Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1005933	03/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric And Adolescent Clinic	1806 Carter Street, Vidalia, 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 March 12, 2024 at Pediatric & Adolescent Clinic, CLIA ID # 19D1005933. 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 review of the laboratory's temperature logs and policies as well as interview with personnel, the laboratory failed to define an acceptable room temperature for the laboratory. Findings: 1. Review of the following laboratory documents revealed the laboratory had different acceptable room temperature limits defined for the laboratory: a) The laboratory's temperature logs defined the acceptable room temperature limits for the laboratory as 68 - 78 degrees Fahrenheit. b) The laboratory's policy "Daily Temperature Monitoring" defined the acceptable room temperature limits for the laboratory as 68 - 90 degrees Fahrenheit. 2. In interview on March 12, 2024 at 12 p. m., the Technical Consultant confirmed the laboratory had different acceptable room temperature limits for the laboratory as identified above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policies and quality control records, as well as interview with laboratory personnel, the laboratory failed to document corrective actions taken when hematology quality control was outside of acceptable limits for nine (9) of sixteen (16) days reviewed. Findings: 1. Observation by surveyor during the laboratory tour on March 12, 2024 at 8:44 a.m. revealed the laboratory utilized a Cell-Dyn analyzer for hematology testing. 2. Review of the laboratory's policy "Quality Control" under section "Cell Dyn 18 Plus Controls" revealed "Run all three levels of QC daily - prior to patient testing ..." 3. Further review of the "Quality Control" policy under section "Trouble Shooting {sic} QC Failures" revealed "If quality control falls outside of the acceptable limits, patient samples will not be analyzed until the problem has been detected and resolved. Remedial action documentation will state the problem and the steps taken to rectify the situation." 4. Review of November 2023 quality control records revealed quality control was outside of the acceptable limits and retested on the following days, but the laboratory did not document all corrective action steps: a) 11/1/2023 - L3205 - tested two (2) times - N3205 - tested four (4) times - H3205 - tested three (3) times b) 11/2/2023 - L3205 - tested three (3) times - N3205 - tested three (3) times - H3205 - tested three (3) times c) 11/6/2023 - L3289 - tested two (2) times d) 11/7/2023 - L3289 - tested fourteen (14) times e) 11/10/2023 - L3289 - tested two (2) times f) 11/14/2023 - L3289 - tested two (2) times g) 11/17/2023 - L3289 - tested two (2) times h) 11/20 /2023 - L3289 - tested four (4) times i) 11/22/2023 - L3289 - tested three (3) times 3. In interview on March 12, 2023 at 10:40 a.m., the Technical consultant confirmed corrective action steps taken by the laboratory were not documented for 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 record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.
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 documented when deviations from laboratory's policies occurred. Refer to D5783.
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 D6051.
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, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to define an acceptable room temperature for the laboratory. Refer to D5413. 2. The laboratory failed to document corrective actions taken when hematology quality control was outside of acceptable limits for nine (9) of sixteen (16) days reviewed. Refer to D5783.
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 of the Laboratory Personnel Report and personnel records as well as interview with laboratory personnel, the Technical Consultant failed to ensure all moderate complexity testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples for one (1) of three (3) testing personnel reviewed. Findings: 1. Review of the laboratory's Laboratory Personnel Report revealed the following testing personnel: Personnel 1 Personnel 2 Personnel 3 2. Review of the laboratory's personnel records revealed annual competency assessment forms for Personnel 3 for 2022 and 2023, but the laboratory did not have documentation to support the performance of blind sample testing. 3. In interview on March 12, 2024 at 10 a.m., the Technical Consultant confirmed Personnel 3 did not perform blind sample testing as identified above.