Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0700813	08/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Revere Health Provo Main Campus	1055 N 500 W, Provo, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to verify frozen section histopathology test accuracy at least twice annually in 2017 and 2018. The laboratory performed histopathology slide diagnosis on approximately 800 frozen sections per year. Findings include: 1. The laboratory lacked documentation they performed twice a year verification for frozen section histopathology testing in 2017 and 2018. 2. In an interview conducted on 08/07/2019 at approximately 10:40 A. M. staff confirmed the laboratory performed accuracy verification in 2019 for testing performed in previous years versus performing test accuracy verification twice annually in 2017 and 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 record review, lack of documentation and interview with staff, the laboratory failed to verify the reportable range for analytes without a 3 point calibration for the minimal, mid level and upper level of the reportable ranges for Sodium, Potassium, Chloride, Ammonia, Bilirubin, and Unsaturated Iron Binding Capacity tests for two six month periods in 2018. The laboratory performed approximately 800,000 tests per year for all chemistry sub-specialties. Findings include: 1. The laboratory failed to verify the reportable ranges for Sodium, Potassium, Chloride, Ammonia, Bilirubin, and Unsaturated Iron Binding Capacity tests at the zero or minimal level, at the mid-range level, and the upper level of the test's reportable ranges. 2. In an interview with the laboratory manger and the quality assurance manager on 08/07/2019 at approximately 5:45 P.M. staff confirmed the laboratory failed to verify the reportable ranges for tests that did not have calibration materials at the upper or lower levels of the reportable ranges.