Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0688964	07/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Acadiana Family Practice Lab, Inc	717 Curtis Drive, Rayne, 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 July 10, 2024 at Acadiana Family Practice Lab, INC, CLIA ID # 19D0688964. 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 surveyor, review of manufacturers' storage requirements, and interview with personnel, the laboratory failed to monitor the room temperature of the closet where laboratory supplies were stored. Findings: 1. Observation by surveyor on July 10, 2024 at 1:20 p.m. revealed the laboratory stored the following supplies in a closet that was not monitored for temperature: a) Greiner bio-one Vacuette Tube 3.5 mL 9NC Coagulation sodium citrate 3.2% High Altitude - manufacturer's storage requirements 4 - 25 degrees Celsius b) BD Vacutainer K2 EDTA - manufacturer's storage requirements 4 - 25 degrees Celsius c) Greiner bio-one Vacuette Tube 5 mL CAT Serum Sep Clot Activator - manufacturer's storage requirements 4 - 25 degrees Celsius d) BD Vacutainer C&S Preservative Urine Tube - manufacturer's storage requirements 4 - 25 degrees Celsius 2. In interview on July 10, 2024 at 2:41 p.m., the Laboratory Director confirmed the laboratory did not monitor the temperature of the closet as identified above.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to document the opened expiration date for hematology quality control (QC) materials as required. Findings: 1. Observation by surveyor during the laboratory tour on July 10, 2024 at 1: 20 p.m. revealed the laboratory utilized Boule Con-Diff Tri-Level quality control (QC) materials for hematology testing on the Medtronic analyzer. 2. Further observation revealed the following vials of QC were in use, but the opened expiration date was not documented: - Boule Con-Diff Low: Lot 22405-01, Manufacturer's expiration date 9/23/24, opened date 7/8/24 - Boule Con-Diff Normal: Lot 22405-02, Manufacturer's expiration date 9/23/24, opened date 7/8/24 - Boule Con-Diff High: Lot 22405-03, Manufacturer's expiration date 9/25/24, opened date 7/8/24 3. Review of the Boule Con-Diff Tri-Level package insert revealed "Open vial stability 14 days after opening when returned to refrigerator after each use." 4. In interview on July 10, 2024 at 3:21 p.m., the Laboratory Director confirmed the laboratory did not document the opened expiration date as identified above.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish corrective action procedures for temperatures outside of the manufacturers' acceptable limits. Findings: 1. Review of the laboratory's policies revealed the laboratory did not include a corrective action procedure for temperatures that exceed manufacturers' limits. 2. In interview on July 10, 2024 at 2:41 p.m., the Laboratory Director confirmed the laboratory did not have a policy on what actions to take when a temperature exceeded the acceptable limits.
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 observation, review of manufacturers' storage requirements and laboratory temperature records, and interview with personnel, the laboratory failed to take corrective action when the room temperature exceeded the manufacturer's acceptable temperature limits for forty-two (42) of one hundred seventy (170) days reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 10, 2024 at 1: 20 p.m. revealed the laboratory stored supplies in the laboratory to include the following: a) Greiner bio-one Vacuette Tube 3.5 mL 9NC Coagulation sodium citrate 3.2% High Altitude - manufacturer's storage requirements 4 - 25 degrees Celsius b) BD Vacutainer K2 EDTA - manufacturer's storage requirements 4 - 25 degrees Celsius c) Copan Transystem Amies W/O CH Plastic Applicator Rayon Tipped - manufacturer's storage requirements 5 - 25 degrees Celsius d) BD Universal Viral Transport for Viral, Chlamydial, Mycoplasmal, and Ureaplasmal Specimens - manufacturer's storage requirements 2 - 25 degrees Celsius 2. Review of the laboratory's temperature records from November 2023 through June 2024 revealed the laboratory failed to maintain the room temperature below 25 degrees Celsius as required by the manufacturers listed above on the following days: a) 11/1/2023 - 32.0 degrees Celsius b) 11/2/2023 - 32.0 degrees Celsius c) 11/3/2023 - 32.0 degrees Celsius d) 11/6/2023 - 32.0 degrees Celsius e) 11/7/2023 - 32.0 degrees Celsius f) 11/8 /2023 - 32.0 degrees Celsius g) 11/9/2023 - 32.0 degrees Celsius h) 11/10/2023 - 32.0 degrees Celsius i) 11/13/2023 - 31.2 degrees Celsius j) 11/14/2023 - 31.8 degrees Celsius k) 11/15/2023 - 32.0 degrees Celsius l) 11/16/2023 - 31.7 degrees Celsius m) 11/17/2023 - 31.6 degrees Celsius n) 11/20/2023 - 29.8 degrees Celsius o) 11/21/2023 - 30.0 degrees Celsius p) 11/22/2023 - 32.0 degrees Celsius q) 11/24/2023 - 32.0 degrees Celsius r) 11/27/2023 - 28.3 degrees Celsius s) 11/28/2023 - 31.5 degrees Celsius t) 11/29/2023 - 29.4 degrees Celsius u) 11/30/2023 - 28.7 degrees Celsius v) 12/1/2023 - 31.1 degrees Celsius w) 12/4/2023 - 32.0 degrees Celsius x) 12/5/2023 - 32.0 degrees Celsius y) 12/6/2023 - 32.0 degrees Celsius z) 12/7/2023 - 32.0 degrees Celsius aa) 12/8/2023 - 32.0 degrees Celsius bb) 12/11/2023 - 32.0 degrees Celsius cc) 12/12/2023 - 29.8 degrees Celsius dd) 12/13/2023 - 31.8 degrees Celsius ee) 12/14 /2023 - 32.0 degrees Celsius ff) 12/15/2023 - 32.0 degrees Celsius gg) 12/18/2023 - 28.7 degrees Celsius hh) 12/19/2023 - 29.0 degrees Celsius ii) 12/20/2023 - 32.0 degrees Celsius jj) 12/21/2023 - 32.0 degrees Celsius kk) 12/22/2023 - 29.3 degrees Celsius ll) 12/26/2023 - 32.0 degrees Celsius mm) 12/27/2023 - 29.8 degrees Celsius nn) 12/28/2023 - 31.8 degrees Celsius oo) 12/29/2023 - 32.0 degrees Celsius pp) 6/24 /2024 - 28.3 degrees Celsius 3. In interview on July 10, 2024 at 2:41 p.m., the Laboratory Director confirmed the laboratory did not perform corrective actions for the room temperature on the days 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 surveyor, record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to monitor the room temperature of the closet where laboratory supplies were stored. Refer to D5413. 2. The laboratory failed to document the open expiration date for hematology quality control (QC) material as required. Refer to D5415.
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 performed and documented when room temperatures exceeded the manufacturers' limits. Refer to D5781.
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. Refer to D5779.