

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0897163	(X3) Date Survey Completed 04/20/2021
Name of Provider or Supplier Covington Pediatrics, Llc	Street Address, City, State 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 20, 2021. 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:
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of policy and procedure manual and interviews with the laboratory director and Testing Personnel (TP#1 CMS 209), the laboratory failed to include a policy for dealing with panic or alert values for the Horiba Micros 60 Hematology</p>

	<p>analyzer. Findings include: 1. Policy and procedure manual review revealed no panic or alert values in the laboratory manual or the laboratory from January 2019 to April 2021 for Hematology testing. 2. An interview with the laboratory director and TP #1 (CMS 209) in the breakroom on 04/20/2021 at approximately 12:30 pm, confirmed there was no policy in the procedure manual or in the laboratory for panic or alert values from January 2019 to April 2021.</p>
<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual (SOP) and interviews with the laboratory director and TP #1 (CMS 209), the laboratory director (LD) failed to sign, date and approve the procedure manual for Hematology testing on the Horiba Micros 60 Hematology Analyzer from January 2019 to April 2021. Findings include: 1. SOP document review revealed the LD failed to approve, sign, and date the current test procedures on the Horiba Micros 60 Hematology analyzer from January 2019 to April 2021. 2. The laboratory director (LD) also failed to to approve, sign, and date the validation and installation studies for the Horiba Micros 60 Hematology analyzer prior to use in January 2019. 3. An interview with the laboratory director and TP #1 (CMS 209) in the breakroom room on 04/20/2021 at approximately 12:43 pm confirmed the LD had not approved, signed, and dated the current SOP for Hematology testing since January 2019 to April 2021.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interviews with both Laboratory director and TP#1 (CMS 209), the laboratory failed to provide laboratory maintenance records from February 2019 to April 2021. Findings include: 1.) Document review revealed no laboratory maintenance record logs for the followings: Room Temperature, Humidity, or Refrigerator from February 2019 to April 2021. 2.) No daily, weekly, or monthly maintenance logs for the Horiba Micros 60 Hematology analyzer from February 2019 to April 2021. 3.) An interview with the Laboratory director and TP#1 (CMS 209) at approximately 12:55 pm on 04/20/2021 in the break room confirmed the absence of the aforementioned documents from February 2019 to April 2021 at the time of Survey.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on Quality Assurance (QA) manual review and interviews with the laboratory director and TP #1 (CMS 209), the lab director who is also the Technical Consultant (TC) is not reviewing all QA documents on a regular basis as required by Clinical Laboratory Improvement Amendments (CLIA) in 2019, 2020 and 2021. Findings include: 1.) Quality Assurance (QA) documents review revealed the laboratory director, who is also the Technical Consultant(TC), did not review or sign maintenance records in 2019, 2020 and 2021. 2.) An interview with the laboratory director and TP#1 (CMS 209) in the break room on 04/20/2021 at approximately 12:50 pm confirmed the lab director did not review QA documents as required in 2019, 2020 and 2021.