Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0893300	05/30/2023
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 May 30, 2023 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.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of temperature logs, manufacturers' storage requirements, and interview with personnel, the laboratory failed to define room temperature limits that met manufacturer requirements for supplies. Findings: 1. Review of the laboratory's temperature log revealed the acceptable room temperature range was defined as 4-35 degrees Celsius. 2. Observation by surveyors during the laboratory tour on May 30, 2023 at 9:45 am and review of manufacturers' storage requirements revealed the following items were stored in the laboratory: a) BioMerieux BACT/ALERT PF Plus blood culture bottles: manufacturer's storage temperature requirements 15 - 30 degrees Celsius b) Vacuette blood collection tubes, Serum separator clot activator: manufacturer's storage temperature requirements 4 - 25 degrees Celsius 3. In interview on May 30, 2023 at 1:06 pm, the Technical Consultant confirmed the laboratory's defined acceptable room temperature range did not meet the manufacturers' storage requirements for the identified supplies.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of maintenance records, and interview with laboratory personnel, the laboratory failed to ensure the weekly maintenance on the Sysmex XP-300 was performed as required by the manufacturer for two (2) of thirty (30) weeks reviewed. Findings: 1. Observation by surveyors during the laboratory tour May 30, 2023 at 9:45 a.m. revealed laboratory utilized a Sysmex XP-300 analyzer for hematology testing. 2. Review of maintenance records for the XP-300 revealed "Clean SRV Tray" as the weekly task. 3. Further review of Sysmex XP-300 maintenance records revealed the laboratory did not perform weekly maintenance for the following two (2) weeks: November 28, 2022 January 30, 2023 4. In interview on May 30, 2023 at 12:30 p.m., the Technical Consultant confirmed the weekly maintenance identified above was not performed.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's humidity logs and interview with personnel, the laboratory failed to have complete documentation of corrective actions performed when the humidity was not maintained between 30-80% per the laboratory's policy for nine (9) of seventy-nine (79) days reviewed. Findings: 1. Review of the laboratory's humidity logs for January 2022, December 2022, and January 2023 revealed the following nine (9) dates had humidity readings outside the laboratory's established limits (30-85%): January 11, 2022: documented humidity of 27% January 12, 2022: documented humidity of 29% January 22, 2022: documented humidity of 25% January 24, 2022: documented humidity of 26% January 27, 2022: documented humidity of 27% January 28, 2022: documented humidity of 24% December 24, 2022: documented humidity of 18% December 26, 2022: documented humidity of 22% December 27, 2022: documented humidity of 24% 2. Further review of the identified humidity logs revealed the laboratory included the following notes; however, the laboratory did not document the new humidity reading after adjustment of the temperature: a) January 2022: "Humidity out of range. Tried adjusting temp. came back down again. Brought in a humidifier during cold weather." b) December 2022: "12/26-adjusted temp" and "12/27-cold weather, readjusted temp" 3. In

	interview on May 30, 2023 at 2:45 pm, the Technical Consultant confirmed the laboratory did not have complete documentation of corrective actions for humidity that included the new humidity readings after temperature adjustment on the dates identified above.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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. This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
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 D5781.

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 review of personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The Technical Consultant failed to ensure competency assessment for testing personnel performing Complete Blood Count (CBC) testing included direct observation of test performance for four (4) of five (5) testing personnel in 2022. Refer to D6047. 2. The Technical Consultant failed to ensure competency assessment for testing personnel performing Complete Blood Count (CBC) testing included monitoring the recording and reporting of test results for four (4) of five (5) testing personnel in 2022. Refer to D6048.
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 surveyors, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5429.
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 documented when deviations from the laboratory's policies occurred. Refer to D5781.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i)

	The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of laboratory's personnel records and interview with personnel, the Technical Consultant failed to ensure competency assessment for testing personnel performing Complete Blood Count (CBC) testing included direct observation of test performance for four (4) of five (5) testing personnel in 2022. Findings: 1. Review of the laboratory's personnel records revealed the laboratory did not have documentation to support direct observation of "Specimen preparation/collection, handling, processing, testing and result interpretation" for CBC testing for the following four (4) of five (5) testing personnel in 2022: a) Personnel 1 b) Personnel 2 c) Personnel 3 d) Personnel 4 2. In interview on May 30, 2023 at 11:33 a.m., the Technical Consultant confirmed that she did not perform direct observation of CBC test performance as part of competency assessment for the identified testing personnel.
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on review of laboratory's personnel records and interview with personnel, the Technical Consultant failed to ensure competency assessment for testing personnel performing Complete Blood Count (CBC) testing included monitoring the recording and reporting of test results for four (4) of five (5) testing personnel in 2022. Findings: 1. Review of the laboratory's personnel records revealed the laboratory did not have documentation to support "Proper test results recording/reporting" for CBC testing for the following four (4) of five (5) testing personnel in 2022: a) Personnel 1 b) Personnel 2 c) Personnel 3 d) Personnel 4 2. In interview on May 30, 2023 at 11:33 a.m., the Technical Consultant confirmed that for the competency assessment of the testing personnel identified above she did not have supporting documentation of her review of their reporting of test results for CBC testing.