

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1080883	(X3) Date Survey Completed 07/21/2022
Name of Provider or Supplier Primary Pediatrics Of Wr	Street Address, City, State 6082 Lakeview Road, Warner Robins, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on July 21, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 American Proficiency Institute (API) Proficiency Testing (PT) document and staff interview, the laboratory had no documentation of the results that were sent in for 2020, 2021, or 2022, for the Specialties of Chemistry, Hematology, and Microbiology. Findings: 1. Review of the API PT documents, the laboratory did not have any documentation of the results that were sent from the facility or instrument printouts for 2020, 2021, and 2022. For Speciaties - Chemistry, Hematology, and Mircobiology, there was no proof of documentation for the results that were sent to API for evaluation for the following years and events: 2020 - Chemistry, Event 2 and 3, there were no result sheets available Hematology Event 1, there were no result sheets or instrument printouts available Microbiology Event 1 and</p>

2, there were no result sheets available 2021- Hematology, Event 1,2,and 3, there were no result sheets or instrument printouts available 2022- Chemistry, Event 2, there were no results sheets available 3. Interview with the laboratory manager, on July 21, 2022 at approximately 1:30 pm, in the office, confirmed the aforementioned statements

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) document and staff interview, The Laboratory Director (LD) failed to ensure that the laboratory was performing the PT samples as they should and verify the documentation of the results that were sent in for 2020, 2021,and 2022, for the Specialties-Chemistry, Hematology, and Microbiology. Findings: 1. Review of the API PT documents, the laboratory did not have any documentation of the results that were sent from the facility or instrument printouts for 2020, 2021, and 2022. For Specialty- Chemistry, Hematology, and Microbiology, the lab did not have documentation of the results that were sent to API for evaluation for the following years and Events: 2020 - Chemistry, Event 2 and 3, there were no result sheets available Hematology Event 1, there were no result sheets or instrument printouts available Microbiology Event 1 and 2, there were no result sheets available 2021- Hematology, Event 1,2,and 3, there were no result sheets or instrument printouts available 2022- Chemistry, Event 2, there were no results sheets available 3. Interview with the laboratory manager, on July 21, 2022 at approximately 1:30 pm, in the office, confirmed the aforementioned statements