

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2200185	(X3) Date Survey Completed 05/07/2021
Name of Provider or Supplier Revere Health St George Multi-Specialty	Street Address, City, State 2825 East Mall Dr, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant, temperature for the reagent fridge freezer, and room temperature on the Urgent Care side were not monitored appropriately. Findings include: 1. Room temperature was not recorded for 4 dates in February and March 2021. 2. Fridge and freezer temperatures were not recorded on Saturdays and Sundays January through March 2021. 3. In an interview on 5/6/21 at approximately 3 pm, the Technical Consultant confirmed that temperatures were not routinely being monitored and recorded by the Urgent Care staff.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and interview with the Laboratory Director and Technical Consultant, instrument maintenance was not being performed and documented according to manufacturer's instructions. Findings include: 1. Biweekly cleaning on the Pochi instrument was not documented during January 2021, and only once in March 2021 and once in April 2021. 2. Daily shutdown on the Pochi instrument was not documented on 2 days in January 2021, 2 days in February 2021, and 3 days in April 2021. 3. Reagent replacement on the Pochi instrument was not documented in January 2021 or March 2021. 4. Daily cleaning on the Access2 instrument was not documented from December 2020 through March 2021, and from April 16, 2021 through May 6, 2021. 5. Weekly maintenance on the Access2 instrument was not documented from 4/16/21 through 5/6/21. 6. System check on the Access2 instrument was not documented at all prior to 3/3/21, and not documented again from 4/16/21 through 5/6/21. 7. Shutdown for the XN-550 instrument was not documented from 4/19/21 through 5/6/21. 8. Weekly cleaning on the XN-550 instrument was missed for one week in each month of January, March, and April 2021. 9. In an interview on 5/6/21 at approximately 4:55 pm, the Laboratory Director and Technical Consultant confirmed that instrument maintenance was not being performed and documented according to manufacturer's instructions .

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on record review and interview with the Technical Consultant, testing personnel did not follow Standard Operating Procedure (SOP) when performing manual entry of patient test results. Findings include: 1. Patient 517420 CBC test report included an incorrect MCV result in the electronic record. 2. Patient 1187850 CBC test report included an incorrect Lymph # result in the electronic record. 3. SOP for manual result entry requires a second testing personnel to double check manual entry of patient results into the electronic record, and initial that they performed the double check on the test form. 4. CBC test forms for both patient 517420 and 1187850 did not include initials that a double check of manual test result entry was performed. 5. In an interview on 5/6/21 at approximately 5:25 pm, the Technical Consultant confirmed that data entry errors had occurred, and testing personnel were not following the SOP.