

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0315253	(X3) Date Survey Completed 08/17/2021
Name of Provider or Supplier Pediatrics East, Inc Germantown	Street Address, City, State 2002 Exeter Rd, Germantown, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to maintain satisfactory participation in two out of three proficiency testing (PT) events for the hematocrit analyte, resulting in the first unsuccessful PT occurrence for the hematocrit analyte. (Refer to D2130)</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p>

This STANDARD is not met as evidenced by:

Based on a desk review of the Centers for Medicare and Medicaid Services Casper Report 155 (CMS 155) and the laboratory's 2020 and 2021 proficiency testing (PT) records, the laboratory failed to maintain satisfactory performance for the hematocrit analyte in two out of three PT events, resulting in the first unsuccessful PT occurrence for the hematocrit analyte. The findings include: 1) Review of the CMS 155 revealed the following unsatisfactory PT scores for the hematocrit analyte: 2020 event three: 60% 2021 event two: 60% 2) Review of the laboratory's proficiency testing records revealed the following: 2020 event three: Sample numbers HD-12 and HD-13 scored as unacceptable, resulting in an overall score of 60% for the hematocrit analyte. 2021 event two: Sample numbers HD-7 and HD-10 scored as unacceptable, resulting in an overall score of 60% for the hematocrit analyte, and the first unsuccessful PT occurrence for the hematocrit analyte.