Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0525920	10/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Revere Health-St George Lab	736 S 900 E #203, St George, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation and interview with staff, the laboratory failed to sign and date they performed proficiency testing in the same manner as patient tests for 5 of approximately 18 events reviewed. Findings include: 1. The laboratory failed to sign approximately 5 of 18 American Proficiency Institute (API) events reviewed from October 2017 to October 2019. o 2019 Chemistry 2nd event o 2019 Hematology 1st event o 2018 Chemistry 3rd event o 2018 Chemistry 1st event o 2017 Chemistry 3rd event 2. In an interview with staff on 10/30/2019 at approximately 2:00 P.M. the director confirmed the attestation statement signatures were not present for events in 2017 and 2018.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems

	activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on Erythrocyte Sedimentation Rate (ESR) instrument print out direct observation on 10/30/2019 at approximately 1:00 P.M. and confirmation by staff, the laboratory instrument print out was not legible. The laboratory performed approximately 2 to 5 ESR tests per day. Findings include: 1. The laboratory retained ESR print outs for each test performed. The values were so faint as to be illegible. 2. The laboratory print outs from tests performed on 10/30/2019 at approximately 1:00 P. M. were also not legible. 3. In an interview with staff on 10/30/2019 at approximately 1:00 P.M. staff stated they recorded the results in the laboratory information system using the Streck instrument digital reading. Staff also confirmed the instrument printout was not legible for results printed on the day of survey as well as those scanned into the patient's test record.
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, FDA test complexity data base review, and interview with staff, the laboratory failed to verify D-Dimer test accuracy at least twice annually in 2018 and 2019. The laboratory performed approximately 2 D-Dimer tests per month. Findings include: 1. The laboratory staff performed D-Dimer tests using the Alere Triage test method. 2. The FDA test complexity data base lists no D-Dimer tests as being a waived test. 3. The laboratory failed to perform twice annual test accuracy verification from October 2017 to October 2019. 4. In an interview with the director and technical consultants/supervisors on 10/30/2019 at approximately 2:00 P.M., staff stated they believed the D Dimer tests were waived and not subject to the twice annual verification requirement.
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 applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation on 10/30/2019 at approximately 8:55 A.M., specimen collection procedures review, and confirmation by staff, the laboratory specimen collection staff failed to follow the written policy to label the patient's specimen in the presence of the patient for 1 of 2 patient's collections observed. Findings include: 1. Newly hired test person B collected the patient's specimen and returned to the laboratory accessioning area to enter the test as collected and received and print the

	specimen labels to attach to the tubes collected. The tubes were unlabeled while sitting atop the sticky note with the patient's name and test ordered beside the laboratory centrifuge and sink. 2. In an interview with staff at the time of collection and at approximately 2:00 P.M. on 10/30/2019 staff confirmed the phlebotomist did not follow the procedure to label specimens at the time of collection while in the patient's presence.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of documentation, manufacturer's instructions for gel collection tube separation review, and interview with staff, the laboratory failed to establish a procedure for Centrifuge function checks for 2 of 2 centrifuges in use to separate specimen cells from serum or plasma. Findings include: 1. In an interview with staff, the director stated the lab did not have documentation of centrifuge speed (Revolutions Per Minute {RPM} or relative Centrifugal Force) function check performance from October 2017 to October 2019. 2. The laboratory lacked an function check protocol for centrifuge speed and timer checks to ensure they followed collection tube manufacturer's requirements for specimen separation speeds for serum separation tubes for the RPM to be at least 1000 to 2000 x g for 10 minutes. 3. In an interview with staff on 10/30/2019 at approximately 2:00 P.M. staff stated they had not performed centrifuge speed and timer checks between October 2017 and October 2019 to verify the centrifuge was operating at the recommended time and speed. The laboratory director stated they were unaware of a laboratory specific function check procedure.
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 instrument calibration records review, lack of documentation, and interview with staff, the laboratory failed to verify the reportable range at least once every six months for 22 of 22 tests Sodium, Potassium, Chloride, Urine Creatinine, Cholesterol, High Density Lipoprotein, Triglycerides, Total bilirubin, Unsaturated Iron Binding Capacity, Aspartate Transaminase, Alanine Transaminase, Blood Urea Nitrogen, Creatinine, Glucose, Iron, Lipase, Uric Acid, Magnesium, Total Protein, Amylase and Creatine Kinase; that did not utilize calibration materials at the minimum or zero level, mid-level and at the upper level of the reportable range . Findings include: 1. The laboratory calibration records failed to include documentation the 22 tests listed above were calibrated using materials at the zero or minimal, midrange level, and at the upper levels of the reportable ranges on the Beckman Au 480 instrument at least once every 6 months from October 2017 to October 2019. 2. In an interview with staff, the director confirmed the laboratory did not perform the reportable range verification for tests from October 2017 to October 2019 for analytes that did not have a zero or minimal level, mid-range level, or a material of known concentration at the upper level of the reportable ranges for tests that did not use 3 levels of calibrators.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to perform two levels of quality control each day of D-Dimer testing from October 2017 to October 2019. The laboratory performed approximately 2 D-Dimer tests per month. Findings include: 1. The laboratory failed to perform two levels of quality control each day D-Dimer tests were performed from October 2017 to October 2019. 2. In an interview with laboratory staff, the laboratory director stated they believed D-Dimer testing was a waived test if performed on the Alere Triage instrument and was not subject to the requirement to perform a positive and negative control for each day patients were tested or develop an Individualized Quality Control Program.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

	This STANDARD is not met as evidenced by: Based on quality control records review, patient test records review. lack of documentation and interview with staff, the laboratory failed to follow their policy to record corrective actions taken when daily quality control (QC) performance fails to meet the laboratory's criteria for acceptance for 1 of 1 test reviewed where QC was not within the acceptable range. Findings include: 1. Quality control records review for Vitamin B12 for patient test date of 12/26/2018 were not within the acceptable range for 3 QC test runs (the 4th time the QC was in range). 2. The laboratory failed to record the corrective actions taken to correct the out of range results prior to reporting patient test results. 3. In an interview conducted on 10/30/2019 at approximately 2:00 P.M. the testing person performing the test stated the corrective actions were not recorded for B12 QC out of range results on 12/26/2018.
D5817	TEST REPORT CFR(s): 493.1291(i) If a laboratory refers patient specimens for testing-- (i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory; (i)(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and (i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed. This STANDARD is not met as evidenced by: Based on patient test reports review and confirmation by staff, the laboratory information system failed to ensure test reports received from reference laboratories were not revised when transitioning from the interface to the electronic medical record system for 1 of 1 reference laboratory report reviewed for Parathyroid Hormone concentration testing. 1. Patient parathyroid hormone test reviewed included a graph with the patient test results review directly from the interface was marked by an "X" within a box of possible results for the provider to use for interpretation for where the patient's test results were in relation to normal values. The patient's chart results graph was distorted to make the box a series of lines versus a contiguous structure. 2. In an interview with staff on 10/20/2019 at approximately 2:00 P.M. staff confirmed the test report as viewed from the provider's view was altered by the transition from the reference laboratory to the electronic medical record report.