Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2153842	11/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Gastroenterology Virginia	12041 Bournefield Way Suite A, Silver Spring, MD	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on review of the Maryland State licensing database and interview with the general supervisor (GS), the laboratory failed to apply for a Maryland State Permit for medical laboratory testing as required in the Code of Maryland Regulations COMAR10.10.01-08 Laboratories. Findings: 1. Review of the Maryland state licensing database showed that the laboratory failed to submit a Maryland State license application when the laboratory moved from another state. 2. The GS confirmed that the laboratory had moved to Maryland in August of 2021 and was not aware of the licensing requirement. 3. During the survey on 11/10/2022 at 2:20 PM, the GS confirmed that the laboratory had not submitted an application to be licensed to perform laboratory testing in the state of Maryland. The laboratory failed to be in compliance with the applicable Maryland State laboratory requirements.
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 standard operating procedure manual (SOPM) and interview with the general supervisor (GS), the laboratory's written policies and procedures failed to include additional acceptance criteria and identification of color coded cassettes for all of the doctors that they prepare slides for at the laboratory. Findings: 1. The "Specimen Acceptance/Rejection Criteria" procedure states, "All specimens are received in 100% neutral buffered formalin (NBF) specimen containers and specimen biohazard bags provided by FPL [Fairfax Pathology Laboratory], LLC." While reviewing the acceptability criteria, the GS stated that they also receive specimens in a "zinc based fixative" that was not provided by FPL, LLC. The GS confirmed that these specimens are not rejected and the SOPM should be updated to reflect the current acceptance criteria. 2. The "Accessioning and Grossing of Specimens" procedure states, "7. Once dictated and placed in the designated cassette, each case is loaded in the processing basket and placed in the tissue processor for the appropriate run." The GS explained that the "designated cassette" is a specific color for each of the doctors that they prepare slides for. The GS confirmed that the SOPM did not specifically link each doctor with their "designated cassette" color. 3. During the survey on 11/10/22 at 2:20 PM, the GS confirmed that the written policies and procedures failed to include additional acceptance criteria and identification of color coded cassettes for all of the doctors that they prepare slides for at the laboratory.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patients final reports and interview with the general supervisor (GS), the laboratory failed to ensure that the final test reports listed the correct address of the laboratory from August 2021 through August 2022, the location of where the testing (slide interpretation) was performed and the correct name of the laboratory director (LD) of the laboratory. Findings: 1. The laboratory moved to its new location in August of 2021. Final patient reports reviewed from January 2022 and July 2022 still had the old address listed on the final report. 2. When interviewed, the GS stated

	that the two pathologists listed as testing personnel do not perform the interpretation of the slides at the laboratory. The slides are couriered to the pathologists at multiple locations for review and the interpretation is entered into a secure laboratory information system. The GS stated that the address of where the interpretation is performed is not included in the final report. 3. The new LD started working at the laboratory in August 2022. The previous LD was at the laboratory from April 2021 through July 2022. A final report with the completion date of 02/02/2022 was reviewed. The LD listed at the top of the report was the LD that had been working for the laboratory prior to April 2021. The GS confirmed that the final report from 02/02 /2022 listed the wrong LD for that time period and the wrong address of the laboratory. 4. During the survey on 11/10/2022 at 2:20 PM, the GS confirmed that the final test reports failed to list the correct address of the laboratory from August 2021 through August 2022, the location of where the slide interpretation was performed and the correct name of the LD of the laboratory from August 2021 through August 2022.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the standard operating procedure manuals (SOPM) and interview with the general supervisor (GS), the laboratory director failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: 1. The SOPM that were reviewed only included the job descriptions for "Histology, Grossing Technician and Data Entry Duties" and "Histotechnician Histology Management Data Entry FPL [Fairfax Pathology Laboratory]." There were no other duties and responsibilities described. 2. During the exit interview on 11/10 /2022 at 2:20 PM, the GS confirmed that the laboratory's approved procedure manual did not specify in writing the duties and responsibilities of the laboratory director, clinical consultant, technical supervisor, general supervisor, and testing personnel (staff that perform the technical interpretation of the prepared slides).