

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0999066	(X3) Date Survey Completed 07/13/2023
Name of Provider or Supplier Pontchartrain Pediatrics	Street Address, City, State 4405 Highway 190 E Service Road, Covington, LA	
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 Recertification survey was performed July 13, 2023 at Pontchartrain Pediatrics, CLIA ID # 19D0999066. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and quality assessment records as well as interview with laboratory personnel, the laboratory failed to follow their quality assessment policy. Findings: 1. Review of the laboratory's policy "Quality Assessment Program" revealed "On at least a yearly basis, the Laboratory staff will review all instrument, quality control, and proficiency testing, patient CBC result and laboratory specimen collection corrective action logs. Data will be compiled and a report will be produced to be shared with all physician and laboratory testing staff." 2. Review of quality assessment records revealed the laboratory did not have documentation of a yearly review performed for 2022. 3. In interview on July 13, 2023 at 12:20 p.m., Testing Personnel 1 confirmed the laboratory did not have documentation of the yearly review for 2022.</p>
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,</p>

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 laboratory's policy and procedure manual and interview with testing personnel, the laboratory failed to establish complete policies and procedures for hematology testing. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not define panic or alert values for hematology testing and the actions to take if a panic value occurs. 2. In interview on July 13, 2023 at 11:38 a.m., Testing Personnel 1 confirmed the laboratory policies did not include panic values and the action to take if a panic value occurs for hematology testing.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation, review of the laboratory's temperature records and policy and procedure manual, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for supplies stored in the laboratory. Findings: 1. Observation by surveyors during the laboratory tour on July 13, 2023 at 10:19 a.m. revealed the laboratory stored the following supplies in the laboratory: a) BD Microtainer Tubes K2EDTA Ref 365974 - Manufacturer's storage requirement: Lower limit not defined, upper limit 25 degrees Celsius b) Greiner Vacuette Tube K2EDTA Ref 454209 - Manufacturer's storage requirement: 4 - 25 degrees Celsius 2. Review of the laboratory's temperature records and policy titled "Monitoring Ambient Temperature and Humidity" revealed the laboratory defined the acceptable room temperature range as 65-86 degrees Fahrenheit. Conversion of Fahrenheit to Celsius by surveyors revealed 65-86 degrees Fahrenheit equaled 18 - 30 degrees Celsius which exceeded the temperature limits required by the manufacturers. 3. In interview on July 13, 2023 at 11:50 a.m., Testing

	<p>Personnel 1 confirmed the acceptable room temperature limits as defined by the laboratory exceeded the required ranges of the manufacturers.</p>
<p>D6014</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</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 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.</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 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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5291.</p>
<p>D6031</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</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 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on records review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.</p>