

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0963636	(X3) Date Survey Completed 01/03/2020
Name of Provider or Supplier Pediatric Specialists Of Marion County	Street Address, City, State 325 South Cedar Ave Ste 1, South Pittsburg, 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: Based on a proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 153 & 155 (CMS 153 & 155) and American Proficiency Testing (API) evaluation reports, the laboratory failed to maintain satisfactory performance in Red Blood Cell (RBC) for the 1st and 2nd events of 2019 resulting in the first unsuccessful performance occurrence. (Refer to D2123 and D2130).</p>
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p>

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on a proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 153 & 155 (CMS 153 & 155) and American Proficiency Testing (API) evaluation reports, the laboratory failed to participate in the specialty Hematology Complete Blood Count (CBC) for all analytes: Red Blood Cell (RBC), White Blood Cells (WBC), Hemoglobin (HGB), Hematocrit (HCT) Platelets (PLT) and automated WBC Differential for the 2nd event of 2019 resulting in a score of 0%. The findings include: 1. Review of the CMS 153 & 155 report revealed the RBC, WBC, HGB, HCT, PLT and automated WBC Differential with a score of 0% for the 2nd event of 2019. 2. Review of the API evaluation report revealed the RBC, WBC, HGB, HCT, PLT and automated WBC Differential with a score of 0% for the 2nd event of 2019.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

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 proficiency testing (PT) desk review of the Centers for Medicare and Medicaid Services CASPER report 153 & 155 (CMS 153 & 155) and American Proficiency Testing (API) evaluation reports, the laboratory failed to maintain satisfactory performance in Red Blood Cell count (RBC) for the 1st and 2nd events of 2019 resulting in a first unsuccessful performance occurrence. The findings include: 1. Review of the CMS 153 & 155 report revealed the RBC count with a score of 20% for the 1st event and a score of 0% for the 2nd event of 2019. 2. Review of the API evaluation report revealed the RBC count with a score of 20% for the 1st event and a score of 0% for the 2nd event of 2019.