Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0967013	02/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of Johns Creek Pc	4310 Johns Creek Parkway, Suite 150, Suwanee, 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 February 10, 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:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on standard procedure manual(SOP)review and staff interview, the laboratory failed to ensure a policy for maintenance of the eyewash station. The Findings include: 1. SOP review reveal that the laboratory failed to have a policy in place for maintenace of the eyewash station. 2. During an interview with Testing Personnel #1 (CMS 209) on February 10, 2022 at approximately 1:30 PM, confirmed that the laboratory did not have a policy for maintenance of the eyewash station.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by:

	Based on surveyor review of the standard procedure manual(SOP) document records (Pre-analytic and post analytic) and interview with the Testing Personnel(TP), the laboratory failed to establish a written quality assessment (QA) to monitor, assess, and correct problems in the general laboratory system for quality assessment. 1. The laboratory failed to have QA to assess patient confidentially, specimen integrity and identification, complaint, corrective actions, proficiency test performance, and personnel competency. 2. During an interview on February 10, 2022 with TP #1(CMS 209) at 1:00 PM in the conference room, confirmed that the laboratory did not have a written and established QA policy for the laboratory.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and staff interview, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. The SOP did not include a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, or instructions when sending specimens to reference laboratory (Quest). 2. During an interview on February 10, 2022 at 2:00 PM with the Testing Personnel# 1(CMS 209), confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to a reference laboratory.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing, the duties and responsibilities of each person engaged in the performance of the pre-analytic, analytic, and post-analytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify, in writing, the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. During an interview with the Testing Personnel #1 (CMS 209) on February 10, 2022, at

	approximately 1:00 PM, in the conference room, confirmed the SOP did not contain the duties and responsibilities for all personnel engaged in the performance of clinical laboratory testing.