

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1006815	(X3) Date Survey Completed 09/27/2021
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
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> <p>This STANDARD is not met as evidenced by: Based on review of the Proficiency Testing (PT) records and interview with the Office Manager, it was determined the laboratory failed to maintain copies of the instrument printouts, Attestation sheets and Performance summaries for 2020 PT, 1st, 2nd and 3rd events. The findings include: 1. There were no 2020 PT instrument printouts, Attestations sheets and Performance Summaries available for review. 2. An interview with the Office Manager on September 27th at 11:00am, confirmed the laboratory failed to maintain copies of PT instrument printouts, Attestation sheets and Performance Summaries for 2020 PT 1st, 2nd and 3rd events.</p>
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(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</p>

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 Quality Assurance Plan (QA) and interview with the Office Manager, the laboratory failed to perform monthly monitoring of the laboratory QA plan for 2020 and January through September 27, 2021. Findings include: 1. Review of the QA Plan revealed the laboratory failed to perform monthly evaluations in 2020 and January through September 27, 2021. 2. Interview with the Office Manager on September 27, 2021 at 11:00am. confirmed the laboratory failed to perform monthly evaluations of the laboratory for 2020 and January through September 27, 2021.