

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0995453	(X3) Date Survey Completed 10/12/2022
Name of Provider or Supplier Gi For Kids, Pllc	Street Address, City, State 1975 Town Center Blvd, Knoxville, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:</p> <p>===== Based on review of the laboratory proficiency testing (PT) records and interview with the lead testing person, the testing personnel and/or laboratory director failed to sign attestation statements for ten of twenty five PT events in 2021 and 2022. The findings include: 1. Review of the laboratory's PT records revealed the following: Attestation statements not signed by the laboratory director for nine of twenty five events: - No laboratory director signature on the following attestation statements: 2021 hematology event one, 2021 celiac serology event two, 2021 general chemistry and therapeutic drugs event one - No laboratory director signature (testing person signed in lab director space) on the following attestation statements: 2021 hematology event two, 2021 diagnostic allergy events one and three, 2021 diagnostic immunology event three, and 2021 general chemistry and therapeutic drugs events two and three. Attestation statement not signed by testing personnel for one of twenty five events (2022 diagnostic allergy event one). 2. Interview with the lead testing person on October 12, 2022 at approximately 2:30 pm confirmed testing personnel and/or laboratory director failed to sign attestation statements for ten of twenty five events in 2021 and 2022.</p> <p>=====</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,</p>

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.

This STANDARD is not met as evidenced by:

===== Based on review of laboratory records and interview with the lead testing person, the laboratory failed to retain the attestation statement for one of twenty five proficiency testing (PT) events in 2021 and 2022. The findings include: 1. Review of proficiency testing records revealed no retention of the attestation statement for 2021 hematology event three. 2. Interview with the lead testing person on October 12, 2022 at approximately 2:30 pm confirmed the survey findings. =====