

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  46D1054222	<b>(X3) Date Survey Completed</b>  12/07/2021
<b>Name of Provider or Supplier</b>  Advanced Research Institute Lc	<b>Street Address, City, State</b>  5896 S Ridgeline Dr #A, Ogden, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> 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 record review, direct observation, and interview with testing personnel, the laboratory's temporary testing site located at 655 E 4500 S, SLC UT 84107 failed to follow the manufacturer's instructions to monitor storage temperature, testing temperature, not interchanging kit contents from different lots, timer use, and testing on a flat surface. The temporary laboratory space which annually performed approximately 18,000 SARS-CoV-2 Antigen with the Care Start COVID-19 Antigen Rapid Diagnostic Test and COVID-19 antibody tests with the CoronaCHEK COVID-19 IgG/IgM Rapid Test Cassette. Findings include: 1. The temporary testing site failed to follow the Care Start COVID-19 Antigen Test and the CoronaCHEK COVID-19 IgG/IgM Rapid Test manufacturers' requirements for kit storage, testing temperature, and timer usage by not establishing criteria for the monitoring of storage temperature, testing temperature, and timer usage. 2. Direct observation revealed that no thermometer or timer was present in the temporary testing site on 12/07/2021 at approximately 2:30 PM. 3. The temporary testing site failed to follow the Care Start COVID-19 Antigen Test manufacturer's requirement for not interchanging kit contents from different lots by not establishing criteria for the monitoring of interchanging of kit contents from different lots. 4. During observation on 12/07/2021 at approximately 2:30 PM, interchanging kit contents from different lots was observed. 5. The temporary testing site failed to follow the CoronaCHEK COVID-19 IgG/IgM Rapid Test manufacturer's requirement for performing the test on a level surface by not establishing criteria for testing on a level surface. 6. During observation on 12/07/2021 at approximately 2:30 PM, testing on a surface that was not flat was</p>

observed. 7. In an interview with testing personnel 12/07/2021 at approximately 2:45 PM, confirmed timer temperatures were not monitored, timers were not used, interchanging of kit contents from different lots occurred, and testing was performed on a not level surface.

**D1002**

**REPORTING OF SARS-CoV-2 TEST RESULTS**

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 timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:  
Based record review and interview, the laboratory's temporary testing site located at 655 E 4500 S, SLC UT 84107 failed to report SARS-CoV-2 negative test results from December 2020 through December 2021. Findings include: 1. In an interview with laboratory staff on 12/07/2021 at 2:45 PM, they confirmed that negative SARS-CoV-2 test results were not reported to the state health department. 2. Laboratory procedure failed to include instructions for reporting negative SARS-CoV-2 test results to the state health department. 3. The laboratory performed approximately 18,000 SARS-CoV-2 tests annually using the Care Start COVID-19 Antigen test. 4. The site manager confirmed the findings on 12/08/2021 at 3:00 PM.