Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0989849	05/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Assoc	2600 Tower Drive, Monroe, 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 May 31, 2022 at PediatricAssoc, CLIA ID # 19D0989849. 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 the manufacturer's instructions, test menu and interview with personnel, the laboratory failed to include "Fact Sheets" to patients for Emergency Use Authorization (EUA) SARS COV-2 testing. Findings: 1. Observation by surveyor during laboratory tour on May 31, 2022 at 10:00 am revealed the laboratory utilizes the Celltrion DiaTrust Covid-19 Ag Rapid Test for SARS CoV-2 patient testing. 2. Review of the manufacturer's instructions for use under the "Conditions of Authorization for the Laboratory" section revealed "Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under extingent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 3. In interview on May 31, 2022 at 11:16 am, the Technical Consultant stated she was unaware the facility had added waived Covid Ag testing. The Technical Consultant further stated the office manager confirmed the facility does not provide "Fact Sheets" to patients upon testing.
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each

	laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation by surveyor, review of the laboratory's COVID reports and interview with personnel, the laboratory failed to report COVID-19 patient test results to the state as required. Findings: 1. Observation by surveyor during laboratory tour on May 31, 2022 at 10:30 am, the laboratory utilizes the Celltrion Diatrust Covid 19 Antigen Rapid test for SARS COV-2 testing. 2. In interview on May 31, 2021 at 11: 16 am, the Technical Consultant stated that per her discussion with the office manager the laboratory does not report any COVID-19 results to the state. 3. In further interview on May 31, 2022 at 11:16 am, the Technical Consultant further stated the laboratory began testing COVID samples in-house but did not inform the Technical Consultant that Covid testing was being performed. 4. Review of the laboratory's patient logs for May 2022 revealed the laboratory did not report positive or negative results for the Celltrion Diatrust Covid 19 Antigen patient testing. 5. In interview on May 31, 2022 at 11:16 am, the Technical Consultant confirmed the laboratory did not report Covid patient test reports to the state office.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include a policy stating written, detailed instructions for the reporting of SARS CoV-2 test results to the state public health agency, to include but not limited to who is responsible for reporting test results and the frequency at which reporting is performed. 2. In interview on May 31, 2022 at 11:16 am, the Technical Consultant stated she was unaware the laboratory was performing SARS CoV 2 patient testing. The Technical Consultant confirmed the laboratory did not include the above identified policy.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the

	Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory failed to report COVID-19 patient test results to the state as required. Refer to D1002. .
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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; This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401.