Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0665653	(X3) Date Survey Completed 07/15/2025
Name of Provider or Supplier Baton Rouge Clinic - Family Clinic Of Opelousas	**Street Address, City, State** 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 at Baton Rouge Clinic - Family Clinic of Opelousas, CLIA ID 19D0665653 on July 15, 2025. Baton Rouge Clinic - Family Clinic of Opelousas was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.801 CONDITION: Enrollment and Testing of Samples 42 CFR 493.1250: CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing; Technical Consultant 42 CFR 493.1421 CONDITION: Laboratories performing moderate complexity testing; Testing Personnel
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation, review of the laboratory's proficiency testing records and test menu, as well as interview with laboratory personnel, the laboratory failed to enroll in a HHS approved proficiency testing program for urine creatinine testing. Findings: 1. Observation by surveyor during the laboratory tour on July 15, 2025 at 9:21 a.m. revealed the laboratory utilized the DCA Vantage analyzer for urine creatinine testing. 2. Review of the laboratory's proficiency testing records from January 2024 to June 2025 revealed the laboratory did not have proficiency testing records for urine

	creatinine. 3. In interview on July 15, 2025 at 11:08 a.m., Personnel 3 stated the laboratory was under the impression that creatinine testing on the DCA Vantage was waived. She confirmed the laboratory was not enrolled in a HHS approved proficiency testing program for urine creatinine as identified above.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form (Laboratory Personnel Report), policies, and personnel records; as well as interview with personnel, the laboratory failed to follow their competency assessment policy for three (3) of three (3) personnel serving as Technical Consultants. Findings: 1. Review of the laboratory's CMS-209 form revealed the following personnel served as Technical Consultants: a) Personnel 2 b) Personnel 3 c) Personnel 4 2. Review of the laboratory's policy "Technical Consultant" revealed "The Technical Consultant will be evaluated at least 6 months and 12 months post hire and annually thereafter for compliance with these responsibilities by the Medical Director as evidenced by review of monthly meeting notes, review of all quality control and quality assurance, review of all staff competency reports and evaluations, review of all policies and procedures, review of incident reports, review of proficiency testing." 3. In interview on July 15, 2025 at 10: 38 a.m., Personnel 3 stated she and Personnel 4 served as Technical Consultants beginning in January 2024 and Personnel 2 served as Technical Consultant beginning in July 2024. 4. Review of personnel records revealed competency assessments for the personnel identified above were not performed as required by the laboratory as follows: a) Personnel 2 - Competency assessment due December 2024 was not performed and July 2025 competency assessment was not signed by the Laboratory Director. b) Personnel 3 - Competency assessment due June 2024 and January 2025 was not performed. Competency assessment was performed July 2025. c) Personnel 3 - Competency assessment due June 2024 and January 2025 was not performed. Competency assessment was performed July 2025. 5. In interview on July 15, 2025 at 10:52 a.m., Personnel 3 confirmed competency assessments for the Technical Consultants were not performed as required by the laboratory.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's proficiency testing (PT) and quality assurance records, as well as interview with personnel, the laboratory failed to verify the accuracy of performance for microalbumin testing at least twice per year. Findings: 1. Observation by surveyor during the laboratory tour on July 15, 2025 at 9: 21 a.m. revealed the laboratory utilized the DCA Vantage analyzer for microalbumin testing. 2. Review of the laboratory's proficiency testing and quality assurance records

	from January 2024 through June 2025 revealed the laboratory failed to provide documentation of verification of the accuracy of performance at least twice annually for microalbumin testing. 3. In interview on July 15, 2025 at 11:08 a.m., Personnel 3 stated the laboratory believed microalbumin testing on the DCA Vantage was waived. She confirmed the laboratory did not verify the accuracy of microalbumin testing twice per year as identified above.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory failed to ensure quality of testing within the analytic systems. Findings: 1. The laboratory failed to establish quality control (QC) procedures for microalbumin and urine creatinine testing. Refer to D5441. 2. The laboratory failed to perform two (2) levels of controls for microalbumin and creatinine testing on the DCA Vantage analyzer for twenty-eight (28) of twenty-eight (28) days reviewed. Refer to D5447.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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, review of the laboratory's maintenance logs, and interview with laboratory personnel, the laboratory failed to ensure monthly maintenance was performed on the Envoy 500+ analyzer as required by the manufacturer for one (1) of seventeen (17) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 15, 2025 at 9:21 a.m. revealed the laboratory utilized the Envoy 500+ analyzer for routine chemistry testing. 2. Review of the manufacturer's operator's "Envoy 500+ Operator Manual" section "Maintenance" revealed the following: * "Monthly" - "Replace ISE Ground By-Pass Tube" - "Export Quality Control Data" 3. Review of the laboratory's maintenance logs for the Envoy analyzer revealed the laboratory did not document performance of monthly task of "Replace ISE Ground ByPass Tubing" in November 2024. 4. In interview on July 15, 2025 at 2: 45 p.m., Personnel 2 confirmed the laboratory did not document monthly maintenance as identified above.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The

	laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on observation, review of the manufacturer's package insert and the laboratory's policies, and interview with laboratory personnel, the laboratory failed to establish quality control (QC) procedures for microalbumin and urine creatinine testing. Findings: 1. Observation by surveyor during the laboratory tour on July 15, 2025 at 9: 21 a.m. revealed the laboratory utilized the DCA Vantage analyzer for microalbumin and urine creatinine testing. 2. Review of the manufacturer's instructions for use "Siemens DCA Systems Microalbumin/Creatinine Reagent Kit" section "Quality Control" revealed the following: * "Run quality control specimens under the following conditions: - At regular intervals determined by laboratory procedures - With each new lot of reagents - Each time a calibration card is scanned - To train and confirm performance acceptability for new analysts - When results do not match the patient's clinical conditions or symptoms." 3. Review of the laboratory's policies revealed the laboratory did not have a QC policy for performance of external QC on the DCA Vantage. 4. In interview on July 15, 2025 at 3 p.m., Personnel 2 stated the laboratory did not perform external quality control for testing on the DCA Vantage because they thought the testing was waived. She confirmed the laboratory did not have a policy for performance of external QC on the DCA Vantage for microalbumin and urine creatinine testing.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on observation; review of the manufacturer's package insert, laboratory policies, quality control (QC) records, and patient test records; and interview with personnel, the laboratory failed to perform two (2) levels of controls for microalbumin and creatinine testing on the DCA Vantage analyzer for twenty-eight (28) of twenty-eight (28) days reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 15, 2025 at 9:21 a.m. revealed the laboratory utilized the DCA Vantage analyzer for microalbumin and urine creatinine testing. 2. Review of the manufacturer's instructions for use "Siemens DCA Systems Microalbumin/Creatinine Reagent Kit" section "Quality Control" revealed the following: * "Run quality control specimens under the following conditions: - At regular intervals determined by laboratory procedures - With each new lot of reagents - Each time a calibration card is scanned - To train and confirm performance acceptability for new analysts - When results do not match the patient's clinical conditions or symptoms." 3. Review of the laboratory's policies revealed the laboratory did not have a QC policy for the DCA Vantage. 4. Review of the laboratory's quality control records from June 4, 2025 through July 15, 2025 revealed the laboratory did not perform two (2) levels of QC

	before patient testing on the following dates: June 4, 2025 June 5, 2025 June 6, 2025 June 9, 2025 June 10, 2025 June 11, 2025 June 12, 2025 June 13, 2025 June 16, 2025 June 17, 2025 June 18, 2025 June 19, 2025 June 20, 2025 June 23, 2025 June 24, 2025 June 25, 2025 June 26, 2025 June 30, 2025 July 1, 2025 July 2, 2025 July 3, 2025 July 7, 2025 July 8, 2025 July 9, 2025 July 10, 2025 July 11, 2025 July 14, 2025 July 15, 2025 5. Review of a patient test logs from June 4, 2025 through July 15, 2025 revealed the following twenty-eight (28) randomly selected patients were tested without documentation of QC: June 4, 2025 - Patient ID 91663 June 5, 2025 - Patient ID 91712 June 6, 2025 - Patient ID 91757 June 9, 2025 - Patient ID 91813 June 10, 2025 - Patient ID 91846 June 11, 2025 - Patient ID 91942 June 12, 2025 - Patient ID 91732 June 13, 2025 - Patient ID 91985 June 16, 2025 - Patient ID 92091 June 17, 2025 - Patient ID 91923 June 18, 2025 - Patient ID 93173 June 19, 2025 - Patient ID 93216 June 20, 2025 - Patient ID 93357 June 23, 2025 - Patient ID 93419 June 24, 2025 - Patient ID 93530 June 25, 2025 - Patient ID 93532 June 26, 2025 - Patient ID 93637 June 30, 2025 - Patient ID 93737 July 1, 2025 - Patient ID 97365 July 2, 2025 - Patient ID 93808 July 3, 2025 - Patient ID 93877 July 7, 2025 - Patient ID 93887 July 8, 2025 - Patient ID 93962 July 9, 2025 - Patient ID 94026 July 10, 2025 - Patient ID 94091 July 11, 2025 - Patient ID 94120 July 14, 2025 - Patient ID 94242 July 15, 2025 - Patient ID 94281 6. Further review of patient test logs from June 4, 2025 through July 15, 2025 revealed a total of seventy-five (75) patients were tested without QC performance. 7. In interview on July 15, 2025 at 3 p.m., Personnel 2 confirmed QC was not performed as identified above. She stated the laboratory thought testing on DCA Vantage was waived and did not require external QC.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 2. The Laboratory Director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. Refer to D6015. 3. The Laboratory Director failed to ensure the quality control and assessment programs were maintained to assure the quality of laboratory testing. Refer to D6020. 4. The Laboratory Director failed to ensure the laboratory employed testing personnel that met the licensure requirements. Refer to D6064.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (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 D5217.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. Refer to D2000.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the quality control and assessment programs were maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to establish quality control (QC) procedure for microalbumin and urine creatinine testing. Refer to D5441. 2. The laboratory failed to perform two (2) levels of controls for microalbumin and creatinine testing on the DCA Vantage analyzer for twenty-eight (28) of twenty-eight (28) days reviewed. Refer to D5447.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory employed testing personnel that met the licensure requirements. Refer to D6064.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (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 complete policies and procedures for assessing competency of the Technical Consultants were maintained. Refer to D5209.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultants failed to ensure enrollment in an HHS approved proficiency testing program. Refer to D6041. 3. The Technical Consultants failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. 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. Findings: 1. The laboratory failed to verify the accuracy of performance for microalbumin testing at least twice per year. Refer to D5217. 2. The laboratory failed

