

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0999066	(X3) Date Survey Completed 01/25/2022
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 on January 25, 2022 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.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish written procedures for reporting SARS COV-2 results to the state. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have written procedures for reporting SARS COV-2 results, to include, but not limited to who is responsible, and frequency of reporting to the state. 2. In interview on January 25, 2022 at 10:19 am, the Office Manager confirmed the laboratory did not have a written procedure for the reporting of positive and negative SARS COV-2 results to the state.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5)</p>

Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

I. Based on review of patient final test reports, test menu, and interview with personnel, the laboratory failed to include a second patient identifier on SARS COV-2 final reports. Findings: 1. Review of SARS COV-2 final test reports revealed the laboratory did not include a second patient identifier. The patient reports included the patient's name. 2. In interview on January 25, 2022 at 10:10 am, the Office Manager confirmed the patient final reports for SARS COV-2 did not include a second patient identifier. 3. Review of the laboratory's test menu revealed the laboratory performs 7,729 SARS COV-2 tests annually. II. Based on review of patient final test reports, test menu, manufacturer's instructions, and interview with personnel, the laboratory failed to include an Emergency Use Authorization (EUA) disclaimer on patient final reports as required. Findings: 1. Review of the laboratory's test menu revealed the laboratory utilizes the following SARS COV-2 test kits/systems: a) Abbott ID Now (5749 tests performed annually) b) BD Veritor COVID/FLU A+B (628 tests performed annually) c) BD Veritor COVID (1352 tests performed annually) 2. Review of the manufacturer's instructions revealed the following: "This product has not been FDA cleared or approved; but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories." 3. Review of random selection of the following two (2) patient final test reports for SARS COV-2 revealed the laboratory did not include the indicated disclaimer as required: Patient 1273 Patient 1272 4. In interview on January 25, 2022 at 10:10 am, the Office Manager confirmed the laboratory's patient final reports for SARS COV-2 did not include the indicated EUA statement. 5. Review of the of the laboratory's test menu revealed the laboratory 7,729 SARS COV-2 tests annually. III. Based on review of patient final test reports, test menu, and interview with personnel, the laboratory failed to include the specific test system/kit utilized for SARS COV-2 testing on patient final reports. Findings: 1. Review of the laboratory's test menu revealed the laboratory utilizes the following SARS COV-2 test kits/systems: a) Abbott ID Now (5749 tests performed annually) b) BD Veritor COVID/FLU A+B (628 tests performed annually) c) BD Veritor COVID (1352 tests performed annually) 2. Review of random selection of the following two (2) patient final test reports for SARS COV-2 revealed the laboratory did not include the specific test kit utilized: Patient 1273 Patient 1272 3. In interview on January 25, 2022 at 10:10 am, the Office Manager stated the patient's visit notes includes the test system utilized. The Office Manager confirmed the patient final report did not include the test system/kit utilized for SARS COV-2 testing.

D5809

TEST REPORT
CFR(s): 493.1291(e)

The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

This STANDARD is not met as evidenced by:
 Based on observation by surveyor, review of the United States Food and Drug Administration (FDA) Emergency Use Authorization (EUA) instructions, test menu, and interview with personnel, the laboratory failed to include "Fact Sheets" to patients for EUA SARS COV-2 tests. Findings: 1. Observation by surveyor during laboratory tour on January 25, 2022 at 10:35 am and review of the laboratory's test menu revealed the laboratory utilizes the following test kits/systems for SARS COV-2: a) Abbott ID Now (5749 tests performed annually) b) BD Veritor COVID/FLU A+B (628 tests performed annually) c) BD Veritor COVID (1352 tests performed annually) 2. Review of the FDA EUA letter for the identified tests revealed the following statement: "the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients: Fact Sheet for Healthcare Providers Fact Sheet for Patients 3. In interview on January 25, 2022 at 9:53 am, the Office Manager confirmed Fact Sheets are not provided to patients as required.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(8)

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)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:
 Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Findings: 1. The laboratory failed to include a second patient identifier on SARS COV-2 final reports. Refer to D5805 I. 2. The laboratory failed to include an Emergency Use Authorization (EUA) disclaimer on patient final reports as required. Refer to D5805 II. 3. The laboratory failed to include the specific test system /kit utilized for SARS COV-2 testing on patient final reports. Refer to D5805 III. 4. The laboratory failed to include "Fact Sheets" to patients for EUA SARS COV-2 tests. Refer to D5809.

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 record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.