Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0665653	06/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Baton Rouge Clinic - Family Clinic Of Opelousas	3921 I-49 S Service Road, Opelousas, 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 28, 2023 at The Family Clinic, LLC, CLIA ID # 19D0665653. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) form, proficiency testing records, and the laboratory's policy and procedure manual, as well as interview with personnel, the laboratory failed to ensure that proficiency testing (PT) was performed by personnel who routinely perform laboratory testing for nine (9) of nine (9) events reviewed for 2022 and 2023. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) form revealed the laboratory listed the following Testing Personnel: Personnel 1 Personnel 2 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed Personnel 2 tested all PT samples for the following events: a) 2022 Hematology /Coagulation 1st Event b) 2022 Hematology/Coagulation 2nd Event c) 2022 Hematology/Coagulation 3rd Event d) 2022 Chemistry Core 1st Event e) 2022 Chemistry Core 3rd Event f) 2023 Hematology/Coagulation 1st Event g) 2023 Chemistry Core 1st Event h) 2023 Chemistry Core 2nd Event 3. Review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed Personnel 2 performed all routine chemistry samples (CH11-15) for 2022 Chemistry Core 2nd Event. 4. Review of the laboratory policy "Proficiency Testing" revealed "Sample testing will be performed by those who normally test patient samples for that particular method and analyte. 5. In interview on June 28, 2023 at 11:00 a.m., the

	Technical Consultant confirmed the proficiency testing samples were not rotated between testing personnel as required.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policy and procedure manual, and interview with laboratory personnel, the laboratory failed to ensure the policy and procedure manual contained complete quality control policies for chemistry testing. Findings: 1 Observation by surveyors during the laboratory tour on June 28, 2023 at 9: 39 a.m. revealed the laboratory utilized the Envoy 500 + analyzer. 2. Review of the laboratory's policy and procedure manual revealed the following two policies with different instructions for establishing quality control ranges for new lots of chemistry quality control material: a) Procedures for Establishing Means and Ranges for Envoy 500: "Currently the Envoy ranges have been calculated using 5 months of acquired data. Because the ranges for the analytes resulted to be narrow the technical consultant and Laboratory director agreed that it would be advisable to use 3SD for our lab's acceptable ranges. This would minimize false rejection. Also, it has been determined that our 3 SD QC ranges are still narrower than those on the manufacturer's assay sheet, thus capable of detecting instrument error if it occurs. The laboratory director and physicians have reviewed this policy and have agreed that 3 SD are acceptable and does not affect the clinical significance of any lab results." b) Quality Control - General Standards: "For a new lot of control - ...Use the + or - 2SD rule for determining the range." 3. In interview on June 28, 2023 at 10:31 a.m., the Technical Consultant confirmed the instructions in the laboratory policy titled "Procedures for Establishing Means and Ranges for Envoy 500" was not the current practice for establishing ranges for new lots of chemistry quality control material and the policy "Quality Control - General Standards" was the laboratory's current practice.
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 manufacturer's operating manuals, and interview with laboratory personnel, the laboratory failed to monitor the room temperature and humidity of the laboratory where laboratory supplies are stored and testing is performed. Findings: 1. Observation during the laboratory tour on June 28, 2023 at 9: 39 a.m. revealed the laboratory utilized the Envoy 500 +, Beckman Access 2, and Sysmex XN-330 analyzers, as well as stored the following supplies in the laboratory: - BD Vacutainer EDTA Reference 367861 - storage temperature requirement 4 - 25 degrees Celsius -BD Vacutainer SST Reference 367988 - storage temperature requirement 4 - 25 degrees Celsius 2. Further observation during the laboratory tour revealed the laboratory did not monitor the room temperature and humidity of the laboratory. 3. Review of manufacturer's operating manuals revealed the following operating temperature and humidity requirements: - Envoy 500 +: 18 - 32 degrees Celsius, 10% - 90% humidity - Beckman Access 2: 18 - 28 degrees Celsius, 20% to 80% humidity - Sysmex XN-330: 15 - 35 degrees Celsius, 20% - 85% humidity 4. In interview on June 28, 2023 at 1:30 p.m., the Technical Consultant confirmed the laboratory did not monitor the room temperature and humidity of the laboratory.
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, review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2007.
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 laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.
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. Findings: 1. The laboratory failed to ensure the policy and procedure manual contained complete quality control policies for chemistry testing. Refer to D5403. 2. The laboratory failed to monitor the room temperature and humidity of the laboratory where laboratory supplies are stored and testing is performed. Refer to D5413.