

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1103237	(X3) Date Survey Completed 05/05/2021
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 out of three events for the analytes hemoglobin (HGB), white blood cells (WBC), platelets (PLT), mean corpuscular hemoglobin(MCH), and mean corpuscular volume (MCV), resulting in the first unsuccessful proficiency testing (PT) occurrence for HGB, WBC, & PLT. (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 and 2021 Proficiency Testing (PT) performance summary records from the American Proficiency Institute (API) Proficiency Testing program, the laboratory failed to maintain satisfactory performance for the analytes Hemoglobin (HGB), White Blood Cells (WBC), Platelets (PLT), mean corpuscular hemoglobin (MCH), and mean corpuscular volume (MCV) in the 2nd event of 2020 and 1st event of 2021, resulting in the first unsuccessful PT occurrence. The findings include: 1. A review of the CMS 0155D report revealed the scores for the analytes HGB, WBC's, PLT's, MCH, and MCV for the 2nd event of 2020 were 0% and for the 1st event of 2021 were 60%. 2. A review of the laboratory's 2020 API Proficiency Testing records revealed the 2nd event had unacceptable performance scores of 0% for HGB, WBC's, PLT's, MCH, and MCV. 3. A review of the laboratory's 2021 API Proficiency Testing records revealed the 1st event had unacceptable performance scores of 60% for HGB, WBC's, PLT's, MCH, and MCV resulting in the first unsuccessful PT occurrence.

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D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

===== The Laboratory Director failed to provide direction for successful Proficiency Testing (PT) Participation in Three of Three Events for Hematology in 2020 and 2021 resulting in the SECOND Unsuccessful PT occurrence (Reference D6004).

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D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

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Based on review of the CMS 0155D Report and the American Proficiency Institute (API) PT Program Evaluation Report of the Unsatisfactory Scores for Hematology for three of three events for 2020 and 2021, determined the Laboratory Director failed to provide effective direction over Proficiency Testing for Red Blood Cell (RBC) and Hematocrit (HCT) in 2020 and 2021, resulting in the SECOND UNSUCCESSFUL Proficiency Testing performance. The findings include: 1. A review of the CMS 0155D report for 2020 revealed event two as Unsatisfactory with scores of 0% for both RBC and HCT; event three as Unsatisfactory with a score of 60% for RBC and 40% for HCT and event one of 2021 as Unsatisfactory with scores of 60% for both RBC and HCT, resulting in the SECOND UNSUCCESSFUL occurrence for RBC and HCT. 2. A review of the API PT Evaluation Report for 2020 revealed event two as Unsatisfactory with scores of 0% for both RBC and HCT; event three as Unsatisfactory with a score of 60% for RBC and 40% for HCT and event one of 2021 as Unsatisfactory with scores of 60% for both RBC and HCT, resulting in the SECOND UNSUCCESSFUL occurrence for RBC and HCT which determined the Laboratory Director failed to provide effective direction over Proficiency Testing for RBC and HCT in 2020 and 2021 resulting in the SECOND UNSUCCESSFUL Proficiency Testing performance.
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