

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0950316	(X3) Date Survey Completed 09/18/2024
Name of Provider or Supplier Pediatrics East, Inc-Bartlett	Street Address, City, State 8025 Stage Hills Blvd, Bartlett, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory procedures, patient test reports, instrument daily reports, and staff interviews, the laboratory failed to follow the procedure for flagged complete blood count (CBC) patient test results (three of three reviewed) on the Abbott Cell-Dyn Emerald instrument in 2024. The findings include: 1. Observation of the laboratory on 09/18/2024 at 9:40 am revealed the Abbott Cell-Dyn Emerald (Serial #030922-010526) instrument used for CBC patient testing. 2. A review of the laboratory procedure titled " Ordering & Reporting Normal and Alert Lab Values" section, "Reporting Lab Results," revealed the following statement: "If a CBC shows "s" by some results, the lab tech should remix the sample and run the sample a second time." 3. A review of the laboratory patient test results revealed the following results with "s" flags present: Patient A: reported 02/19/2024 at 12:20 pm Lymphocyte Absolute-1.1 (s) Mid Absolute-1.2 (s) Granulocyte Absolute-11.1 (s) Lymphocyte % 8.5 (sh) Mid % 8.8 (sh) Granulocyte % 82.7 (sh) Patient B: reported 02/20/2024 at 9:07 am Lymphocyte Absolute- 0.7 (s) Mid Absolute- 0.4 (s) Granulocyte Absolute- 8.3 (sh) Lymphocyte % 7.8 (sl) Mid % 4.4 (s) Granulocyte % 87.8 (sh) Patient C: reported 08/06/2024 at 1:25 pm Lymphocyte Absolute- 1.5 (s) Mid Absolute- 0.6 (s) Granulocyte Absolute- 22.1 (sh) Lymphocyte % 6.1 (sl) Mid % 2.3 (s) Granulocyte % 91.6 (sh) 3. A review of the instrument daily logs revealed that the laboratory did not repeat Patients A, B, or C on 02/19/2024, 02/20/2024, or 08/06 /2024. 4. An interview with the laboratory technical consultant and testing person three on 09/18/2024 at 1:30 pm confirmed the laboratory failed to follow the</p>

established procedure for repeating CBC results with flags in 2024. Word Key: % - percent