Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0893300	10/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Center For Pediatric And Adolescent Medicine,The	604 North Acadia Road Suite 200, 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 12, 2021 at The Center for Pediatric and Adolescent Medicine, CLIA ID # 19D0893300. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: I. Based on observation by surveyor, 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. Observation by surveyor during the laboratory tour on October 12, 2021 at 11:15 am revealed the laboratory utilizes the following SARS COV-2 tests: a) BD Veritor SARS COV-2 antigen b) Xpert Xpress COV-2/Flu/RSV c) 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. In interview on October 12, 2021 at 10:45 am the Technical Consultant 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 145 Quidel Quickvue, 308 BD Veritor, and 492 Xpert Xpress COV-2/Flu/RSV 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. Observation by surveyor during the laboratory tour on October 12, 2021 at 11:15 am revealed the laboratory utilizes the following SARS COV-2 tests: a) BD Veritor SARS COV-2 antigen b) Xpert Xpress COV-2/Flu/RSV c) Quidel Quickvue SARS COV-2 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: Patient 136130 Patient 53042 Patient 132715 Patient 20178 4. In interview on October 12, 2021 at 10: 54 am, the Technical Consultant 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 145 Quidel Quickvue, 308 BD Veritor, and 492 Xpert Xpress COV-2/Flu/RSV 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 competency forms, personnel records, and interview with personnel, the laboratory failed to follow their established competency policy for two (2) of seven (7) testing personnel reviewed. Findings: 1. In interview on October 12, 2021 at 1:03 pm, the Technical Consultant stated the following two (2) personnel were hired as Testing Personnel in the beginning of 2021.: Testing Personnel 5 Testing Personnel 6 2. Review of the laboratory's "Training and Competency Assessment Form" revealed "Employee has successfully completed the necessary training that is required of them in all areas of the laboratory and they are ready to assume duties. Laboratory Director Review signature/date line." 3. Review of the "Initial Training and Competency Assessment Form" for Testing Personnel 5 and Testing Personnel 6 revealed the Laboratory Director did not approve/sign the identified two (2) personnel for testing. 4. In further interview on October 12, 2021 at 1:03 pm, the Technical Consultant confirmed the Laboratory Director did not approve /sign the identified testing personnel for testing.
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, test menu, and interview with personnel, the laboratory failed to establish complete policies for reporting SARS COV-2 results. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs the following SARS COV-2 tests: a) BD Veritor SARS COV-2

	antigen b) Xpert Xpress COV-2/Flu/RSV c) Quidel Quickvue SARS COV-2 2. Review of the laboratory's policies revealed the laboratory did not have written procedures that included the following: a) Quidel Quickvue SARS COV-2 reporting of positive and negative results to state public health agency b) Process of reporting to include, who is responsible, frequency of reporting 3. In interview on October 12, 2021 a 10:26 am, the Technical Consultant confirmed the laboratory's policies did not include the identified information.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) policy and interview with personnel, the laboratory failed to establish complete QC policies for Complete Blood Count (CBC) testing. Findings: 1. Review of the laboratory's "Sysmex XP 300" policy under "Quality Controls" section revealed the following: a) "The Sysmex XP300 uses three levels of EIGHTCHECK-3WP X-TRA (Low, Normal, and High) and is intended to be used with Sysmex reagents and analyzers only." b) "Frequency of controls will be ran at three levels of different concentrations once each day patient specimens are ran and as instructed based on manufacturer's recommendations. Two out of three control materials that fall within the expected ranges are considered acceptable." 2. In interview on October 12, 2021 at 1:39 pm, the Technical Consultant stated all three levels of the CBC are monitored. The Technical Consultant further stated two levels of quality control are acceptable; however, all three levels are monitored for shifts and trends. 3. Further review of the laboratory's "Sysmex XP 300" policy revealed the laboratory did not include a written procedure for monitoring the third control. 4. In further interview on October 12, 2021 at 1:39 pm, the Technical Consultant confirmed the laboratory's policies did not include the identified information.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of validation records, test menu, and interview with personnel, the laboratory failed to perform precision and reference range studies for the Sysmex XP 300. Findings: 1. Observation by surveyor during laboratory tour on October 12, 2021 at 11:15 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 the following: a) Reference range: Clinical reference or studies to support the reference range in use b) Precision studies to include run-to-run, day-to-day, within-run, operator variance, and acceptability criteria c) Laboratory Director approval/signature 3. In interview on October 12, 2021 at 12:08 pm, the Technical Consultant stated the lab uses the same reference ranges as the laboratory's previous CBC analyzer. The Technical Consultant further stated she thought the method comparison of instruments would cover precision studies. The Technical Consultant confirmed the laboratory did not include documentation of verification of reference ranges in use or complete precision studies that included acceptability criteria. 4. Review of the laboratory's test menu revealed the laboratory performs 7,896 CBC tests annually.
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.
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. Findings: 1. The laboratory failed to establish complete policies for reporting SARS COV-2 results. Refer to D5401. 2. The laboratory failed to establish complete QC policies for Complete Blood Count (CBC) testing. Refer to D5403.
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.