

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2200730	(X3) Date Survey Completed 07/15/2021
Name of Provider or Supplier Americahealth - Rexburg Uc	Street Address, City, State 130 W Main St, Rexburg, ID	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Abbott ID NOW COVID-19 Instructions for use (IFU), Abbott "ID NOW COVID-19 Procedural Control Results and Patient Record" log, laboratory records and interview with the office manager on 7/15/2021, the laboratory failed to follow all the manufacturers instructions. The findings include: 1. The Abbott ID NOW COVID-19 IFU states the laboratory will have a process in place for reporting test results to the relevant public health authorities and that all operators using the test must be appropriately trained in performing and interpreting the results. 2. A review of the Abbott "ID NOW COVID-19 Procedural Control Results and Patient Record" log identified four (4) testing personnel. The laboratory failed to have documentation of training for performing and interpreting the Abbott ID NOW COVID-19 test for 4 of 4 testing personnel as required by the test manufacturer. 3. A review of laboratory records revealed that the laboratory failed to have a documented procedure for reporting COVID-19 test results to the relevant public health authorities as required by the test manufacturer. 4. An interview with the office manager on 7/15/2021 at 2: 30 pm confirms the above findings.</p>
D1002	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such</p>

timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:

Based on record review and an interview with the office manager on 7/15/2021, the laboratory failed to report SARS-Co-V-2 test results as required for 124 of 124 testing days from January 27, 2021 through July 15, 2021. Findings include: 1. Abbott "ID NOW COVID-19 Procedural Control Results and Patient Record" logs from January 27, 2021 through July 15, 2021 were reviewed. 2. SARS-CoV-2 test result reporting documentation was not provided for the testing period from January 27, 2021 through July 15, 2021. 3. Documentation revealed that SARS-CoV-2 test results were not reported as required for 2 days in January 2021, 20 days in February 2021, 24 days in March 2021, 23 days in April 2021, 23 days in May 2021, 21 days in June 2021 and 10 days in July 2021. 4. The laboratory failed to report the results of 309 SARS-CoV-2 tests performed on the Abbott ID NOW from January 27, 2021 through July 15, 2021 as required. 5. The office manager confirmed the above findings on 7/15/2021 at 2:30 pm.