Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464416	10/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Northeast Louisiana Health Center	256 Hwy 3048, Rayville, 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 October 31, 2023 at Northeast Louisiana Health Center, CLIA ID # 19D0464416. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and proficiency testing records as well as interview with personnel, the laboratory failed to ensure testing personnel and laboratory director signed the attestation statements for two (2) of six (6) proficiency testing (PT) events reviewed in 2022 and 2023. Findings: 1. Review of the laboratory's "Proficiency Testing" policy under "Reporting of Results" revealed "After testing is completed and reports are generated, the result forms included in the proficiency testing kit should be completed by the individual assigned to that event. After result forms are completed the individual should sign the attestation statement to document that he/she actually performed testing on the samples in question. The laboratory director must also sign the attestation statement verifying that all samples have been handled in the same manner as patient samples". 2. Review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing (PT) records from 2022 and 2023 revealed the attestation statements were not signed by the laboratory director and/or testing personnel for the following two (2) of six (6) PT events reviewed: a) AAB NonChemistry M1 2022: Laboratory Director and Testing Personnel did not sign attestation) b) AAB NonChemistry M2 2022: Laboratory Director did not sign attestation) 3. In interview on October 31, 2023 at 3:20 pm, the

	technical consultant confirmed the attestations were not signed by the appropriate personnel as required by the laboratory policy.
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 the manufacturer's instructions and laboratory temperature records and interview with personnel, the laboratory failed to monitor the humidity of the laboratory where the Horiba ABX Micros 60 Hematology analyzer was located. Findings: 1. Observation by surveyor during the laboratory tour on October 31, 2023 at 1:10 pm revealed the laboratory utilizes the Horiba ABX Micros 60 analyzer for Complete Blood Count (CBC) testing. 2. Review of the Horiba ABX Micros 60 analyzer's manufacturer requirements under "Humidity and Temperature conditions" revealed the following: * The ABX micros 60 must operate in a temperature range between 18 to 32 degrees celsius (65 to 90 degrees fahrenheit) * Humidity: Up to 95% without condensation 3. Review of the laboratory's temperature records revealed the laboratory did not document the humidity for 2022 and 2023. 4. In interview on October 31, 2023 at 3:20 pm, the technical consultant confirmed the laboratory did not monitor the humidity where the Micros 60 analyzer was located.
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 by surveyor, review of laboratory policy and temperature records as well as interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to monitor the humidity of the laboratory where the Horiba ABX Micros 60 Hematology analyzer was located. Refer to D5413.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of laboratory policy and proficiency testing records and interview with personnel, the Laboratory Director failed to ensure proficiency testing attestation statements were signed by the appropriate personnel. Findings: 1. The laboratory failed to ensure testing personnel and laboratory director signed the attestation statements for two (2) of six (6) proficiency testing (PT) events reviewed in 2022 and 2023. Refer to D2009.
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 by surveyor, review of laboratory policy and temperature records and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to monitor the humidity of the laboratory where the Horiba ABX Micros 60 Hematology analyzer was located. Refer to D5413.