

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1103237	(X3) Date Survey Completed 01/12/2021
Name of Provider or Supplier Pediatric Consultants Of Lenoir City	Street Address, City, State 303 Medical Park Dr, Lenoir City, 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: ===== Hematology: The laboratory failed to maintain satisfactory participation in two consecutive events for red blood cell (RBC) and hematocrit (HCT) analytes, resulting in the first unsuccessful proficiency testing (PT) occurrence for RBC and HCT. (Refer to D2130) =====</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</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.

This STANDARD is not met as evidenced by:

===== Based on a desk review of the CMS CASPER Report 0155D and the laboratory's 2020 Proficiency Testing (PT) performance summary records from the American Proficiency Institute (API) Proficiency Testing program, the laboratory failed to maintain satisfactory performance for the Red Blood Cell (RBC) and Hematocrit (HCT) analytes in the 2nd and 3rd events of 2020, resulting in the first unsuccessful PT occurrence. The findings include: 1. A review of the CMS 0155D report revealed the score for the RBC analyte for the 2nd event of 2020 was 0% and for the 3rd event of 2020 was 60% and score for the HCT analyte for the 2nd event was 0% and for the 3rd event was 40%. 2. A review of the laboratory's 2020 API Proficiency Testing records revealed the 2nd event had unacceptable performance for RBC resulting in a 0% score and for HCT resulting in a 0% score. 3. A review of the laboratory's 2020 API Proficiency Testing records revealed the 3rd event had unacceptable performance for RBC resulting in a 60% score and for HCT resulting in a 40% score, resulting in the first unsuccessful PT occurrence. =====