

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0906813	(X3) Date Survey Completed 02/23/2022
Name of Provider or Supplier Center For Pediatric & Adolescent Medicine	Street Address, City, State 5040 West Main Street, Houma, 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 February 23, 2022 at Center for Pediatric and Adolescent Medicine, CLIA ID # 19D0906813. 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 review of laboratory records, 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. Review of the laboratory's test menu revealed the laboratory utilizes the following kits for SARS COV-2 testing: a) Cepheid Xpert Xpress SARS COV-2 b) Cepheid Xpert Xpress SARS COV-2/Flu/RSV Plus c) BD Veritor SARS COV-2 antigen d) GenBody COVID -19 antigen e) 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 records revealed the laboratory did not have a Fact Sheet for the Cepheid Xpert Xpress SARS COV-2 tests. 4. In interview on February 23, 2022 at 11:08 am the Technical Consultant confirmed the laboratory does not provide "fact sheets" to patients for the Cepheid Xpert Xpress SARS COV-2 tests. 5. Review of the laboratory's test menu revealed the laboratory performs 529 Cepheid SARS COV-2 tests annually.</p>

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 a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have written policies and procedures that included the following: a) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run, as well as, operator variance), reportable and reference range studies, and actions to take when data from the studies fail to meet acceptability criteria 2. In interview on February 23, 2022 at 12:28 pm, the Technical Consultant confirmed the laboratory did not have a written policy for performance specification verification procedures.</p>
D5421	<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) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>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 have complete accuracy studies for the Sysmex XP 300. Findings: 1. Observation by surveyor during the laboratory tour on February 23, 2022 at 10:30 am revealed the laboratory utilizes the Sysmex XP 300 for complete blood count (CBC) testing. 2. Review of the laboratory's validation records for the Sysmex XP 300 revealed the laboratory did not include acceptability criteria for the accuracy (correlation) studies. 3. In interview on February 23, 2022 at 12:31 pm the Technical Consultant stated the laboratory did not define the acceptability criteria for the correlation studies. 4. Review of the laboratory's test menu revealed the laboratory performs 6,474 CBC tests annually.</p>
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's policies, temperature logs, and interview with personnel, the laboratory failed to document corrective actions performed for refrigerator temperatures that exceeded the acceptable range for thirteen (13) days in four (4) of twenty four (24) months reviewed. Findings: 1. Review of the laboratory's refrigerator temperature logs for 2020 and 2021 revealed the laboratory had documented min/max refrigerator temperatures (temp) that were not within acceptable limits (2-8 C) for the following dates without documented corrective action:
 November 18, 2020: Min temp documented 1 C, Max temp documented 23 C
 November 20, 2020: Min temp documented -3 C: Max temp documented -7 C
 November 27, 2020: Min temp documented 0 C November 30, 2020: Min temp documented -2 C, Max temp documented -5 C March 17, 2021: Min temp documented 1 C, Max temp documented 9 C March 24, 2021: Min temp documented 1 C March 25, 2021: Min temp documented 1 C March 26, 2021: Min temp documented 1 C June 16, 2021: Max temp documented 9 C June 25, 2021: Max temp documented 9 C November 23, 2021: Max temp documented 10 C November 24, 2021: Max temp documented 9 C November 26, 2021: Max temp documented 9 C 2. Review of the laboratory's policies revealed the laboratory did not have a written procedure for corrective actions for temperatures that exceed the acceptable range. 3. In interview on February 23, 2022 at 1:18 pm, Testing Personnel 1 stated in November there was an issue with the refrigerator and dates where the max temperature was over 20 degrees was just a fluke. Testing Personnel 1 stated the refrigerator is also digitally monitored and the digital logs are reviewed. Testing Personnel 1 stated the digital log did not indicate the refrigerator temperatures were outside of range. Testing Personnel 1 confirmed the laboratory did not document the actions taken to address the unacceptable min/max temperatures recorded. Testing Personnel 1 confirmed the laboratory did not have a written procedure for corrective actions for temperatures outside of range that included actions to perform and document.

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 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) Cepheid Xpert Xpress SARS COV-2 (529 tests performed annually) b) Cepheid Xpert Xpress SARS COV-2/Flu/RSV Plus (545 tests performed annually and 208 SARS COV-2/Flu tests performed annually) c) BD Veritor SARS COV-2 antigen (291 tests performed annually) d) GenBody COVID -19 antigen (50 tests performed annually) e) Quidel Quickvue SARS COV-2 (117 tests performed annually) 2. Review of random

selection of patient final test reports for SARS COV-2 revealed the laboratory included the following lab test designations: "COVID-19 Rapid" "COVID-19 Rapid Quickvue" "SARS-COV-2 (PCR)" "SARS-COV-2/FLU (PCR)" "SARS-COV-2/Flu /RSV (PCR)" 3. Further review of the random selection of patient final test reports for SARS COV-2 revealed the laboratory did not include the specific test utilized . 4. In interview on February 23, 2022 at 10:16 am, the Technical Consultant stated the GenBody and Quickvue tests have the same CPT code and are not distinguished on the report. The Technical Consultant further stated on the patient final report a patient that had a GenBody test would have "COVID-19 Rapid Quickvue" indicated on their report. The Technical Consultant further stated at 11:15 am that the BD Veritor test is listed as "COVID-19 Rapid." The Technical Consultant confirmed the patient final test reports did not include the test system/kit utilized for SARS COV-2 testing.

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:
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.

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 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. 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 record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.

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.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(2)

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.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.

D6043

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(5)

(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

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. Refer to D5785.