Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1005933	06/29/2022
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 June 29, 2022 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.
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 installation records, test menu, and interview with personnel, the laboratory failed to have complete performance verification studies for the Abbott Cell-Dyn Emerald Hematology analyzer. Findings: 1. Observation by surveyor during the laboratory tour on June 29, 2022 at 9:30 am revealed the laboratory utilizes the Abbott Cell-Dyn Emerald Hematology analzyer for Complete Blood Count (CBC) patient testing. 2. Review of the laboratory's installation records for the Cell-Dyn Emerald Hematology analyzer revealed that the laboratory started patient testing on September 11, 2021; however, the installation records were not signed as ready for patient testing by the Laboratory Director. 3. In interview on June 29, 2022 at 11:14 am, the Technical Consultant stated that she signed off on the performance verification studies but did not have the Laboratory Director sign as well. 4. Review of the laboratory's installation records revealed the laboratory performed performance verification with raw data to support the studies for

	the following: a) Accuracy: Method Comparison b) Precision: Run to Run and Within Run c) Reportable Range: Linearity 5. Further review of the laboratory's installation records revealed the laboratory did not have raw data to support the studies for the following: a) Complete Precision: Day to Day and Operator Variance b) Reference Range 6. In interview on June 29, 2022 at 11:14 am, the Technical Consultant stated she was unaware the identified raw data was not included with the installation records. The Technical Consultant further stated the reference range studies were carried over from the previous Hematology analyzer since the population has not changed for the facility. 7. Review of the laboratory's test menu revealed the laboratory performs two hundred twenty two (222) CBC tests annually.
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 policy and procedure, temperature logs and interview with personnel, the laboratory failed to document corrective actions performed when the refrigerator temperature was not maintained within the acceptable range per laboratory policy for twenty three (23) of two hundred sixteen (216) dates reviewed. Findings: 1. Review of the laboratory's policy for "Daily Temperature Monitoring" revealed under "Protocol" the following: a) Daily temperatures should be recorded on the corresponding temperature chart before testing begins. *Refrigerator temperature should be maintained at 2-8 derees celsius (36-46 degree fahrenheit) *Room temperature should be maintained at 20-32 degrees celsius (68-90 degree fahrenheit) b) When the temperatures are not within range properly document any and all remedial action taken and notify the Laboratory Director. c) If the issue cannot be corrected in a timely manner refrigerated supplies and control material should be moved to another location until the temperature of the reagent refrigerator has returned to the correct range, notify the practitioner on duty. If the room temperature is outside of the optimal range no testing can be performed until the temperature is adjusted and within range, notify the practitioner on duty. d) All temperature logs will be monitored weekly by the Technical Consultant. 2. Review of the laboratory's "Temperature Log for Refrigerator - Fahrenheit" from October 2021 through May 2022 revealed "Take action if temp is out of range - too warm (above 46 degrees fahrenheit) or too cold (below 36 degrees fahrenheit)". 3. Further review of the laboratory's "Temperature Log for Refrigerator - Fahrenheit" from October 2021 through May 2022 revealed the refrigerator temperature was documented as outside of the acceptable limits with no corrective action documented for the following twenty three (23) dates reviewed: a) November 1, 2021 at 5:00 pm documented temperature 46 degrees Fahrenheit (F) b) November 2, 2021 at 8:00 am documented temperature 48 degrees F c) November 5, 2021 at 5:00 pm documented temperature 46 degrees F d) November 9, 2021 at 8:00 am documented temperature 49 degrees F e) November

	16, 2021 at 8:00 am documented temperature 47 degrees F f) November 17, 2021 at 5: 00 pm documented temperature 46 degrees F g) November 18, 2021 at 8:00 am documented temperature 47 degrees F h) November 23, 2021 at 8:00 am documented temperature 48 degrees F i) November 30, 2021 at 5:00 pm documented temperature 47 degrees F j) December 9, 2021 at 8:00 am documented temperature 49 degrees F k) December 10, 2021 at 5:00 pm documented temperature 46 degrees F l) December 13, 2021 at 8:00 am documented temperature 46 degrees F m) December 14, 2021 at 8:00 am documented temperature 46 degrees F n) December 16, 2021 at 5:00 pm documented temperature 46 degrees F o) December 21, 2021 at 8:00 am documented temperature 46 degrees F p) January 4, 2022 at 8:00 am documented temperature 47 degrees F q) January 6, 2022 at 8:00 am documented temperature 51 degrees F r) January 6, 2022 at 5:00 pm documented temperature 48 degrees F s) January 7, 2022 at 5:00 pm documented temperature 46 degrees F t) January 10, 2022 at 8:00 am documented temperature 47 degrees F u) January 10, 2022 at 5:00 pm documented temperature 46 degrees F v) February 4, 2022 at 5:00 pm documented temperature 46 degrees F w) February 24, 2022 at 5:00 pm documented temperature 55 degrees F 4. In interview on June 29, 2022 at 12:06 pm, the Technical Consultant confirmed the laboratory did not have documentation of corrective action performed for unacceptable refrigerator temperatures for the above identified dates.
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, review of installation records, 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 review of laboratory's policy manual and temperature records as well as an

	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.
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, review of installation records, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of laboratory records 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 D5781.