

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1002868	(X3) Date Survey Completed 10/14/2021
Name of Provider or Supplier Preferred Pediatrics Llc	Street Address, City, State 142 Rue Marguerite, Thibodaux, 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 October 14, 2021 at Preferred Pediatrics, LLC, CLIA ID # 19D1002868. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of 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. In interview on October 14, 2021 at 10:00 am, Testing Personnel 1 stated the laboratory utilized the CareStart COVID 19 Antigen test January 2021 through August 17, 2021. Testing Personnel 1 further stated the laboratory discontinued use of the CareStart tests and began use of the Quidel Quickvue SARS COV-2 test August 17, 2021. 2. Review of the manufacturers' instructions 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 October 14, 2021 at 10:09 am Testing Personnel 1 stated the laboratory does not provide "fact sheets" for the COVID tests to patients. 4. Review of the laboratory's test menu revealed the laboratory performs 1,289 SARS COV-2 tests annually. II. Based on observation by surveyor, review of manufacturer's instructions, patient final test reports, test menu, and interview with personnel, the laboratory failed to include the Food and Drug Administration (FDA) Emergency Use Authorization statement on SARS COV-2 patient final reports. Findings: 1. In interview on October 14, 2021 at 10:00 am,</p>

Testing Personnel 1 stated the laboratory utilized the CareStart COVID 19 Antigen test January 2021 through August 17, 2021. Testing Personnel 1 further stated the laboratory discontinued use of the CareStart tests and began use of the Quidel Quickvue SARS COV-2 test August 17, 2021. 2. Review of the manufacturers' instructions revealed "This product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories." 3. Review of the following random selection of patient final reports for SARS COV-2 revealed the laboratory did not include the identified Emergency Use Authorization statement on patient final reports: CareStart: Patient 1 tested March 8, 2021 Quickvue: Patient 2 tested October 14, 2021 4. In interview on October 14, 2021 at 10:09 am, Testing Personnel 1 confirmed the laboratory's patient final reports for SARS COV-2 did not include the identified statement. 5. Review of the laboratory's test menu revealed the laboratory performs 1, 289 SARS COV-2 tests annually.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies, personnel records, and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Technical Consultant were followed. Findings: 1. Review of the laboratory's "Personnel Job Descriptions, Evaluations, & Competency" policy under the "Personnel Policies" section revealed "All laboratory personnel will be given a specific job description/evaluation upon employment that will be reviewed, signed and dated by the personnel fulfilling that position. Annual recheck of competency is performed at each evaluation time." 2. Review of personnel records for the Technical Consultant revealed a competency assessment for her duties was not performed in 2020. 3. In interview on October 14, 2021 at 11:03 am, Testing Personnel 1 stated the laboratory decided not to perform annual competency assessments for the Technical Consultant. Testing Personnel 1 confirmed the laboratory's policy was not updated to include the frequency of the competency assessment for the Technical Consultant. Testing Personnel 1 confirmed the current Laboratory Director did not perform a competency assessment in 2020. 4. In interview via email on October 18, 2021 at 8:23 am, Testing Personnel 1 stated the laboratory changed Laboratory Director's in 2020.

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 establish complete policies for reporting SARS

COV-2 results. Findings: 1. In interview on October 14, 2021 at 10:00 am, Testing Personnel 1 stated the laboratory utilized the CareStart COVID 19 Antigen test January 2021 through August 17, 2021. Testing Personnel 1 further stated the laboratory discontinued use of the CareStart tests and began use of the Quidel Quickvue SARS COV-2 test August 17, 2021. 2. Review of the laboratory's policies 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. 3. In interview on October 14, 2021 at 10:01 am, Testing Personnel 1 confirmed the laboratory did not have a written policy for reporting of positive and negative SARS COV-2 results to the state.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.

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 personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.