	to ensure monthly maintenance was performed on the Envoy 500+ analyzer as required by the manufacturer for one (1) of seventeen (17) months reviewed. Refer to D5429.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to ensure enrollment in an HHS approved proficiency testing program. Refer to D2000.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultants failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to establish quality control (QC) procedure for microalbumin and urine creatinine testing. Refer to D5441. 2. The laboratory failed to perform two (2) levels of controls for microalbumin and creatinine testing on the DCA Vantage analyzer for twenty-eight (28) of twenty-eight (28) days reviewed. Refer to D5447.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 (Laboratory Personnel Report) form, policies, and personnel records; as well as interview with personnel, the Technical Consultants failed to ensure the assessment of test performance through previously analyzed, internal blind samples, or external proficiency testing samples for two (2) of two (2) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 revealed the following testing personnel: a) Personnel 5 b) Personnel 6 2. Review of the laboratory's "Competency Assessment Policy" revealed six (6) criteria for competency assessment which included "Assessment of test performance through previously analyzed specimens, internal blind samples, or external proficiency testing samples." 3. Review of the laboratory's personnel records for Personnel 5 and

	Personnel 6 revealed the laboratory performed competency assessments but failed to provide documentation to support the performance of blind sample testing for urine creatinine and microalbumin testing on the DCA Vantage. 4. In interview on July 15, 2025 at 11:12 a.m., Personnel 2 confirmed competency assessment with blind samples was not performed as identified above.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with personnel, the laboratory failed to provide documentation to ensure all testing personnel met licensure requirements. Refer to D6064.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderate complexity testing must-- (a) possess a current license issued by the State in which the laboratory is located, if such licensing is required; and This STANDARD is not met as evidenced by: Based on observation; review of the laboratory's CMS-209 (Laboratory Personnel Report) form, patient test records, and personnel records; as well as interview with personnel, the laboratory failed to ensure testing personnel met the state of Louisiana licensure requirement for one (1) of three (3) testing personnel reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 15, 2025 at 9:21 a.m. revealed the laboratory utilized the DCA Vantage analyzer for microalbumin and urine creatinine testing. 2. Review of the laboratory's CMS-209 revealed that the following testing personnel performed moderate complexity testing: a) Personnel 5 b) Personnel 6 3. Review of June 2025 patient test records for urine creatinine and microalbumin testing performed on the DCA Vantage revealed one (1) personnel not listed on the CMS-209 performed testing on the following patient specimens: * 6/09 /2025 - Patient 91813 * 6/16/2025 - Patient 92091 * 6/18/2025 - Patient 93173 * 6/19 /2025 - Patient 93263 * 6/19/2025 - Patient 93275 * 6/20/2025 - Patient 93353 * 6/20 /2025 - Patient 93357 * 6/23/2025 - Patient 93419 * 6/23/2025 - Patient 93435 * 6/25 /2025 - Patient 93532 * 6/26/2025 - Patient 93637 4. Review of personnel records for the personnel that performed testing on the patient specimens identified above revealed the laboratory did not include a state license covering moderate complexity testing issued by Louisiana State Board of Medical Examiners (LSBME). 5. In interview on July 15, 2025 at 2:56 p.m., Personnel 2 stated the laboratory believed testing performed on the DCA Vantage analyzer was waived. She confirmed the patient testing identified above was performed by testing personnel that did not have a Louisiana State laboratory license.