

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0316153	(X3) Date Survey Completed 09/21/2020
Name of Provider or Supplier Putnam County Pediatrics, Pllc	Street Address, City, State 758 South Willow Avenue, Cookeville, 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 proficiency testing (PT) performance in two out of three testing events for the Red Blood Cell (RBC) analyte resulting in the 1st unsuccessful PT occurrence for the RBC analyte in 2020. (Refer to D2130)</p>
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a</p>

	<p>score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Casper report 155 (CMS 155), American Proficiency Institute (API) evaluation reports and phone interview with the office manager, the laboratory failed to return the 2nd proficiency testing (PT) event 2020 for the Hematology specialty resulting in a score of 0% for the testing event. The findings include: 1. Review of the CMS 155 report revealed a score of 0% for the following analytes: cell I.D or White Blood Cells (WBC) differential, red blood cell (RBC), hematocrit (HCT), hemoglobin (HGB), WBC and Platelets (PLTs) analytes. 2. Review of API evaluation report revealed a score of 0% for the following analytes: cell I.D or WBC differential, RBC, HCT, HGB, WBC and PLTs analytes. 3. Phone interview on September 15, 2020 at 11:00 A.M. with the office manager revealed the laboratory did not return the PT 2nd event 2020 due to the analyzer has not been calibrated since January 24th 2020.</p>
<p>D2130</p>	<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> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Casper report 155 (CMS 155) and American Proficiency Institute (API) evaluation reports, the laboratory failed to achieve satisfactory performance for Red Blood Cell (RBC) analyte in two out of three testing event resulting in the 1st unsuccessful PT performance in 2020. The findings include: 1. 1) Review of the CMS 155 revealed the following scores for the RBC analyte: 2019 Event three = 20% 2020 Event two = 0% 2. Review of the laboratory's API evaluation report revealed a score of 20% for the 3rd event 2019, and a score of 0% for the 2nd event 2020.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: The Laboratory Director failed to ensure laboratory protocols were followed for Proficiency Test (PT) and Complete Blood Count (CBC) analyzer calibrations in 2020. (Refer to D6007)</p>
<p>D6007</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)</p> <p>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</p>

and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on review of failed PT for the 2nd event 2020 and lack of CBC calibration per phone interview with the office manager, it was determined the Laboratory Director failed to ensure that laboratory protocols were followed for PT and CBC analyzer calibration in 2020. The findings include: 1. Review of the failed Proficiency Test for the 2nd event 2020 revealed PT was not performed. 2. Per phone conversation with the office manager on September 15th, 2020 at 11:00 A.M stated instrument calibration was not performed at 6-month intervals; therefore, PT was not performed for the 2nd event 2020.