

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0950316	<b>(X3) Date Survey Completed</b>  03/09/2020
<b>Name of Provider or Supplier</b>  Pediatrics East, Inc-Bartlett	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test results, the verification of performance specification studies, and interview with the laboratory liaison, the laboratory failed to review and approved the verification of performance specification studies for the CELL-DYN Emerald complete blood count (CBC) instrument prior to patient testing in 2019. The findings include: 1) Observation of the laboratory on March 9, 2020 at 8:15 a.m. revealed the CELL-DYN Emerald CBC instrument (serial #030817-007300) in use for patient testing. The instrument was new since the last survey date. 2) Review of the first patient reported from the instrument revealed that patient testing began on March 1, 2019. 3) Review of the verification of performance specifications studies revealed the studies were not reviewed by the technical consultant until March 28, 2019, after patient testing had begun. 4) Interview with the laboratory liaison on March 9, 2020 at 1:00 p.m. confirmed the laboratory failed to ensure the VoPS studies were reviewed and approved prior to patient testing in 2019.</p>