Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0700813	07/11/2022
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the Sysmex Hematology procedure and an interview with the technical supervisor 1 (TS1), the laboratory failed to include reference intervals (normal values) for Complete Blood Count (CBC) testing. The laboratory performed 30,136 CBC tests annually. Findings include: 1. Review of the procedure manual on July 14, 2022 at 12:45 PM revealed a lack of reference ranges CBC testing. 2. Interview with the TS1 on July 14, 2022 at 2:30 PM confirmed the laboratory failed to include reference ranges in the procedure manual.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, record review, and interview with testing personnel, the laboratory failed to follow the manufacturer's instructions for temperature storage requirements for Enzyme ER Verifier Kit for the Beckman Coulter AU700 DXC. The laboratory performed approximately 875,590 chemistry tests annually on the Beckman Coulter AU700 DXC. Findings include: 1. Direct observation on 07/11 /2022 at approximately 3:35 PM of the Enzyme ER Verifier Kit revealed that the kit components should be stored at -15C to -25C. 2. Record review on 07/11/2022 at approximately 3:35 PM of the Lab Freezer ABT-HC-MFP-20 revealed that temperatures were out of range on 90 of 155 days that temperatures were recorded from January 2022 - June 2022. 3. In an interview on 07/11/2022 at approximately 3: 39 PM, the testing personnel confirmed that laboratory freezer temperatures were out of range for the Enzyme ER Verifier Kit.
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 of expiration dates on reagents and supplies in storage area, and interview with Testing Personnel 1 (TP1), the laboratory failed to ensure that expired reagents were removed. Findings include: 1. Based on direct observation of storage areas on 07/11/2022 at approximately 15:15, the laboratory failed to remove Glucose Drink (Lot#59326) that had an expiration date of 01/31/22 and 10% Formalin Specimen Jars (Lot#092084) that had an expiration date of 06/01/22. 2. In an interview on 07/11/2022 at approximately 15:35, TP1 confirmed that both the Glucose Drink and 10% Formalin containers were expired.