

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2072580	(X3) Date Survey Completed 03/22/2022
Name of Provider or Supplier The Pediatric Center Of Southwest Louisiana	Street Address, City, State 340 North Highway 171, Suite B, Lake Charles, 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 March 22, 2022 at The Pediatric Center of Southwest Louisiana, CLIA ID # 19D2072580. 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: Based on observation by surveyor, review of patient final test reports, manufacturer's instructions, test menu, and interview with personnel, the laboratory failed to include complete "Fact Sheets" to patients for Emergency Use Authorization (EUA) SARS COV-2 testing. Findings: 1. Observation by surveyor during the laboratory tour on March 22, 2022 at 1:00 pm revealed the laboratory utilizes the following kits for SARS COV-2 testing: a) Lumira Dx SARS COV-2 antigen b) Quidel Quickvue SARS COV-2 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. Review of the laboratory's patient final test reports for SARS COV-2 revealed the reports are labeled "Fact Sheets For Patients; however, the information provided to patients was not complete. The fact sheet information provided to patients did not match the information provided in the manufacturer's fact sheets. 4. In interview on March 22, 2022 at 2:51 pm, Testing Personnel 1 confirmed the SARS COV-2 fact</p>

sheets the laboratory provided to patients did not match the manufacturers'. 5. Review of the laboratory's test menu revealed the laboratory performs seven (7) Lumira Dx SARS COV-2 antigen tests and 184 Quidel Quickvue SARS COV-2 antigen tests.

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:

I. Based on review of the laboratory's policies, CMS 209 form, personnel records, and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency of the Technical Consultant. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed one (1) Technical Consultant. 2. Review of the laboratory's "Employee Competency" policy revealed the laboratory did not include performance of competency for the Technical Consultant, to include, but not limited to the frequency. 3. Review of personnel records for the Technical Consultant revealed a competency assessment for her duties as Technical Consultant performed in 2017 by the previous Laboratory Director, not the current. Laboratory Director. 4. In interview on March 22, 2022 at 3:09 pm the Technical Consultant confirmed the laboratory's competency policy did not include competency for the Technical Consultant. The Technical Consultant confirmed the current Laboratory Director did not perform a competency assessment for her duties as Technical Consultant. II. Based on review of the laboratory's personnel competency records and interview with personnel, the laboratory failed to perform competency assessments at each specific laboratory testing location for nine (9) Testing Personnel. Findings: 1. In interview on March 22, 2022 at 3:09 pm, Testing Personnel 1 stated the laboratory utilizes the same employees at each of their three (3) locations. Testing Personnel 1 stated the competency assessments are performed at whichever location the staff is working at the time and the forms are brought to the main location to sign. Testing Personnel 1 confirmed the competency assessments for testing personnel are not performed on site at each laboratory site. 2. Review of the laboratory's testing personnel competency assessment forms revealed the laboratory's location was not specified.

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 written policies for reporting SARS COV-2 results. 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. 2. In

interview on March 22, 2022 at 1:06 pm, the Technical Consultant and Testing Personnel 1 confirmed the laboratory did not have a written policy for reporting positive and negative SARS COV-2 results to the state.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of quality control records, patient test records, and interview with personnel, the laboratory failed to take corrective action when quality control (QC) values were unacceptable for Complete Blood Count (CBC) testing for one (1) of twenty eight (28) days reviewed in February 2021. Findings: 1. Observation by surveyor during laboratory tour on March 22, 2022 at 1:22 pm revealed the laboratory utilizes the Medonic for CBC testing. 2. Review of quality control records and patient test records for February 2021 revealed the following QC was reported outside of acceptable limits without corrective actions: February 1, 2021: Level 1, Lot 2201121, WBC 3.9 H reported at 9:05 am; Patient 196020 3. Further review of the quality control records revealed the Technical Consultant reviewed and signed the QC record for that day on February 5, 2021. 4. In interview on March 22, 2022 at 2:25 pm, Testing Personnel 1 stated the laboratory runs three levels of controls for CBC testing. Testing Personnel 1 stated the employee who ran the identified control no longer works for the laboratory and thought maybe the QC level 1 was accepted since it was initially run at 9:00 am. Testing Personnel 1 stated she was unsure why the identified QC was repeated. Testing Personnel 1 confirmed the identified patient was reported without corrective actions for unacceptable QC.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of manufacturer instructions, test menu, and interview with personnel, the laboratory failed to take corrective actions when the storage of quality control (QC) for the Lumira DX SARS COV-2 testing did not meet the manufacturer's requirements. Findings: 1. Observation by surveyor during the laboratory tour on March 22, 2022 at 1:22 pm revealed the laboratory utilizes the Lumira DX SARS COV-2 Antigen test kits with Lumira DX SARS COV-2 Antigen Quality Controls. 2. Further observation by surveyor during the laboratory tour on March 22, 2022 at 1:36 am revealed the laboratory stored one (1) box of Lumira DX

SARS COV-2 Antigen Controls, Lot 2002200198, at 71.1 degrees Fahrenheit. 3. Review of the manufacturer's instructions for the QC under the "Storage and Stability" section revealed "Store controls between 2 C and 8 C (36-46 F). Once opened the vials has a 30 day expiry." 4. In interview on March 22, 2022 at 1:36 pm, Testing Personnel 1 stated the laboratory recently received the controls. Testing Personnel 1 stated she thought the controls could be stored at room temperature, since the manufacturer did not ship them cold. 5. Review of the laboratory's test menu revealed the laboratory performs seven (7) Lumira DX SARS COV-2 Antigen tests annually.

