2025, 01/23/2025, 01/24/2025, 01/30/2025, 01/31/2025, 02/03/2025, 02/10/2025, 02 /12/2025, 02/26/2025, 02/28/2025) L5034: Repeat Quality control runs performed for results that were not acceptable for 12 of 42 dates (03/06/2025, 03/07/2025, 03/13 /2025, 03/17/2025, 03/20/2025, 03/27/2025, 04/04/2025, 04/10/2025, 04/17/2025, 04 /24/2025, 04/28/2025, 05/01/2025) N5034: Repeat Quality control runs performed for results that were not acceptable for 5 of 42 dates (03/14/2025, 03/27/2025, 04/18 /2025, 04/21/2025, 04/24/2025). Two of the 42 dates did not have repeats for results that were not acceptable for the PLT analyte (04/25/2025 and 04/28/2025). 6. The laboratory did not have documentation of corrective actions for repeat quality control runs or of the corrective actions noted on the technical consultant's reviews from 11/18 /2024 through 05/06/2025 on the date of the survey, 05/29/2025. 7. A telephone interview with the laboratory's technical consultant on 06/03/2025 at 9:22 a.m. confirmed the laboratory's quality assessment process did not include reviews of corrective action documentation. Word Key: QC- Quality Control PLT- Platelet RBC- Red Blood Cell HCT- Hematocrit