Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0665653	05/21/2019
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 conducted at Family Clinic, MD-CLIA ID # 19D0665653 on May 21, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard 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, record review, and interview with personnel, the laboratory failed to have complete performance specification verification studies for the Envoy 500 + Chemistry analyzer. Findings: 1. Observation by surveyor during the laboratory tour on May 21, 2019 revealed the laboratory utilizes the Envoy 500+ analyzer for Chemistry testing to include: Alkaline Phosphatase (ALP), Albumin (ALB), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Blood Urea Nitrogen (BUN), Calcium (CA), Cholesterol (CHOL), Chloride (CL), Carbon Dioxide (CO2), Creatinine (CREA), Direct Bilirubin (DBIL), Glucose (GLUC), High Density Lipoprotein (HDL), Potassium (K+), Sodium (NA), Total Bilirubin (TBIL), Total Protein (TP), and Triglycerides (TRIG) 2. Review of the laboratory's data revealed the following studies performed: a) Precision: day to day, run to run and within run b) Accuracy c) Reportable Range d) Reference Range 3. Further review of the laboratory's data revealed the following information was not included: a) Complete Precision: operator variance 4. In interview on May 21, 2019 at 03:58 pm, the

	Technical Consultant stated she was unaware the studies did not have documentation of personnel performing the precision testing. The Technical Consultant confirmed the performance studies were not complete. 5. Review of the Task 1 & 3 test list provided to surveyor revealed the laboratory performs the following tests annually on the Envoy 500 + Chemistry analyzer: Alkaline Phosphatase (ALP) - 4,954 Albumin (ALB) - 4,954 Alanine Aminotransferase (ALT) - 5,086 Aspartate Aminotransferase (AST) - 5,086 Blood Urea Nitrogen (BUN) - 5,784 Calcium (CA) - 4,954 Cholesterol (CHOL) - 8,743 Chloride (CL) - 5,784 Carbon Dioxide (CO2) - 5,784 Creatinine (CREA) - 5,784 Direct Bilirubin (DBIL) - 5,128 Glucose (GLUC) - 5,862 High Density Lipoprotein (HDL) - 8,743 Potassium (K+) - 5,784 Sodium (NA) - 5,784 Total Bilirubin (TBIL) - 5,089 Total Protein (TP) - 4,954 Triglycerides (TRIG) - 8,743
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to perform and document instrument maintenance as defined by the manufacturer for the Sysmex K-Series Hematology analyzer. Findings: 1. Observation by surveyor during the laboratory tour on May 21, 2019 revealed the laboratory utilized the Sysmex K-Series Hematology analyzer for Complete Blood Count (CBC) testing. 2. Review of the laboratory's Sysmex K-Series Maintenance Log revealed the laboratory performs the following maintenance: a) Weekly Clean SRV Tray b) Monthly Clean Transducer Clean Waste Chamber c) Quarterly Clean SRV 3. Further review of the laboratory's maintenance logs for January 2018 through April 2019 revealed the following month without the required quarterly maintenance performed: a) March 2018 4. In interview on May 21, 2019 at 17:05 pm, Testing Personnel stated the analyzer will not continue to run without the quarterly maintenance being performed. Testing Personnel confirmed the laboratory did not document the quarterly maintenance as required.
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, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.

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 laboratory personnel performed testing as required. Refer to D5429.
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 Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D5429.
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, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.