Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 44D1006815	**(X3) Date Survey Completed** 06/18/2019
Name of Provider or Supplier Tennessee Pediatric & Adolescent Center	**Street Address, City, State** 435 N Cedar Ave, 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**
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) temperature records for 2017-2019, and an interview with the office manager, the laboratory failed to retain one year of temperature logs for 2018. Findings include: 1. Review of QC records disclosed that temperature logs were not retained for 2018. 2. In an interview, on June 18, 2019, at 11:30am, the office manager confirmed the temperature logs were not retained for one year in 2018 as required.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and on interview with the office manager, determined the laboratory failed to establish procedures for Quality Assessment to include: Patient Confidentiality, Specimen Identification and integrity, Complaint Investigations, Personnel Competency and Proficiency Testing

	Performance for 2017-2019. The findings include: 1. A review of the Laboratory's procedure manual revealed no written policies to monitor, assess and correct problems identified in the laboratory. 2. Upon interview at approximatley 11:30 a.m. on June 18, 2019, with the office manager, confirmed there were no Quality Assessment monitors in place for 2017-2019.
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 Laboratory's Calibration Verification records for the Hematology analyzer, patient test records and upon interview with the office manager, determined the laboratory failed to ensure that calibration verification was performed at six month intervals since May 16, 2017 until May 7, 2018. The findings include: 1. A review of Calibration Verification records for the hematology analyzer revealed calibration verification documented in May 16, 2017, until May 7, 2018, thus not being performed at 6 months for patients. 2. Review of 1 of 5 patient test records revealed no Calibration Verification records for the hematology analyzer for patient #2 (service date 2/10/18). 3. An interview with the Office Manager at 12:00pm on June 18, 2019, confirmed the calibration verifications for the Hematology Analyzer documentation could not be located since May 16, 2017 until May 7, 2018.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on a review of 2017-2019 proficiency testing (PT) records and an interview with the office manager, the laboratory director failed to document signed reviews and corrective actions for the 2018 Hematology/Coagulation 1st Event for the White Blood Cell differential (WBC diff) in April 2018. Findings include: 1. There was no laboratory director signed reviews and corrective actions available for review for the 2018 Hematology/Coagulation 1st Event for the White Blood Cell differential (WBC diff) in April 2018. 2. In an interview, on June 18, 2018, at approximately 11:00 AM, the office manager confirmed no Laboratory Director signed reviews and corrective actions were available for review for the 2018 Hematology/Coagulation 1st Event for the White Blood Cell differential (WBC diff) in April 2018.
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 2017-2018 and interview with the office manager, 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 for 2017-2018 did not reveal documentation of 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 office manager on June 18, 2019 at 11:30am confirmed 4 of 4 testing personnel evaluated during 2017 and 2018 were not evaluated using the six criteria for competency required by Centers for Medicare and Medicaid (CMS).
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's employee competency evaluations and upon interview with the laboratory supervisor, determined the Technical Consultant failed to perform and document an initial competency evaluation for testing personnel (TP) #5 who began laboratory testing in January of 2019. The findings include: 1. A review of the laboratory's semi-annual competency evaluation results were not available for testing person # 5 (1 of 5 TP) who began patient testing for Complete Blood Counts (CBC's) in January of 2019. 2. An interview with the office manager at 12:00pm on

	June 18, 2019, confirmed that no semi-annual competency evaluation was documented for testing person #5 who performed CBC's since hire date in January of 2019.