Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D0463720	**(X3) Date Survey Completed** 12/30/2021
Name of Provider or Supplier Highland Clinic Laboratory	**Street Address, City, State** 1455 E Bert Kouns Ind Loop, Suite 109, Shreveport, 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 on December 29, 2021 through December 30, 2021 at Highland Clinic Laboratory, CLIA ID # 19D0463720. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have written, detailed instructions that included the following: a) Normal Mean Prothrombin Time Study questionnaire to include the CLSI 28-A3 recommendation for donor requirements: No medication including oral contraceptives and estrogen 2. In interview on December 29, 2021 at 2:44 pm, Personnel 2 stated she was unaware the above information needed to be included in the laboratory policy.
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 direct observation by surveyor, review of laboratory policy and procedure and interview with personnel, the laboratory failed to ensure supplies did not exceed their expiration date. Findings: 1. Direct observation by surveyor during the laboratory tour on December 29, 2021 at 10:10 am revealed the following expired supplies located in a drawer in phlebotomy room #5: a) BD vacutainer Sodium Heparin 10.0 mL tubes, Lot 9220473, Expiration 8/31/21, Quantity: two (2) b) BD vacutainer Lithium Heparin 6.0 mL tube, Lot 0072519, Expiration 8/31/21, Quantity: one (1) c) BD vacutainer Lithium Heparin 6.0 mL tube, Lot 0133380, Expiration 10/31 /21, Quantity: one (1) 2. Review of the laboratory's policy "Reagent Labeling and Expiration" revealed "Reagents, solutions, culture media, controls, calibration materials and other supplies are not to be used when they have exceeded expiration dates, have deteriorated or are of sub-standard quality". 3. In interview on December 29, 2021 at 11:19 am, Personnel 2 confirmed the above identified supplies located in phlebotomy room 5 were expired.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 by surveyor, review of the laboratory's maintenance logs and interview with personnel, the laboratory failed to ensure monthly maintenance for the Roche Hitachi Cobas 6000 Chemistry analyzer was performed per manufacturer instructions for two (2) of twenty four (24) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on December 29, 2021 at 10:41 am revealed the laboratory utilizes the Roche Hitachi Cobas 6000 analyzer for the following chemistry testing: Creatinine (CREA), Glucose (GLUC), Albumin (ALB), Alkaline Phosphatase (ALP), Alanine Transaminase (ALT), Amylase (AMY), Aspartate Aminotransferase (AST), Direct Bilirubin (DBIL), Total Bilirubin (TBIL), Blood Urea Nitrogen (BUN), Calcium (CA), Carbon Dioxide (CO2), Cholesterol (CHOL), Gamma-Glutamyl Transferase (GGT), High Density Lipoprotein (HDL), Iron (FE), Lactate Dehydrogenase (LDH), Low Density Lipoprotein (LDL), Lipase (LIP), Magnesium (MG), Phosphorous (PHOS), Total Protein (TP), Triglycerides (TRIG), Unsaturated Iron Binding Capacity (UIBC), Uric Acid (UA), Sodium (NA), Potassium (K), Chloride (CL), C-Reactive Protein (CRP), Rheumatoid Factor (RF), Urine Creatinine (UCREA), Urine Protein (UPROT), Hemoglobin A1C (HGB A1C), Beta-Human Chorionic Gonadotropin (BHCG), Progesterone (PROG), Ferritin (FER), Folate (FOLA), Free Triiodothyronine (FT3), Free Thyroxine (FT4), Prolactin (PROL), Prostate-Specific Antigen (PSA), Testosterone (TEST), Total Triiodothyronine (TT3), Total Thyroxine (TT4), Thyroid Stimulating Hormone (TSH), Vitamin B12 (B12), Carcinoembryonic Antigen (CEA) 2. Review of the laboratory's "Cobas 6000 analyzer series Sampling Unit" maintenance log revealed the following monthly maintenance tasks: a) Clean Sampling unit filter b) Inspect /Clean DI water tank 3. Further review of the laboratory's "Cobas 6000 analyzer series Sampling Unit" maintenance log from January 2020 through December 2021 revealed the laboratory did not have documentation of performing the monthly maintenance for

	the following two (2) of twenty four (24) months reviewed: a) April 2020: Clean Sampling unit filter, Inspect/Clean DI water tank b) September 2021: Clean Sampling unit filter 4. In interview on December 30, 2021 at 10:47 am, Personnel 2 confirmed the above monthly maintenance was not documented as performed for identified months.
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 during laboratory tour, review of laboratory records and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(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 by surveyor during laboratory tour, review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Findings: 1. The laboratory failed to ensure monthly maintenance for the Roche Hitachi Cobas 6000 Chemistry analyzer was performed per manufacturer instructions for two (2) of twenty four (24) months reviewed. Refer to D5429.
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 review of laboratory policy and procedure manual and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. 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 during the laboratory tour, review of laboratory records and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417. 2. The laboratory failed to ensure monthly maintenance for the Roche Hitachi Cobas 6000 Chemistry analyzer was performed per manufacturer instructions for two (2) of twenty four (24) months reviewed. Refer to D5429.