Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464416	08/08/2019
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 August 8, 2019 at Northest 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.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform an assessment for unsatisfactory Hematology proficiency test (PT) results. Findings: 1. Review of proficiency testing performance summary revealed the laboratory was enrolled with American Association of Bioanalysts (AAB) for Hematology. 2. Review of proficiency testing records for four (4) events from 2018 and 2019 revealed the laboratory did not perform assessments for the following "unacceptable" results for the following two (2) of four (4) events reviewed: a) Q1 Nonchemistry 2019 Hematology with Differential A with total score of eighty-six percent (86%) *WBC: Sample 2, "unacceptable" - 80% *RBC: Sample 2, "unacceptable" - 80% *HGB: Sample 2, "unacceptable" - 80% *HCT: Sample 2, "unacceptable" - 80% b) Q2 Nonchemistry 2018 Hematology with Differential A with total score of ninety-three percent (93%) *RBC: Sample 2, "unacceptable" - 80% *HCT: Sample 2, "unacceptable" - 80% 3. In interview on August 8, 2019 at 02:53 pm, the Technical Consultant stated she was unaware that corrective action should be performed for any unacceptable analyte or test event score. The Technical Consultant confirmed that remedial action was not performed for the above events.
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 record review and interview with personnel, the laboratory failed to establish a laboratory policy and procedure manual. Findings: 1. Review of the laboratory's documents and records revealed the laboratory did not have written polices and procedures that included: a) Performance specification: detailed procedures for performing accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference range studies, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability criteria 2. In interview on August 8, 2019 at 03:15 pm, the Technical Consultant confirmed the above policies were not included in the laboratory policy and procedure manual.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to ensure supplies have not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on August 8, 2019 revealed the following expired items: a) R&D Systems CBC Line Hematology Linearity Kit: Lot CL133, Expiration date: 07 /25/2019 *RBC 133 - six (6) vials *LL 133 - six (6) vials *PLT 133 - six (6) vials *WBC 133 - six (6) vials b) Horiba Medical Minocal Whole Blood Hematology Calibrator: Lot CX436, Expiration date: 08/05/2019, one (1) vial 2. In interview on August 8, 2019 at 01:25 am, the Technical Consultant stated that both supplies were used for the installation of the new Hematology analyzer and she was unaware the supplies had expired. The Technical Consultant confirmed the identified supplies were expired.
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, record review, and interview with personnel, the Laboratory

	Director failed to ensure the laboratory personnel were performing test methods as required. Refer to D5417.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D5221.
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 laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.
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, 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 laboratory policy and procedure manual. Refer to D5401. 2. The laboratory failed to ensure supplies have not exceeded their expiration date. Refer to D5417.