

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0312617	(X3) Date Survey Completed 09/12/2018
Name of Provider or Supplier Pediatric Consultants North	Street Address, City, State 100 Tech Center Drive, Knoxville, 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 out of two events for the automated White Blood Cell (WBC) differential, resulting in the first unsuccessful proficiency testing (PT) occurrence for the automated WBC differential analyte (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 0155D report and the laboratory's 2018 Proficiency Testing (PT) records, the laboratory failed to maintain satisfactory performance for the automated WBC (White Blood Cell) Differential in the 1st and 2nd events of 2018, resulting in the first unsuccessful occurrence. The findings include: 1. Review of the CMS 0155D report revealed the 2018 automated WBC Diff event one score is 0% and event two score is 73%. 2. Review of the laboratory's 2018 PT records revealed event one sample numbers HEM-01, HEM-02, HEM-03, HEM-04 and HEM-05 had unacceptable grades for Granulocytes, Lymphocytes and Monocytes resulting in a score of 0% and event two sample numbers HEM-06, HEM-08, HEM-09 and HEM-10 had unacceptable grades for Monocytes/Mids resulting in a score of 20% for a total score of 73% for the WBC Differential, resulting in the first unsuccessful PT occurrence.

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