Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0696771	07/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Northern Louisiana Medical Center	401 East Vaughn Street, Ruston, 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 Northern Louisiana Medical Center -CLIA ID # 19D0696771 on July 21, 2025 through July 24, 2025. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard level deficiencies were cited.
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: I. Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to maintain complete policies and procedures for

	Microbiology. Findings: 1. Review of all laboratory policy and procedure manuals revealed the laboratory did not include complete policies and procedures for Microbiology including but not limited to: *Step-by-step performance of cultures for all specimen types to include: - Specimen stability - Specimen rejection criteria - Pathogens - Normal flora - Mixed flora - Biochemical tests and documentation of reactions, disc susceptibility zone measurements, etc. - Quantitation if applicable - Interpretation and reporting of results * Gram stain to include the detection of inadequately prepared gram stain slides. 2. In interview on July 22, 2025 at 3:45 p.m., Technical Supervisor 4 confirmed the laboratory's policies did not have complete information as identified above. II. Based on observation, review of the laboratory's policies, and interview with laboratory personnel, the laboratory failed to ensure the policy and procedure manual contained complete quality control policies for Hematology. Findings: 1. Observation by surveyors during the laboratory tour on July 22, 2025 at 9:07 a.m. revealed the laboratory utilized a Fisherbrand Horizon 6 Flex centrifuge for centrifugation of coagulation specimens. 2. Review of the laboratory's policies "Coagulation Centrifuge Procedure," "CA-600 PTT Testing Procedure," "CA-600 Prothrombin Time (PT) Testing Procedure" and "D-Dimer CA-600 Procedure" revealed the policies contained the following conflicting instructions for centrifugation of coagulation specimens: a) "Coagulation Centrifuge Procedure" stated the following: "For the coagulation tubes used in our lab, the correct settings validated for the centrifuge are: RCF: 1650g Spin Time: 10 minutes" b) "CA-600 PTT Testing Procedure," "CA-600 Prothrombin Time (PT) Testing Procedure" and "D-Dimer CA-600 Procedure" stated the following: "Centrifuge the capped specimen tube for a minimum of 15 minutes at 1500 g to consistently produce platelet poor plasma..." 3. In interview on July 23, 2025 at 10:45 a.m., Technical Supervisor 1 stated the laboratory followed the speed and time included in the "Coagulation Centrifuge Procedure."
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: I. Based on review of the laboratory's temperature records and interview with personnel, the laboratory failed to document the refrigerator temperature for one (1) of five hundred sixteen (516) days reviewed. Findings: 1. Review of the laboratory's "Refrigerator Temperature Record" for the Hematology Follett M38844 refrigerator revealed "Record current temperature and verify recordings are within acceptable range." 2. Review of the laboratory's hematology refrigerator temperature records from January 2024 through May 2025 revealed the laboratory did not document the temperature of the refrigerator on May 28, 2025. 3. In interview on July 24, 2025 at 11 a.m., Technical Supervisor 1 confirmed the laboratory did not document the temperature of the refrigerator on the date identified above. II. Based on review of the laboratory's humidity records and interview with personnel, the laboratory failed to

	document the humidity for one (1) of five hundred sixteen (516) days reviewed. Findings: 1. Review of the laboratory's "Room Temperature and Humidity Form" for the "Hematology/Coag" area revealed "Record current temperature and humidity. Verify recordings are within acceptable range." 2. Review of the laboratory's hematology/coagulation humidity records from January 2024 through May 2025 revealed the laboratory did not document the humidity on April 27, 2025. 3. In interview on July 24, 2025 at 10:13 a.m., Technical Supervisor 1 confirmed the laboratory did not document the humidity on the date identified above.
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 manufacturer's operator's manual, the laboratory's policies, and the laboratory's maintenance records; as well as interview with personnel, the laboratory failed to perform maintenance on the Sysmex CA-600 for two (2) of seventeen (17) months reviewed. Findings: 1. Observation by surveyors during the laboratory tour on July 22, 2025 at 9:07 a.m. revealed the laboratory utilized a Sysmex CA-600 for coagulation testing. 2. Review of the manufacturer's operator's manual "Sysmex Instructions for Use Automated Blood Coagulation Analyzer CA-600 series" section "Maintenance and Supplies Replacement" revealed "The main unit includes a filter to block the entry of dust. The filter should be cleaned regularly." 3. Review of the laboratory's policy "CA-600 Instrument Maintenance Procedure" section "Quarterly Maintenance" revealed "Inspect and clean filter." 4. Review of the laboratory's maintenance records from January 2024 through May 2025 revealed the laboratory did not document quarterly inspection and cleaning of the filter when due as follows: * April 2024 (last performed January 2024) * August 2024 (last performed May 2024) 5. In interview on July 23, 2025 at 12:15 p.m., Technical Supervisor 1 confirmed maintenance was not performed as identified above.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers 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 observation; review of the manufacturer's package inserts, patient test records, and the laboratory's quality control records; as well as interview with personnel, the laboratory failed to document purity plate results for bacteriology identification and antibiotic susceptibility testing. Findings: 1. Observation by surveyors during the laboratory tour on July 22, 2025 at 9:07 a.m. revealed the laboratory utilized a Microscan Walkaway analyzer for bacteriology identification and antibiotic susceptibility testing. 2. Review of the manufacturer's package inserts "Microscan Gram Negative Procedure Manual" and "Microscan Gram Positive Procedure Manual" section "Panel Rehydration/Incoculation" revealed purity plates are used "To ensure viability and purity of the organism tested...if two or more colony

