

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0316153	(X3) Date Survey Completed 04/02/2018
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of 2016 and 2017 Proficiency Testing (PT) attestation records and an interview with the primary testing person, it was determined the laboratory did not involve 3 of 5 testing personnel in rotating PT samples for complete blood counts during the 2 year period. Findings include: 1. A review of PT records from 2016 and 2017 disclosed the 2 lab persons did all testing of PT samples. 2. An interview with the primary testing person at 12:30pm on April 2, 2018 confirmed only 2 of 5 persons running PT samples for the 2 year period.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p>

This STANDARD is not met as evidenced by:
 Based on review of the proficiency testing attestation sheets and interview with the Laboratory Supervisor determined that the attestation sheets were not signed by the Medical Director or testing personnel in 2016 and 2017. The findings include: 1. Review of the proficiency testing attestation sheets revealed 5 out of 6 attestation sheets were not signed by the Medical Director or testing personnel in 2016 and 2017. 2. Interview with the Laboratory Supervisor on April 2, 2017 at 12:40 confirmed 5 out of 6 attestation sheets were not signed by the Medical Director or testing personnel in 2016 and 2017.

D2016

SUCCESSFUL PARTICIPATION
 CFR(s): 493.803(a)(b)(c)

(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.

This CONDITION is not met as evidenced by:
 Based on review of American Proficiency Institute (API) Performance Summary statement and interview with the Laboratory Supervisor determined the laboratory has Unsuccessful participation in Hematology Erythrocyte count during 2016 and 2017. The findings include: 1. Review of API Performance Summary statement revealed the laboratory failed to achieve successful participation for the 3rd event in 2016 score of 60% and 2nd event in 2017 score of 40% for Hematology Erythrocyte count. 2. Interview with the Laboratory Supervisor on April 2, 2018 at 12:45 confirmed that the lab failed to achieve e successful participation for the 3rd event in 2016 score of 60% and 2nd event in 2017 score of 40% for Hematology Erythrocyte count.

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 review of the Proficiency testing agency, American Proficiency Institute (API), performance summary document and interview with the Laboratory Supervisor

	<p>determined the laboratory failed to achieve satisfactory performance for the 3rd event in 2016, score of 60% and the 2nd event in 2017 score of 40%. The findings include: 1. Review of API Performance Summary revealed the laboratory failed to achieve satisfactory performance for the same analyte in the 3rd event in 2016 and the 2nd event in 2017. 2. Interview with the Laboratory Supervisor on April 2, 2018 at 12:55 confirmed the laboratory failed to achieve satisfactory performance for the same analyte in the 3rd event in 2016 and the 2nd event in 2017.</p>
<p>D3031</p>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control records and an interview with the Laboratory Supervisor determined the laboratory failed to retain daily quality control and analyzer background check printouts for 2016 and 2017. The findings include: 1. There were no quality control and analyzer background check printouts available for review from 2016 and 2017. 2. Interview with the Laboratory Supervisor on April 2, 2018 at 1:00 pm confirmed the laboratory failed to retain the quality control and analyzer background checks printouts for 2016 and 2017.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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 and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on review of the Proficiency testing agency, American Proficiency Institute (API), performance evaluation document and interview with the Laboratory Supervisor determined the Laboratory Director did not evaluate the laboratory's performance for all 3 events in 2016 and 2nd event in 2017. The findings include: 1. Review of API Performance Summary statement revealed the Laboratory Director failed to evaluate the laboratory's performance for all 3 events in 2016 and 2nd event in 2017. 2. Interview with the Laboratory Supervisor on April 2, 2018 at 12:50 confirmed the Laboratory Director did not review the performance evaluation document for all 3 events and 2nd event in 2017.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least</p>

annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of nine testing personnel competency evaluations and an interview with the technical consultant, the laboratory failed to document annual competency evaluations for 4 of 4 employees during 2016-17. Findings include: 1. A review of four testing persons' personnel files disclosed 4 of 4 employees did not have annual competency checks during 2016 and 2017. 2. An interview with the technical consultant at 11:30 AM on April 2, 2018, confirmed five of nine employees did not have annual competency checks during 2016 and 2017.