Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1086156	06/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center The	919 South 10th Street, Leesville, 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 on June 17, 2021 at The Pediatric Center, CLIA ID # 19D1086156. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturer's instructions and test menu, as well as interview with personnel, the laboratory failed to include "Fact Sheets" to providers or patients for Emergency Use Authorization (EUA) SARS COV-2 testing. Findings: 1. Observation during laboratory tour on June 17, 2021 at 1:29 pm revealed the laboratory performs SARS COV-2 testing utilizing the Abbott BinaxNow test kit.. 2. Review of the manufacturer's instructions for use under "Conditions of Authorization of the Laboratory" section revealed "Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 3. In interview on June 17, 2021 at 1:40 pm, Testing Personnel confirmed the laboratory was not aware of and does not provide the "fact sheets" for the COVID test to patients.
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 by surveyor, review of manufacturer's temperature requirements, and interview with personnel, the laboratory failed to monitor the room temperature where supplies are stored per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on June 17, 2021 at 1:04 pm revealed the laboratory did not monitor the room temperature of the office area where the following extra test kits were stored: a) Consult Diagnostics Strep A test kit b) Abbott BinaxNow RSV Card c) Abbott BinaxNow Covid-19 test kit d) Immunocard State Flu A&B test kit e) OSOM Mono test kit 2. Review of the manufacturer's storage requirements for the above supplies revealed the following: 2 - 30 degrees celsius. 3. In interview on June 17, 2021 at 2:08 pm, Testing Personnel confirmed the laboratory did not monitor the room temperature of the office area where extra test kits were stored.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. 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 were performing test methods as required. Refer to D5413.