Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0461162	01/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Acadia Laboratory Llc	715 North Eastern Avenue, Crowley, 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 Certification survey was performed on January 26, 2023 at Acadia Laboratory, LLC, CLIA ID 19D0461162. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of policies, quality control (QC) records, and interview with personnel, the laboratory failed to retain QC raw data to support QC range adjustments for Chemistry testing for at least two (2) years as required. Findings: 1. Review of the laboratory's "Quality Control" policy under the "Record Retention" section revealed "Analytic systems records-Retain quality control and patient test records (including instrument printouts, if applicable) and all analytic systems activities for at least 2 years." 2. Review of the laboratory's "Determination of Target Values Multiqual Unassayed Lot # 56691/56693" document revealed a summary chart that included the "mean, 2 SD, and group mean" of Level 1 and 3 for chemistry analytes. 3. Further review of the laboratory's "Determination of Target Values Multiqual Unassayed Lot # 56691/56693" document revealed the following statement "6 month re-assessment of Multiqual values based on cumulative data. 6-8-22." The document did not include the supporting raw data that included, but not limited to, the six (6) months of data assessed. 4. In interview on January 26, 2023 at 1:45 pm, Technical Consultant 2 stated he did not retain data for QC adjustments.
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 policies and interview with personnel, the laboratory failed to establish a complete written competency assessment policy for Technical Consultants. Findings: 1. Review of the laboratory's "Competency Assessment Policy" revealed the laboratory did not include performance of competency assessment for the Technical Consultants, to include, but not limited to the frequency. 2. In interview on January 26, 2023 at 11:38 am, Technical Consultant 1 confirmed the laboratory's policies did not address competency assessment for Technical Consultants.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written quality control procedure for blood culture bottles that included visual inspections. 2. In interview on January 26, 2023 at 4:33 pm, Technical Consultant 1 confirmed the laboratory did not have a procedure for visual inspections of blood culture bottles.
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 review of the laboratory's policies and procedures, quality control logs, and interview with personnel, the laboratory failed to ensure the policy and procedure manual contained complete quality control policies for syphilis testing. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include detailed quality control instructions that included, but not limited to, type, number, identity, and frequency of performance for syphilis testing. 2. In interview on January 26, 2023 at 3:19 pm, Technical Consultant 1 confirmed the laboratory's policies did not include the identified information for syphilis testing.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, test menu, and interview with personnel, the laboratory failed to document the date of discontinuance for the Activated Partial Thromboplastin Time (APTT) test. Findings: 1. Review of the laboratory's "Hemostasis Policy and and Procedure" revealed procedures related to APTT testing. 2. Review of the laboratory's test menu revealed the laboratory did not include APTT testing. 3. In interview on January 26, 2023 at 2:47 pm, Technical Consultant 2 stated APTT testing was discontinued in mid October 2022. Technical Consultant 2 confirmed the laboratory's policies did not include the date of discontinuance for APTT testing.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on observation by surveyor, review of policies, manufacturer's instrument manual, donor questionnaires, normal patient mean study, test menu, and interview with personnel, the laboratory failed to utilize acceptable patient donors per manufacturer requirements for Prothrombin Time (PT) normal patient mean studies. Findings: 1. Observation by surveyor during the laboratory tour on January 26, 2023 at 9:58 am revealed the laboratory utilized the Sysmex CA-600 instrument for Prothrombin Time (PT) and International Normalized Ratio (INR) testing. 2. Review of the laboratory's "Hemostasis Policy and Procedure" under "Establishing A New Normal Patient Mean" section revealed " 20 normal individuals. 10 male, 10 female. Medication history: A signed statement from each patient stating no aspirin, no hormones and no herbal supplements." 3. Review of the laboratory's "Reference Study Questionnaire" revealed the following questions: a) "Do you consider yourself to be

