Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0696771	05/17/2019
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	An Offsite revisit survey was conducted at Northern Louisiana Medical Center - CLIA ID # 19D0696 5, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories. Nc were cited. A Validation survey was conducted at Northern Louisiana Medical Center -CLIA ID # 19D0696771 through May 17, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for L however, standard deficiencies were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Condit specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Spec This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to ensure pat Lactic Acid testing are separated within 15 minutes according to the manufacturer for six (6) of fifty- reviewed. Findings: 1. Observation by the surveyor on May 14, 2019 revealed the laboratory was per Acid testing on the Siemens Dimension EXL-LM Chemistry Analyzer. 2. Review of the Siemens Dir Acid package insert revealed "Blood is best collected without stasis in a container of sodium fluoride/ oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes on ice and analyze promptly." 3. Review of patient records for Lactic Acid from March 1, 2019 throu 2019 revealed the laboratory did not receive the following six (6) of fifty-two (52) patients within 15 to separate as required by the manufacturer: On March 2, 2019 Patient Number 8630166 was collecte and received at 14:18 pm - exceeding the fifteen (15) minutes required by the manufacturer by three (March 3, 2019 Patient Number 8630254 was collected at 19:45 pm and received at 20:05 pm - exceed

	(15) minutes required by the manufacturer by five (5) minutes. On March 3, 2019 Patient Number 86 collected at 22:00 pm and received at 22:18 pm - exceeding the fifteen (15) minutes required by the n three (3) minutes. On March 7, 2019 Patient Number 8630498 was collected at 17:36 pm and receive exceeding the fifteen (15) minutes required by the manufacturer by four (4) minutes. On March 8, 20 Number 8631041 was collected at 18:05 pm and received at 18:48 pm - exceeding the fifteen (15) mi the manufacturer by twenty eight (28) minutes. On March 8, 2019 Patient Number 8631054 was colle and received at 21:49 pm - exceeding the fifteen (15) minutes required by the manufacturer by four (4 interview on May 16, 2019 at 1:41 pm, Technical Consultant 1 confirmed the laboratory separates the patient samples after receiving them and the above patient samples were not received within the fiftee required by the manufacturer. 5. Review of the Task 1 & 3 form provided to surveyor revealed the lab performs 2,412 Lactic Acid tests annually.
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 manufa instructions and in a manner that provides test results within the laboratory's stated performance speci each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to ensure the questionnaires for Mean Prothrombin Time studies corresponds with the raw data on the instrument t 1. Observation by surveyor during laboratory tour on May 15, 2019 revealed the laboratory utilizes th 600 analyzer for Prothrombin Time (PT) and International Normalized Ratio (INR) testing. 2. Review laboratory's policy and procedure manual revealed the laboratory did not have detailed , written instru identification of the donor questionnaire and the corresponding raw data. 3. Review of the Normal M Time study (NMPT) revealed the laboratory did have twenty (20) donor questionnaires; however, the not identify each questionnaire to correspond with the raw data provided for the NMPT study. 3. In ir 15, 2019 at 02:48 pm, the General Supervisor confirmed the laboratory did not have a system in place which normal donor questionnaire corresponds to the raw data provided for the study. 4. Review of th forms provided to surveyors revealed the laboratory performs 3,114 PT/INR tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform a maintenance as defined by the manufacturer and with at least the frequency specified by the manufac This STANDARD is not met as evidenced by: I. Based on observation, record review and interview with personnel, the laboratory failed to docume instrument maintenance as defined by the manufacturer for the Siemens Dimension EXL-LM Chemis Findings: 1. Observation by surveyor during the laboratory tour on May 14, 2019 revealed the laborat Siemens Dimension EXL-LM analyzer for Electrolye (IMT) testing. 2. Review of instrument manual Dimension EXL revealed the following monthly maintenance required by the manufacturer: a) Montl Check Drain on IMT Port Replace IMT Pump Tubing Clean IMT System* Replace/Clean Air Filters Wash Probes Replace HM Pump Heads^ Clean R2 Drain Clean R3 Drain** 3. Review of the mainter January 2018 through April 2019 revealed the laboratory did not document the monthly maintenance System* for the following two (2) of sixteen (16) months reviewed: a) March 2018 b) December 201 on May 14, 2019 at 01:38 pm, the Chemistry General Supervisor stated the IMT clean is done monthl (30) days so it sometimes does not fall when the other monthly maintenance is performed. The Gener confirmed there was not any documentation to show that maintenance was performed. II. Based on ob

	record review, and interview with personnel, the laboratory failed to document the Heater Temperatu Autostainer XL as required. Findings: 1. Observation by surveyor during the laboratory tour on May revealed the laboratory utilizes the Leica Autostainer XL for staining of slides in the Pathology depar of the package insert for the Leica Autostainer XL revealed the acceptable range for the the Heater Te to 65 degrees celsius. 3. Review of the Leica Stainer Quality Control Chart revealed the laboratory is heater temperature daily. 4. Further review of the Leica Stainer Quality Control Chart revealed the lab document the heater temperature with an actual temperature reading for the following two (2) of six (reviewed: a) Janury 2019 b) April 2019 5. In interview on May 16, 2019 at 11:34 am, Pathology pers the heater temperatures for the Leica Autostainer XL was not documented as required by laboratory p
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, in employment of personnel who are competent to perform test procedures, and record and report test re accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laborat must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as require 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 laboratory personnel performed testing as required. Findings: 1. The laboratory failed to ensure patien Lactic Acid testing are separated within 15 minutes according to the manufacturer for six (6) of fifty- reviewed. Refer to D5311. 2. The laboratory failed to ensure the donor questionnaires for Mean Proth studies corresponds with the raw data on the instrument tapes. Refer to D5411. 3. The laboratory faile monthly instrument maintenance as defined by the manufacturer for the Siemens Dimension EXL-LM analyzer. Refer to D5429. 4. The laboratory failed to document the Heater Temperatures for the Leica as required. Refer to D5429 II.
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 t technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure patien Lactic Acid testing are separated within 15 minutes according to the manufacturer for six (6) of fifty- reviewed. Refer to D5311. 2. The laboratory failed to ensure the donor questionnaires for Mean Proth studies corresponds with the raw data on the instrument tapes. Refer to D5411. 3. The laboratory faile monthly instrument maintenance as defined by the manufacturer for the Siemens Dimension EXL-LM analyzer. Refer to D5429 I. 4. The laboratory failed to document the Heater Temperatures for the Lei XL as required. Refer to D5429 II.