D5805

TEST REPORT
CFR(s): 493.1291(c)

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) 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:
Based on observation by surveyor, review of patient final test reports, and interview with personnel, the laboratory failed to include the name and address of the laboratory performing the SARS COV-2 testing. Findings: 1. Observation by surveyor during the laboratory tour on March 22, 2022 at 1:22 pm revealed the laboratory utilizes the following kits for SARS COV-2 testing: a) Lumira Dx SARS COV-2 antigen b) Quidel Quickvue SARS COV-2 2. Review of the following random selection of final patient test reports revealed the laboratory's name and address were not included on the report: Patient ID 147160 Patient ID 206100 3. In interview on March 22, 2022 at 2:51 pm the Technical Consultant confirmed the name and address of the laboratory were not included on patient final reports. 4. Review of the laboratory's test menu revealed the laboratory performs seven (7) Lumira DX SARS COV-2 antigen tests and 184 Quidel SARS COV-2 antigen tests

D6024

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

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 corrective actions were taken and documented when deviations from laboratory's policies occurred. Findings: 1. The laboratory failed to take corrective action when quality control (QC) values were unacceptable

for Complete Blood Count (CBC) testing for one (1) of twenty eight (28) days reviewed in February 2021. Refer to D5783. 2. The laboratory failed to take corrective actions when the storage of quality control (QC) for the Lumira DX SARS COV-2 testing did not meet the manufacturer's requirements. Refer to D5785.

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. Refer to D5805.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure one (1) of nine (9) Testing Personnel had documentation of training for moderate complexity testing. Findings: 1. In interview on March 22, 2022 at 1:00 pm Testing Personnel 1 stated Testing Personnel 6 was hired July 31, 2019. 2. Review of personnel records for Testing Personnel 6 revealed the laboratory did not have documentation of an initial training for moderate complexity testing. 3. In interview on March 22, 2022 at 3:12 pm Testing Personnel 1 stated the initial training for Testing Personnel 6 was located at their other location. Testing Personnel 1 confirmed the laboratory did not have documentation of performance of an initial training for Testing Personnel 6 for the location surveyed.

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. Findings: 1. The laboratory failed to establish written policies and procedures to assess competency of the Technical Consultant. Refer to D5209 I. 2. The laboratory failed to perform competency assessments at each specific laboratory testing location for nine (9) Testing Personnel. Refer to D5209 II. 3. The Technical Consultant failed to evaluate the competency of two (2) of eight (8) testing personnel. Refer to D6046. 4. The Technical Consultant failed to perform a competency assessment semi-annually during the first year for one (1) of eight (8) testing personnel reviewed. Refer to D6053. 5. The Technical Consultant failed to evaluate competency annually in 2020 for one (1) of eight (8) personnel reviewed. Refer to D6054.

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.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to establish written policies for reporting SARS COV-2 results. Refer to D5401. 2. The laboratory failed to include the name and address of laboratory performing the SARS COV-2 testing. Refer to D5805.

D6044

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(6)

(b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Findings: 1. The laboratory failed to take corrective action when quality control (QC) values were unacceptable for Complete Blood Count (CBC) testing for one (1) of twenty eight (28) days reviewed in February 2021. Refer to D5783. 2. The laboratory failed to take corrective actions when the storage of quality control (QC) for the Lumira DX SARS COV-2 testing did not meet the manufacturer's requirements. Refer to D5785.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with personnel, the Technical Consultant failed to evaluate the competency of two (2) of eight (8) testing personnel. Findings: 1. Review of the following personnel records revealed the testing personnel competency assessments were performed by Testing Personnel 1, not the laboratory's Technical Consultant: Testing Personnel 6: Annual competency in February 2022 Testing Personnel 7: Annual competency in February 2022 2. In interview on March 22, 2022 at 3:09 pm, Testing Personnel 1 confirmed she performed the competency assessments for the identified testing personnel, not the Technical Consultant.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with personnel, the Technical Consultant failed to perform a competency assessment semi-annually during the first year for one (1) of eight (8) testing personnel reviewed. Findings: 1. In interview on March 22, 2022 at 1:00 pm, Testing Personnel 1 stated Testing Personnel 6 was hired July 31, 2019. 2. Review of the personnel records for Testing Personnel 6 revealed the laboratory did not have documentation of a semi-annual competency assessment due January 2020. 3. In interview on March 22, 2022 at 3:12 pm, Testing Personnel 1 stated the semi-annual competency assessment was located at their other location. Testing Personnel 1 confirmed the laboratory did not have documentation of

performance of a semi-annual competency assessment for Testing Personnel 6 for the location surveyed.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with personnel, the Technical Consultant failed to evaluate competency annually in 2020 for one (1) of eight (8) personnel reviewed. Findings: 1. Review of personnel records revealed a 2020 competency assessment was not performed for Testing Personnel 4. 2. In interview on March 22, 2022 at 3:09 pm, Testing Personnel 1 stated the 2020 competency assessment for Testing Personnel 4 was at the laboratory's other location. Testing Personnel 1 confirmed the laboratory did not have documentation of a 2020 competency assessment for Testing Personnel 4 for the location surveyed.