

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0462025	(X3) Date Survey Completed 03/24/2022
Name of Provider or Supplier Pediatric Center Of Southwest Louisiana, The	Street Address, City, State 600 Cypress Street, Sulphur, 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	<p>A Recertification survey was performed at The Pediatric Center of Southwest Louisiana, CLIA ID # 19D0462025, on March 24, 2022. The Pediatric Center of Southwest Louisiana was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing, Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories Performing Moderate Complexity Testing, Technical Consultant</p>
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 24, 2022 at 9:06 am 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</p>

	<p>March 24, 2022 at 10:17 am, Technical Consultant 2 confirmed the SARS COV-2 fact sheets the laboratory provided to patients did not match the manufacturers'. 5. Review of the laboratory's test menu revealed the laboratory performs twenty two (22) Lumira Dx SARS COV-2 antigen tests and 538 Quidel Quickvue SARS COV-2 antigen tests.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to label Wright stain stored in secondary container with expiration date. Refer to D5415. 2. The laboratory failed to perform complete performance verification studies for complete blood count (CBC) testing on the Medonic M series analyzer. Refer to D5421. 3. The laboratory failed to perform quality control (QC) for Group A B-hemolytic Streptococcus (Bacteriology) testing per their IQCP for three (3) of three (3) lot numbers reviewed. Refer to D5445.</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the laboratory failed to label Wright stain stored in secondary container with expiration date. Findings: 1. Observation by surveyor during laboratory tour on March 24, 2022 at 9:14 am revealed the laboratory had a container labeled "3/22/22 Wright Stain." The container did not include the lot information or expiration date of the stain. 2. In interview on March 24, 2022 at 9:14 am, Technical Consultant 2 confirmed the identified container did not include the required information.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)</p>

Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of validation studies, test menu, and interview with personnel, the laboratory failed to perform complete performance verification studies for complete blood count (CBC) testing on the Medonic M series analyzer. Findings: 1. Observation by surveyor during the laboratory tour on March 24, 2022 at 9:06 am revealed the laboratory utilizes the Medonic M series analyzer for CBC testing. 2. In interview on March 24, 2022 at 10:59 am, Technical Consultant 2 stated the laboratory replaced their previous Medonic analyzer with a new one in May 2021. 3. Review of the laboratory's "Verification of Performance Specifications" revealed "Each laboratory that introduces a new, non-waived, unmodified, FDA-cleared or approved test is required to check (verify) the manufacturer's performance specifications provided in the package insert for the following before reporting patient test results: Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: a) accuracy b) precision c) reportable range of the test results for the system Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population Quantitative Tests: Precision: Perform five repetitions of at least three samples with different values, spanning the reportable range. Test the samples: In the same run (2 of the 5 repetitions; in a different run on the same day (3rd repetition); and on different days (4th and 5th repetitions performed on different days). If possible have different staff perform the 3rd, 4th, and 5th repetitions to check for operator variance Reportable Range: Using the same process used to evaluate accuracy, evaluate reportable range. If a zero calibrator is available for the analyte, then you may extend the low end of your reportable range down to zero, provided you actually obtain a zero result when you test that sample. Reference Range: Collect specimens from twenty (20) normal patients a minimum of ten (10) patient specimens may be used if necessary. Test each specimen only once, and spread the testing over a minimum of three days. Calculate the normal patient mean. Calculate the standard deviation (SD) and determine the range of the plus and minus two SD from the mean. Compare this range to the manufacturer's range. 4. Review of the "Medonic M Series Method Validation Evaluation" form revealed the following: "The Lab Director should review the the results of the Reportable Range/Linearity study. No patient results may be reported outside this linear range unless procedures/protocols are developed to use when results are outside the validated linear (reportable) range. Reference Range Validation: The Laboratory Medical Director must examine all reference ranges provided by the manufacturer and determine if they are appropriate for the lab's patient population. This can be done empirically , or by using the methods outlined in the CLSI Document C28-A2E 'How to Define and Determine Reference Intervals in the Clinical Laboratory.' " 5. Review of the laboratory's validation records for the Medonic M series analyzer revealed the laboratory did not include the following: Precision studies: to include run-to run, day to day, within-run, operator variance studies Reference Range studies Reportable Range: to include the range the laboratory verified for each blood cell parameter 6. In interview on March 24, 2022 at 11:06 am, Technical Consultant 2 confirmed the laboratory's validation studies did not include the identified information. 7. Review of the laboratory's test menu revealed the laboratory performs 3,276 CBC tests annually.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of the laboratory's policies, Individualized Quality Control Plan (IQCP), control records, test menu, and interview with personnel, the laboratory failed to perform quality control (QC) for Group A B-hemolytic Streptococcus (Bacteriology) testing per their IQCP for three (3) of three (3) lot numbers reviewed. Findings: 1. Observation by surveyor during laboratory tour on March 24, 2022 at 9:06 am, the laboratory utilizes the Quidel Solana GAS Assay for Group A B-hemolytic Streptococcus testing 2. Review of the laboratory's "Solana GAS Assay" policy under "Quality Control" section revealed "It is recommended that the reactivity of each new lot and each new shipment of the Solana GAS Assay be verified on receipt and before use. External control tests should be performed thereafter every time patient samples are assayed." 3. Review of the laboratory's IQCP for the Solana GAS Assay revealed "It is recommended that the reactivity of each new lot and each new shipment of the Solana GAS Assay be verified on receipt and before use and every 30 days." 4. Review of random selection of the laboratory's QC records for the Solana GAS assay revealed the laboratory did not perform QC at least every thirty (30) days for the following three (3) lot numbers: Lot 204022 Lot 201236 Lot 180383 5. In interview on March 24, 2022 at 9:52 am, Technical Consultant 1 and Technical Consultant 2 confirmed the laboratory did not test external controls at least every thirty (30) days as required by the laboratory's IQCP. Technical Consultant 1 and Technical Consultant 2 stated external controls were tested every new lot and shipment. 6. Review of the laboratory's test menu revealed the laboratory performs 842 Group A Streptococcus testing annually on the Solana GAS assay.

