Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0463720	10/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Highland Clinic Laboratory	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 Certification survey was performed on October 18, 2023 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.
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 laboratory policy, proficiency testing records and interview with personnel, the laboratory failed to ensure the Laboratory Director and/or designee signed the attestation statement for one (1) of sixteen (16) proficiency testing (PT) events reviewed in 2022 and 2023. Findings: 1. Review of the laboratory's policy for "External Proficiency Testing Guideline" revealed "The analyst and laboratory director or designee must sign the attestation statement provided by the PT agency documenting that the proficiency testing samples were tested in the same manner as patient samples". 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records from 2022 and 2023 revealed the Laboratory Director or designee did not sign the attestation statement for the following one (1) of sixteen (16) PT events reviewed: a) 2023 Chemistry Core 3rd event 3. In interview on October 18, 2023 at 12:25 pm, the General Supervisor confirmed the Laboratory Director or designee did not sign the attestation statements as required for the identified event.
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 maintenance records and interview with personnel, the laboratory failed to ensure the monthly maintenance on the Roche Cobas C 501 chemistry analyzer was performed as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on October 19, 2023 at 10:00 am revealed the laboratory utilizes the Roche Cobas analyzer for chemistry tests. 2. Review of the laboratory's Roche Cobas C 501 module maintenance records revealed the laboratory performs the following monthly maintenance: a) Clean: Incubation water bath KCL aspiration filter Detergent aspiration filters Circuit board rack filter Power supply filter Radiator filter b) Replace: Reaction cells 3. Further review of the Roche Cobas c 501 module maintenance records from 2022 and 2023 revealed the laboratory did not perform the following monthly maintenance for one (1) of twenty one (21) months reviewed: a) September 2022 4. In interview on October 18, 2023 at 12:30 pm, the General Supervisor confirmed the laboratory did not perform the identified maintenance.
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 the laboratory's proficiency testing records and interview with personnel, the Laboratory Director failed to ensure proficiency testing evaluations were maintained and signed by the Laboratory Director. Refer to D2009.
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 review of laboratory policy and records as well as interview with personnel,

	the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
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 review of laboratory policies and records as well as interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5429.