	types are present on the purity plate, reisolate the colonies and retest." 3. Review of the laboratory's patient test records and quality control records revealed the laboratory inoculated purity check plates but did not document the results. 4. In interview on July 23, 2025 at 9:25 a.m., Technical Supervisor 4 stated laboratory personnel check the purity plates to ensure they do not have growth of more than one colony type before reporting patient results. She confirmed the laboratory did not document the results of the purity checks as identified above.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policies and instrument to instrument comparison studies, and interview with personnel, the laboratory failed to perform instrument comparison studies for reticulocyte testing on the Sysmex XN analyzers. Findings: 1. Observation by surveyors during the laboratory tour on July 22, 2025 at 9: 07 a.m. revealed the laboratory utilized two (2) Sysmex XN analyzers for reticulocyte testing. 2. Review of the laboratory's policy "Instrument Correlation and Regression Procedure" section "Hematology" revealed "Semiannually, hematology technologists will perform correlation studies, comparing results obtained between the two hematology analyzers." 3. Further review of the policy revealed "Data that is correlated from CBC instrumentation are the following: WBC, RBC, hemoglobin, hematocrit, MCV, MCH, MCHC, RDW, platelet count, and differential" but the policy did not include reticulocyte testing. 4. Review of the laboratory's 2024 instrument to instrument comparison study records for the laboratory's two (2) Sysmex XN analyzers revealed the laboratory performed a comparison study that included reticulocyte testing in May 2024, but did not perform a second comparison in 2024 and did not perform a comparison from January 2025 through June 2025. 5. In interview on July 24, 2025 at 9:58 a.m., Technical Supervisor 1 stated prior to August 2024 the laboratory utilized a Sysmex XN and a Sysmex XS and only the Sysmex XN was utilized for reticulocyte testing. She further stated the laboratory started testing reticulocytes on two analyzers in August of 2024 when the laboratory replaced the Sysmex XS with another Sysmex XN. She confirmed comparison studies were not performed as identified above.
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, record review, and interview with personnel, the laboratory failed to establish complete procedures to identify issues within the analytic system. Findings: 1. Review of the laboratory policy and procedures revealed the laboratory

	had a quality assessment process in place; however, the following deficient practices were not identified: a) The laboratory failed to document the refrigerator temperature for one (1) of five hundred sixteen (516) days reviewed. Refer to D5413 I. b) The laboratory failed to document the humidity for one (1) of five hundred sixteen (516) days reviewed. Refer to D5413 II. c) The laboratory failed to perform maintenance on the Sysmex CA-600 for two (2) of seventeen (17) months reviewed. Refer to D5429. d) The laboratory failed to perform instrument comparison studies for reticulocyte testing on the Sysmex XN analyzers. Refer to D5775.
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, 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 document the refrigerator temperature for one (1) of five hundred sixteen (516) days reviewed. Refer to D5413 I. 2. The laboratory failed to document the humidity for one (1) of five hundred sixteen (516) days reviewed. Refer to D5413 II. 3. The laboratory failed to perform instrument comparison studies for reticulocyte testing on the Sysmex XN analyzers. Refer to D5775.
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 that quality programs were in place to assure quality laboratory testing. Refer to D5791.
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.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)

	(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and 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. Refer to D5403 II.
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 document the refrigerator temperature for one (1) of five hundred sixteen (516) days reviewed. Refer to D5413 I. 2. The laboratory failed to document the humidity for one (1) of five hundred sixteen (516) days reviewed. Refer to D5413 II. 3. The laboratory failed to perform maintenance on the Sysmex CA-600 for two (2) of seventeen (17) months reviewed. Refer to D5429. 4. The laboratory failed to perform instrument comparison studies for reticulocyte testing on the Sysmex XN analyzers. Refer to D5775.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 the quality control programs were established to assure the quality of laboratory testing. Refer to D5481.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and 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. Refer to D5403 I.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(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, record review, and interview with personnel, the Technical Supervisors failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5481.