Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0316153	01/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Putnam County Pediatrics, Pllc	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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, and interview with the lead testing person, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency. The findings include: 1) Review of the laboratory procedure manual revealed the following six criteria were not included in the annual competency assessment procedure: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills in 2020. 2) Interview on January 16, 2020 at 12:30 p.m. with the lead testing person confirmed the testing personnel annual competency procedure did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS).
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that

	provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on procedure manual review, manufacturer's instructions for the Hematology CELL-DYN Emerald Operator's Manual on calibration and interview with the lead testing person the laboratory failed to have a written procedure manual for the Complete Blood Count (CBC) test and calibration records for the Cell-Dyn Emerald CBC analyzer in 2018 and 2019. (Refer to D5403 and D5439).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the lead testing person determined the laboratory failed to have a written procedure for the Complete Blood Count (CBC) test in 2020. The findings include: 1. Review of the laboratory's procedure manual failed to include specimen labeling, storage, processing, specimen acceptability, specimen rejection, corrective action for calibration or control results that fail, limitation in the test, panic or alert values, the laboratory's system for entering results in the patient record and reporting patient results for complete blood count (CBC) in 2020. 2. Interview with the lead testing person on January 16, 2020 at 12:30 p.m. confirmed the laboratory did not have a written procedure manual to include specimen labeling, storage, processing, specimen acceptability, specimen rejection, corrective action for calibration or control results that fail, limitation in the test, panic or alert values, the laboratory's system for entering results in the patient record and reporting patient results for the CBC test in 2020.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Manufacturer's Instructions for the Hematology CELL-DYN Emerald Operator's Manual on calibration and an interview with the lead tesing person, the laboratory failed to test calibration verifications every six months per Manufacturer's Instructions for the Hematology Complete Blood Cell (CBC) instrument for 2018-2019. Findings include: 1. A review of the Manufacturer's Instructions for the Hematology CELL-DYN Emerald Operator's Manual (Section 6-3 which states ..."Calibration verification criteria include: At least every six months.") confirmed the laboratory failed to analyze calibration verifications which were due in Feburary 2018, and Feburary 2019. 2. An interview with the lead testing person on January 16, 2020, at 12:40 p.m. confirmed the laboratory failed to perform calibration verifications every six months per Manufacturer's Instructions for the Hematology (CBC) instrument.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of employee personnel records for 2018 and 2019 and interview with the lead testing person, the laboratory's technical consultant failed to document the six required criteria for assessing personnel competency. The findings include: 1) Review of employee personnel records of 2018 and 2019 revealed 2019 missing annaul competency for the six required criteria of competency that include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test

	performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills. 2) An interview with the lead testing person on January 16, 2020 at 12:30 a.m. confirmed 5 of 5 testing personnel were not evaluated during 2019 using the six criteria for competency required by Centers for Medicare and Medicaid (CMS).