	healthy?" b) "Have you recently been ill?" c) "Details of recent illness" d) "Are you taking any medications?" e) "Are you taking any medications that include aspirin?" f) "Please list all medications" g) "Do you have a medical condition that requires ongoing treatment by a physician? If yes, please describe" 4. Review of the "Seimens Healthcare Diagnostics Sysmex CA-600 Series System Installation Package" under the "Reference Interval Verification of Reference Interval Section" revealed "Donors must be from a healthy population (no known pathological condition; no pre-surgical or hospitalized patients). Donors should not hake any medications, including aspirin." 5. Review of the laboratory's normal patient mean study (performed August 11, 2022) and donor questionnaires for Innovin lot 564604B revealed the laboratory utilized the following three (3) unacceptable donors: Donor 278641: The donor did not answer questions related to medications (Questions C through G listed above) Donor: 278660: The donor documented the following responses a) Do you consider yourself to be healthy? "Somewhat" b) Are you taking any medications? "No" c) Are you taking any medications that include aspirin? "Yes, non-aspirin 325 mg" d) "Yes", to having an on-going medical condition that requires on-going treatment; however, no description was provided Donor 278774: The donor listed "Baby Aspirin 1 X D" as medications taken 6. In interview on January 26, 2023 at 2:35 pm, Technical Consultant 2 stated it must have been an oversight using the unacceptable donors. 7. Review of the laboratory's test menu revealed the laboratory performs 1,083 PT/INR tests annually. II. Based on observation by surveyor, review of the laboratory's policies, manufacturer's package insert, and interview with personnel, the laboratory failed to document the visual inspection of blood culture bottles per manufacturer's requirements. Findings: 1. Observation by surveyor during the laboratory tour on January 26, 2023 at 9:58 am revealed the laboratory utilizes BacT/ALERT Adult Blood Culture Collection Kits (lot number 2205160030). 2. Review of the laboratory's policies revealed the laboratory did not have a policy related to visual inspection of blood culture bottles. 3. Review of the manufacturer's package insert revealed "Inspect each blood culture bottle before use to ensure integrity of bottle and sensor on bottom of bottle is intact. The sensor is normally a uniform grayish-green color and a yellow color would indicate contamination of the medium. Discard any bottle found to be damaged or with a sensor that is yellow." 4. In interview on January 26, 2023 at 4:33 pm, Technical Consultant 1 confirmed the laboratory does not document visual inspections of the blood culture bottles received.
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' requirements, and interview with personnel, the laboratory failed to monitor the room temperature of storage area where blood collection supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on January 26, 2023 at 9:58 am revealed the following items were stored in room without temperature monitoring: a) BD

	Vacutainer Buffered Na Citrate blood collection tubes, Quantity: one and a half (1 1 /2) packs b) BD Vacutainer Serum blood collection tubes, Lot 2314732, Quantity: one (1) pack c) BD Vacutainer SST blood collection tubes, Lot 2321121, Quantity: three (3) packs d) Vacuette Drawing needles, Lot 22B28C e) Vacuette K2 K2EDTA blood collection tubes, Quantity: twenty (20) tubes 2. Review of the manufacturers' storage requirements for the identified blood collection supplies revealed the following: a) BD Vacutainer blood collection tubes: storage requirement 4-25 degrees Celsius b) Vacuette Drawing needles: storage requirement 4-30 degrees Celsius c) Vacuette blood collection tubes: storage requirement 4-25 degrees Celsius 3. In interview on January 26, 2023 at 10:55 am, Technical Consultant 2 confirmed the temperature of the room where blood collection supplies were stored was not monitored.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of policies, quality control (QC) records, patient test records, and interview with personnel, the laboratory failed to document external reactive and non-reactive controls for rheumatoid factor (RF) testing for one (1) of four (4) test dates. Findings: 1. Observation by surveyor during the laboratory tour on January 26, 2023 at 9:58 am revealed the laboratory utilizes the ASI RF Direct Slide test for RF testing. 2. Review of the laboratory's "ASI RF Direct Slide Test" policy under the "Quality Control" section revealed "REACTIVE and NONREACTIVE CONTROLS should be included in each test run to confirm optimal reactivity of the LATEX REAGENT." 3. Review of quality control and patient test records from July 2022 through December 2022 revealed quality control was not documented on December 5, 2022 for RF testing. 4. Further review of patient test records for December 5, 2022 revealed the following five (5) samples were reported without quality control performance: ID 287695 ID 287697 ID 287698 ID 287699 ID 287701 5. In interview on January 26, 2023 at 3:07 pm, Technical Consultant 2 confirmed the laboratory did not have documentation of performance of external controls prior to RF testing on the identified date.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, quality control (QC) logs, and interview with personnel, the laboratory failed to document the sample type of the QC for human chorionic gonadotropin (hCG) testing. Findings: 1. Review of the laboratory's test menu revealed the laboratory utilizes the Icon 25 hCG test kit for

	serum and urine testing 2. Review of the laboratory's quality control logs for hCG testing revealed the sample type (serum or urine) of the controls were not indicated. 3. In interview on January 26, 2023 at 3:45 pm, Technical Consultant 2 confirmed the laboratory does not document the sample type of control performed for hCG.
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 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 retain QC raw data to support QC range adjustments for at least two (2) years for Chemistry testing as required. Refer to D3031. 2. The laboratory failed to utilize acceptable patient donors per manufacturer requirements for Prothrombin Time (PT) normal patient mean studies. Refer to D5411 I. 3. The laboratory failed to document the visual inspection of blood culture bottles per manufacturer's requirements. Refer to D5411 II. 4. The laboratory failed to monitor the room temperature of storage area where blood collection supplies were stored. Refer to D5413.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to document external reactive and non-reactive controls for rheumatoid factor (RF) testing for one (1) of four (4) test dates. Refer to D5449. 2. The laboratory failed to document the sample type of the QC for human chorionic gonadotropin (hCG) testing. Refer to D5481.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(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 personnel competency were established. Findings: 1. The laboratory failed to establish complete written competency assessment policies for Technical Consultants. Refer to D5209. 2. The Technical Consultant failed to evaluate the competency of one (1) of two (2) Testing Personnel in 2022. Refer to D6046.
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. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to ensure the policy and procedure manual contained complete quality control policies for syphilis testing. Refer to D5403. 3. The laboratory failed to document the date of discontinuance for the Activated Partial Thromboplastin Time (APTT) test. Refer to D5409.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by:

	Based on review of the CMS 209 (Laboratory Personnel Report) form, laboratory's policies, personnel records, and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Technical Consultants. Findings: 1. Review of the laboratory's CMS 209 form revealed the laboratory has two (2) Technical Consultants. 2. Review of the laboratory's policies and personnel records revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities to Technical Consultants. 3. In interview on January 26, 2023 at 11:27 am, Technical Consultant 1 confirmed there was not a written delegation of duties for the Technical Consultants. Based on review of the laboratory's policy and procedure manual, personnel records and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Clinical Consultant. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities for the Clinical Consultant. 2. In interview on March 29, 2022 at 11:03 am, the Laboratory Director confirmed she did not have written documentation of delegation of responsibilities for the Clinical Consultant.
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 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 establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to ensure the policy and procedure manual contained complete quality control policies for syphilis testing. Refer to D5403. 3. The laboratory failed to document the date of discontinuance for the Activated Partial Thromboplastin Time (APTT) test. Refer to D5409. 4. The laboratory failed to utilize acceptable patient donors per manufacturer requirements for Prothrombin Time (PT) normal patient mean studies. Refer to D5411 I. 5. The laboratory failed to document the visual inspection of blood culture bottles per manufacturer's requirements. Refer to D5411 II. 6. The laboratory failed to monitor the room temperature of storage area where blood collection supplies were stored. Refer to D5413.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (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 record review and interview with personnel, the Technical Consultants failed to ensure the quality control program was established and maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to retain QC raw data to support QC range adjustments for Chemistry testing for at least two (2) years

	as required. Refer to D3031. 2. The laboratory failed to document external reactive and non-reactive controls for rheumatoid factor (RF) testing for one (1) of four (4) test dates. Refer to D5449. 3. The laboratory failed to document the sample type of the QC for human chorionic gonadotropin (hCG) testing. Refer to D5481.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) form, personnel records, and interview with personnel, the Technical Consultant failed to evaluate the competency of one (1) of two (2) Testing Personnel in 2022. Findings: 1. Review of the laboratory's CMS 209 form revealed the laboratory has two (2) Testing Personnel. 2. Review of personnel records for Technical Consultant 2, who also serves as Testing Personnel, revealed his 2022 competency assessment was performed by Testing Personnel 1, not Technical Consultant 1. 3. In interview on January 26, 2023 at 11:37 am, Technical Consultant 1 confirmed the 2022 Testing Personnel competency assessment for Technical Consultant 2 was not performed by herself or the Laboratory Director.