Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0897163	05/15/2025
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 May 15, 2025. 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:
D3003	FACILITIES CFR(s): 493.1101(a)(2) (a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: A tour of the laboratory with Testing Personnel #1 (TP1), as dentified on the CMS Form 209-Laboratory Personnel Report, confirmed that the facility failed to provide adequate facilities to minimize potential contamination. THE FINDINGS INCLUDE: 1.A tour of the clinical laboratory confirmed that one sink was serving as the clean (non-contaminated) sink and the dirty (contamiinated) sink for disposal of completed testing specimens. 2. Interview with TP1 during the tour confirmed that the singular sink was in use for the disposal of test specimens as well as used for handwashing and the eyewash station. 3. An exit interview conducted with TP1 on May 15, 2025 at 11:30am in the conference room confirmed that the facility failed to provide adequate facilities to minimize potential contamination.
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: A review of the 2025 Personnel Competency Records confirmed that the laboratory failed to perform personnel competencies as required. THE FINDINGS INCLUDE: 1. A review of the 2025 Personnel Competency Records confirmed that testing personnel (TP) performed competencies on each other. 2. A review of the Testing Personnel Qualifications revealed that the Testing Personnel did not meet the qualifications required to perform competencies. 3. A review of the Procedure Manual confirmed that no written delegation for the perfomance of competencies was available during the time of inspection. 4. An exit interview, conducted with TP1, on May 15, 2025, at 11:30am, in the conference room confirmed the findings above.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A review of the current Procedure Manual confirmed that the Procedure Manual failed to meet regulatory requirements. THE FINDINGS INCLUDE: 1. A review of the current Procedure Manual confirmed that the Safety Standard Operating Procedure (SOP), failed to include procedures for Specimen Storage and Retention, Sample and Document Retention or General Maintenance procedures. 2. A review of the current Procedure Manual confirmed that written documentation of qualifications and duties for all laboratory personnel positions was not available at the time of inspection. 3. A review of the Hematology CBC Procedure confirmed that expected normal values, critical values, the evaluation, acceptance, and releasing of results were not included in the procedure. 4. An exit interview, conducted with TP1, on May 15, 2025, at 11: 30am, in the conference room confirmed that the Procedure Manual failed to meet regulatory requirements.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: A review of 2025 Personnel Competency Records, current Procedure Manual, and the general tour of the laboratory confirmed that the Laboratory Director (LD) failed to provide the required oversight of all aspects of laboratory operations. THE FINDINGS INCLUDE: 1. A review of the 2025 Personnel Competency Records revealed that the LD did not perform personnel competencies as required. 2. A review of the current Procedure Manual confirmed that the Hematology SOP did not contain reportable ranges for the CBC analyzer, the expected normal values established for the CBC testing, critical values established for the CBC testing and corrective actions taken, and the evaluation and acceptance of results. 3. A tour of the laboratory revealed that a designated sink for the disposal of specimens, reagents, etc. was absent from the clinical laboratory. 4. An exit interview conducted with TP1, on May 15, 2025, at 11:30am, in the conference room confirmed that the LD failed to provide the required oversight of all laboratory operations.