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:

I. Based on 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 23, 2022 at 9:00 am 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 220510 Patient ID 117460 3. In interview on March 24, 2022 at 10:17 am Technical Consultant 2 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 twenty two (22) Lumira DX SARS COV-2 antigen tests and 538 Quidel Quickvue SARS COV-2 antigen tests. II. Based on review of the patient final test reports and interview with personnel, the laboratory failed to ensure the name and address of the reference laboratory performing urine culture identification and susceptibility were included on patient final test reports for two (2) of two (2) patients reviewed. Findings: 1. In interview on March 24, 2022 at 10:514 am, Technical Consultant 2 stated that urine culture identification is performed at a hospital in Sulphur. 2. Review of the following random review selection of patient test results for urinalysis revealed the name and address of the reference laboratory performing the urine culture identification and susceptibility testing were not included: Patient 212470 Patient 145240 3. In interview on March 24, 2022 at 10:14 am, Technical Consultant 1 and Technical Consultant 2 confirmed the name and address of the reference laboratory performing the urine culture identification and susceptibility tests were not included on the patient final test reports.

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 Director failed to ensure performance verification studies were complete. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D6026.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

	<p>Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.</p>
D6014	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5415.</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>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 that a quality control program was maintained to assure quality laboratory services were provided. Refer to D5445.</p>
D6026	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8)</p> <p>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.</p> <p>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 I and D5805 II.</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY</p>

	<p>CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultants failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultants failed to ensure performance specification verification studies were complete. Refer to D6040. 3. The Technical Consultants failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042.</p>
<p>D6036</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to label Wright stain stored in secondary container with expiration date. Refer to D5415. 2. The laboratory failed to include the name and address of the laboratory performing the SARS COV-2 testing. Refer to D5805 I. 3. The laboratory failed to ensure the name and address of the reference laboratory performing urine culture identification and susceptibility were included on patient final test reports for two (2) of two (2) patients reviewed. Refer to D5805 II.</p>
<p>D6040</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p> <p>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultants failed to ensure performance specification verification studies were complete. Refer to D5421.</p>
<p>D6042</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are</p>

maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the Technical Consultants failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5445.