

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0316153	(X3) Date Survey Completed 11/08/2022
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
D0000	Based on a proficiency testing desk review survey performed on 11.08.2022 the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
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 desk review of the Center for Medicare and Medicaid Services CASPER Report 0155D (CMS 155), the laboratory's American Proficiency Institute (API) proficiency testing records, and staff interview, the laboratory failed to successfully</p>

	<p>participate in the specialty of Hematology for the analytes automated white blood cell differential (WBC Diff), Hematocrit (HCT), and Platelet (PLT) for three out of five testing events, resulting in non-initial unsuccessful PT participation (refer to D2130 and D2131).</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 a desk review survey of the CMS 155, the laboratory's 2020 and 2021 API PT records, and phone interview with the office manager, the laboratory failed to maintain satisfactory performance in three out of five PT events for the WBC Diff, HCT, and PLT analytes, resulting in non-initial unsuccessful PT participation. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory PT scores for the WBC Diff , HCT and PLT analytes: 2020 Event two: WBC Diff: 0% HCT: 0% PLT: 0% 2021 Event one: WBC Diff: 27% HCT: 40% PLT: 40% 2021 Event three: WBC Diff: 47% HCT: 20% PLT: 20% 2. Review of the laboratory's API PT performance evaluation records revealed the following unsatisfactory scores for WBC Diff, HCT and PLT analytes: 2020 Event two: WBC Diff: 0% HCT: 0% PLT: 0% 2021 Event one: WBC Diff: 27% HCT: 40% PLT: 40% 2021 Event three: WBC Diff: 47% HCT: 20% PLT: 20% 3. Phone interview with the office manager on November 8, 2022 at approximately 9:45 am confirmed the survey findings.</p>
<p>D2131</p>	<p>HEMATOLOGY CFR(s): 493.851(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review survey of the CMS 155 report, the laboratory's 2020 and 2021 American Proficiency Institute (API) proficiency testing (PT) records, and interview with the office manager, the laboratory failed to achieve satisfactory performance for the overall specialty of Hematology in three out of five PT events in 2020 (event 2) and 2021 (events 1 and 3). The findings include: 1. Review of CASPER CMS 155 report, the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for specialty of Hematology in three of five events: 2020 Event 2: 0% 2021 Event 1: 64% 2021 Event 3: 24% 2. Review of the American Proficiency Institute (API) performance evaluation records revealed the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for specialty of Hematology in three of five events: 2020 Event 2: 0% 2021 Event 1: 64% 2021 Event 3: 24% 3. Phone interview with the office manager on November 8, 2022 at approximately 9:45 am confirmed the survey findings.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</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.

This CONDITION is not met as evidenced by:
Based on review of the CMS 155 report, the laboratory's API PT records, and interview with the office manager, the laboratory director failed to provide overall management and direction to the lab for successful participation in proficiency testing (refer to D6016).

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on a desk review survey of the CMS 155 and the laboratory's 2020 and 2021 API PT evaluation records, staff interview, and laboratory communication, the laboratory director failed to ensure successful participation in an HHS approved proficiency program (refer to D2130 and D2131).