Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2072580	11/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
The Pediatric Center Of Southwest Louisiana	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 November 7, 2023 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.
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 policies, CMS 209 form (Laboratory Personnel Report), personnel records, and interview with personnel, the laboratory failed to follow their policy to assess competency of the Technical Consultant for one (1) of three (3) Technical Consultants reviewed. Findings: 1. Review of the laboratory's policy and procedure manual revealed "Technical Consultant Competencies will be evaluated upon initial designation and upon any change in Laboratory Director designation." 2. Review of the laboratory's CMS 209 revealed Personnel 2 served as testing personnel and Technical Consultant. 3. Review of personnel records for Personnel 2 revealed the laboratory did not have documentation of a competency assessment for her role as Technical Consultant. 4. In interview on November 7, 2023 at 2:51 p.m., Personnel 2 confirmed the laboratory did not have documentation of a competency assessment for her role as Technical Consultant.
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, review of the laboratory's temperature records and policy and procedure manual, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for supplies stored in the laboratory. Findings: 1. Observation by surveyor during the laboratory tour on November 7, 2023 at 1:03 p.m. revealed the laboratory stored BD Microtainer Tubes with K2EDTA (manufacturer's upper temperature limit 25 degrees Celsius) stored in the laboratory. 2. Review of the laboratory's temperature logs revealed the laboratory defined the acceptable room temperature limits as 15-30 degrees Celsius (59-86 degrees Fahrenheit). 4. Review of the laboratory's policy "Temperature Logs Documentation" revealed the acceptable room temperatures defined as 15-30 degrees Celsius (59-86 degrees Fahrenheit). 5. In interview on November 7, 2023 at 4:15 p.m., Technical Consultant 1 confirmed the laboratory's acceptable range was outside of the manufacturer's limits as identified above.
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 review of temperature records, laboratory's policy and procedure manual, as well as interview with personnel, the laboratory failed to perform and document corrective actions when the laboratory refrigerator temperature was not maintained within the acceptable range for nine (9) of four hundred twenty-five (425) days reviewed. Findings: 1. Review of the laboratory's temperature records for September 2022 to October 2023 revealed the laboratory defined the acceptable temperature limits for the refrigerator as 2 - 8 degrees Celsius (35 - 46 degrees Fahrenheit). 2. Further review of the temperature records revealed the refrigerator temperature was outside of the acceptable limits without corrective action on the following nine (9) days: November 7, 2022 - 46.4 degrees Fahrenheit March 16, 2023 - 34.5 degrees Fahrenheit March 17, 2023 - 34.2 degrees Fahrenheit March 22, 2023 - 34.5 degrees Fahrenheit March 27, 2023 - 34.3 degrees Fahrenheit March 30, 2023 - 34.0 degrees Fahrenheit April 13, 2023 - 34.9 degrees Fahrenheit July 10, 2023 - 34.9 degrees Fahrenheit July 20, 2023 - 34.7 degrees Fahrenheit 3. Review of the laboratory's "Temperature Logs Documentation" policy revealed the following: - If any temperature falls out of range, the temperature is to be verified on the back-up thermometer. - If the temperature is also out of range on the back-up thermometer, corrective action must be performed and documented in the problem log. 4. In interview on November 7, 2023 at 4:15 p.m., Technical Consultant 1 confirmed the refrigerator temperature was outside of the acceptable range on the days identified above.

D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's quality assessment monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for supplies stored in the laboratory. Refer to D5413. 2. The laboratory failed to perform and document corrective actions when the laboratory refrigerator temperature was not maintained within the acceptable range for nine (9) of four hundred twenty-five (425) days reviewed. Refer to D5785.
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 record review and interview with personnel, the laboratory failed to include the name and address of the laboratory location where complete blood count (CBC) manual differential testing was performed on patient final reports for three (3) of four (4) patients reviewed. Findings: 1. Review of patient test reports revealed the laboratory did not include the name and physical address of the laboratory where the cell blood count (CBC) manual differential testing was performed for the following three (3) patients: - Chart 266210 - Manual Differential Testing performed 03/25/2022 - Chart 162210 - Manual Differential Testing performed 07/08/2022 - Chart 308980 - Manual Differential Testing performed 10/05/2022 2. In interview on November 7, 2023 at 4:45 p.m., Personnel 2 stated the physical printout from the instrument had the initials of testing personnel from a sister facility indicating it was performed laboratory's sister location. She confirmed the patient reports identified above did not include the name and address of the laboratory where the manual differential was performed.
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, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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 and quality assessment programs are established and maintained to identify failures in quality as they occur. 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 assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.
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 final reports for hematology testing included 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: ***Repeat deficiency from survey conducted on March 22, 2022*** Based on review of the laboratory's CMS 209 form (Laboratory Personnel Report) and personnel records as well as interview with personnel, the Laboratory Director failed to ensure testing personnel had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the following individuals as testing personnel: - Personnel 2 - Personnel 7 2. Review of personnel records for Personnel 2 revealed the laboratory had documentation of a 6 month competency performed in August 2023 but did not have documentation of an initial training. 3. In interview on November 7, 2023 at 3:25 p. m., Personnel 2 stated she was hired in January 2023 and was trained at a sister facility. 4. Review of personnel records for Personnel 7 revealed the laboratory had documentation of a 6 month competency performed in February 2023 and an annual competency in July 2023 but did not have documentation of an initial training. 5. In interview on November 7, 2023 at 3:31 p.m., Technical Consultant 1 confirmed the laboratory did not have documentation of initial trainings for the testing personnel identified above.
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 established and maintained. Findings: 1. The laboratory failed to follow their policy to assess competency of the Technical Consultant for one (1) of three (3) Technical Consultants reviewed. Refer to D5209. 2. The Technical Consultant failed to evaluate the competency of two (2) of four (4) Testing Personnel in 2022. Refer to D6046. 3. The Technical Consultant failed to ensure testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples for one (1) of (4) testing personnel in 2023. Refer to D6051.
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 the laboratory's policy and procedure manual and personnel records as well as interview with personnel, the Technical Consultant failed to evaluate the competency of two (2) of four (4) Testing Personnel in 2022. Findings: 1. Review of the laboratory's policy "Employee Competency" revealed "The Laboratory Director or Technical Consultant will conduct the orientation and competency of all personnel that perform moderate and high complexity testing." 2. Review of personnel records for the following testing personnel revealed the laboratory did not have documentation of annual competency performed in 2022: - Personnel 5 - Personnel 6 3. In interview on November 7, 2023 at 3:18 p.m., Technical Consultant 1 confirmed the laboratory did not have documentation of annual competency in 2022 for the personnel identified above
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review the laboratory's CMS-209 (Laboratory Personnel Report) form and personnel records as well as interview with personnel, the Technical Consultant failed to ensure testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples for one (1) of (4) testing personnel in 2023. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed Personnel 5 served as Testing Personnel. 2. Review of the laboratory's personnel records revealed a competency assessment form for Personnel 5 in 2023. 3. Review of the 2023 competency assessment form for Personnel 5 revealed no documentation for "Assessment of test

	performance (PT/blind samples)." 4. In interview on November 7, 2023 at 2:45 p.m., Technical Consultant 1 confirmed Personnel 5 did not perform a proficiency testing (PT) sample or blind sample for competency assessment in 2023.