Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D1062345	08/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Revere Health American Fork Main Lab	1175 E 50 S Ste 151, American Fork, UT	

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
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 and interview with staff, the laboratory failed to ensure instrument wash solutions were not used past their expiration dates for approximately 1.5 months of prothrombin time (PT) and activated partial thrombin time (APTT) tests from June 30, 2018 to 08/13/2018. The laboratory performed approximately 20 PT and 3 APTT tests per month. Findings include: 1. The wash reagent, lot number 662848 expired 06/2018 as stated on the reagent bottle on the Instrumentation Laboratory ACL 1000 coagulation test instrument on 08/13/2018 at approximately 4: 15 P.M. 2. In an interview conducted on 08/13/2018 at approximately 4:15 P.M. staff stated the reagent was expired and in use for patient testing since the expiration date of 06/30/2018.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test

	system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on calibration verification documentation review, lack of documentation, and interview with staff, the laboratory failed to verify calibration of tests performed on the Abbot AU480 instrument at least once every 6 months in 2017 for approximately 30 tests performed. The laboratory performed approximately 250,000 tests per year on the analyzer. Findings include: 1. Calibration verification documentation failed to include 2017 verification the laboratory checked values at minimal or zero values, midlevel values, and values at the upper limit of the reportable range for comprehensive metabolic profile tests, lipid, renal, and hepatic function panels, troponin, amylase, magnesium, and uric acid tests. 2. In an interview conducted on 08 /13/2018 at approximately 4:30 P.M. staff confirmed the laboratory did not verify calibration every six months in 2017 for tests performed on the AU480 instrument.