Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0897163	04/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Covington Pediatrics, Llc	5211 Highway 278, Ne, Covington, 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 April 25, 2023. 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 review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to ensure a policy for the eyewash station. Findings include: 1. SOP review revealed the laboratory failed to establish an eyewash procedure for safety of testing personnel. 2. During an interview with Testing Personnel #1(CMS-209) on April 25, 2023 in the breakroom, confirmed that there was not an eyewash procedure present, during the survey.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual and interview with

	Testing Personnel, the laboratory failed to have a policy and procedure in place for complaint investigations. The Finding include: 1. SOP document review revealed that the laboratory did not have a policy and procedure for complaint investigations, during the time of the survey. 2. During an interview with Testing Personnel#1(CMS-209) on April 25, 2023 at approximately 11:20 AM, in the breakroom, confirmed that the laboratory did not have a SOP in place for complaint investigations.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel records and interview with Testing Personnel (TP) revealed that the laboratory failed to establish a written policy to assess the six required criteria for employee competency for hematology and microbiology testing. The findings include: 1. The laboratory failed to have a written policy and procedure for competency that included the six criteria for testing personnel for 2021, 2022, and thus far 2022 (January-April). 2. During an interview with Testing Personnel #1(CMS-209) on April 25, 2023, at approximately 11:15 AM in the breakroom, confirmed the laboratory did not have a policy to assess the required six competency criteria for testing personnel in the laboratory.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the American Academy of Family Physicians (AAFP) Proficiency Testing (PT) documents for 2021 for Hematology, and staff interview, the laboratory failed to provide evaluation documentation. The Findings include: 1. A review of the AAFP-PT hematology overall score (90%) for the specific analyte red blood cell (80%), hemoglobin (80%), and hematocrit (80%) evaluation report for event C, the laboratory failed to provide corrective action. 2. During an interview with the Testing Personnel #1 (CMS-209) on April 25, 2023 at 11:15 AM in the breakroom, confirmed the findings above.
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 general laboratory standard operating procedure manual (SOP) and staff interview, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. A review of the SOP confirmed that a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance) was not available for staff to follow when sending specimens to a reference laboratories: Quest and LabCorp. 2. During an interview with Testing Personnel #1(CMS-209) on April 25, 2023, at 11:30 AM, in the breakroom, confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to reference laboratories.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the standard operating procedures (SOP) documents and the staff interview, the laboratory director failed to review, approve, sign, and date the procedure manual prior to use. The Findings include: 1. SOP review revealed that the laboratory director failed to review, approve, sign, and date the procedure manual.prior to use. 2. During an interview with Testing Personnel #1(CMS-209) on April 25, 2023 in the breakroom, confirmed the laboratory director failed to review, approve, sign , and date the procedure manual.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on Standard operating procedure (SOP) review and staff interview, the laboratory failed to develop a corrective action prodecure for the laboratory. The Findings include: 1. SOP review revealed the laboratory failed to develop and implement a corrective action procedure for the laboratory. 2. During an interiew with Testing Personnel#1(CMS-209) on April 25, 2022 at approximately 11: 35 AM, in the breakroom, confirmed the lack of a corrective action procedure for the laboratory.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on American Academy of Family Physicians (AAFP) Proficiency Testing (PT) and staff interview, the laboratory director(LD) failed to review and document corrective action for proficiency testing. The findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the Laboratory Director (LD) failed to review and document PT corrective action for hematology (red blood count, hematocrit, and hematocrit) Event C in 2021. 2. During an interview with Testing Personnel #1 (CMS-209) on April 25, 2023 in the breakroom confirmed the findings above.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results. 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 preanalytic, analytic, and postanalytic 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 Testing Personnel#1 (CMS-209), in the breakroom, on April 25, 2023, at 11:20 AM, confirmed the laboratory SOP did not contain duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing.