

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0461162	(X3) Date Survey Completed 07/21/2026
Name of Provider or Supplier Acadia Laboratory Llc	Street Address, City, State 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 Recertification survey was performed at Acadia Laboratory, LLC, CLIA ID 19D0461162, on July 21, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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, personnel records, and interview with personnel, the laboratory failed to follow their established competency policy for competency assessments for one (1) of two (2) Technical Consultants reviewed. Findings: 1. Review of the laboratory's "Competency Assessment" policy revealed "All testing personnel in the laboratory will be evaluated and recorded indicating that all individuals are competent to perform their duties." 2. Review of the laboratory's job responsibilities revealed "Technical Consultants are competency assessed once per employment or with change in laboratory directorship or when deemed necessary by the Lab Director." 3. Review of personnel records for Technical Consultant 2, hired in 2025, revealed a "Technical Supervisor/Technical Consultant Competency Assessment and Delegation of Duties Performed" form that stated "A checkmark or initials in the Director Review column indicates the individual fulfills the required responsibility and has been delegated to perform the task." 4. Further review of the "Technical Supervisor/Technical Consultant Competency Assessment and Delegation of Duties Performed" form for Technical Consultant 2 revealed the Laboratory Director did not use checkmarks or initial the "Director Review" column to assess competency. The "Director Review" column was blank. The Laboratory Director signed the form "10-3-25." 5. In interview on July 21, 2026 at 10:08 am, Technical

	Consultant 1 confirmed the competency assessment form for Technical Consultant 2 was not completed per laboratory policy. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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, quality control records, and interview with personnel, the laboratory failed to update quality control policies for Complete Blood Count (CBC) testing on the Sysmex XN-550 instrument. Findings: 1. Review of the laboratory's policies and quality control records revealed the laboratory is enrolled in Sysmex's BeyondCare Quality Monitoring (BCQM) program. 2. Further review of the laboratory's policies revealed the laboratory did not update their quality control procedures to include detailed written procedures for monitoring the manufacturer's daily adjusted quality control ranges following the implementation of the updated BCQM. 3. In interview on July 21, 2026 at 11:24 am, Technical Consultant 1 stated the laboratory was not aware the manufacturer had made changes to the quality control procedures. Technical Consultant 1 confirmed the laboratory did not have detailed written procedures for monitoring the manufacturer's adjusted quality control ranges.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(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 label three

	(3) of three (3) glass staining jars with the identity of the contents, lot numbers, and/or expiration dates. Findings: 1. Observation during the laboratory tour on July 21, 2026 at 9:13 am revealed stains in three (3) unlabeled glass staining jars without the identity of the contents, lot numbers, and/or expiration dates: 2. In interview on July 21, 2026 at 9:37 am, Technical Consultant 1 stated the three (3) unlabeled glass staining jars contained stains from the Quick III Stain Set. Technical Consultant 1 confirmed the laboratory did not label the identified staining jars with the identity of the contents, lot numbers, and/or expiration dates.
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 laboratory's policies, manufacturer document, quality control records, and interview with personnel, the laboratory failed to have established quality control procedures for Complete Blood Count (CBC) testing on the Sysmex XN-550 instrument. Findings: 1. Observation during the laboratory tour on July 21, 2026 at 9:13 am revealed the laboratory utilizes the Sysmex XN-550 for CBC testing. 2. Review of the laboratory's quality control records revealed the laboratory is enrolled in Sysmex's BeyondCare Quality Monitor (BCQM) program. Further review of the laboratory's quality control records revealed the target for each CBC analyte was adjusted daily by the manufacturer. 3. Review the laboratory's policies revealed the laboratory did not update their quality control policies for Complete Blood Count (CBC) testing on the Sysmex XN-550 instrument. Refer to D5403. 4. Review of the manufacturer's memo "Product Notification BeyondCare Quality Monitor (BCQM) v1.3 Additional Notification" revealed "BCQM and Insight for Sysmex XN-and XN-L Series hematology analyzers will reach end-of-life on April 24, 2026. Beginning March 16, 2026, BCQM will serve as the primary quality system for supported analyzers, and all users must fully transition to BCQM v1.3. BCQM and Insight User Actions: Ensure BCQM v1.3 is actively being used, log in using Customer Resource (CRC) credentials, and complete BCQM training through self-enrollment via Caresphere Academy." 5. In interview on July 21, 2026 at 11:24 am, Technical Consultant 1 stated the laboratory was not aware the manufacturer had made changes to the quality control procedures. Technical Consultant 1 confirmed the laboratory had not established quality control procedures to reflect the manufacturer changes.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on observation, review of records, and interview with personnel, the laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to update quality control policies for Complete Blood Count (CBC) testing on the Sysmex XN-550 instrument. Findings: Refer to D5403. 2. The laboratory failed to label three (3) of three (3) glass staining jars with the identity of the contents, lot numbers, and/or expiration dates. Refer to D5415. 3. The laboratory failed to have established quality control procedures for Complete Blood Count (CBC) testing on the Sysmex XN-550 instrument. Refer to D5441.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient final test reports and interview with personnel, the laboratory failed to report race-free values for the estimated glomerular filtration rate (eGFR) calculations for four (4) of four (4) randomly selected patients. Findings 1. Review of random selection of patient final reports with eGFR results revealed race was included. 2. Further review of the random selection of patient final reports revealed the following four (4) patients had race based eGFR results reported: December 1, 2025: Patient 372735 December 3, 2025: Patient 372977 April 28, 2026: Patient 383957 July 16, 2026: Patient 390678 3. In interview on July 21, 2026 at 12: 58 pm, Technical Consultant 1 confirmed the laboratory included information for race based calculation for eGFR on patient final reports.
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 observation and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5415.
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 record review and interview with personnel, the Laboratory Director failed to ensure complete quality control and assessment programs were established to assure the quality of laboratory testing results. Findings: 1. The laboratory failed to update quality control policies for Complete Blood Count (CBC) testing on the Sysmex XN-550 instrument. Findings: Refer to D5403. 2. The laboratory failed to have established quality control procedures for Complete Blood Count (CBC) testing on the Sysmex XN-550 instrument. Refer to D5441. 3. The laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.
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 personnel competency were maintained. Refer to D5209.
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 and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D5415.
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 record review and interview with personnel, the Technical Consultants failed to ensure that a complete quality control program was established to assure the

	quality of laboratory testing. Findings: 1. The laboratory failed to update quality control policies for Complete Blood Count (CBC) testing on the Sysmex XN-550 instrument. Findings: Refer to D5403. 2. The laboratory failed to have established quality control procedures for Complete Blood Count (CBC) testing on the Sysmex XN-550 instrument. Refer to D5441.
D6061	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1419(c) (c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and This STANDARD is not met as evidenced by: Based on review of random selection of patient final reports and interview with personnel, the Clinical Consultant failed to ensure race-free estimated glomerular filtration rate (eGFR) calculations were reported. Refer to D5807.