

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D1054222	<b>(X3) Date Survey Completed</b> 03/18/2022
<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>D0000</b>	A complaint survey was performed at the following temporary testing site: February 3, 2022, at 3:00 PM at 6028 S Ridgeline Drive Ogden, UT 84405 Management personnel confirmed that the COVID-19 rapid antigen testing was performed under Advanced Research Institute LC, CLIA #46D1054222.
<b>D1001</b>	<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 the CareStart COVID-19 Antigen test kit manufacturer's instructions for use (IFU), observation of testing, and interviews with management, and testing personnel, the laboratory failed to follow the manufacturer's IFU. Findings include: 1. Review of the CareStart COVID-19 Antigen manufacturer's IFU showed, "Store the test kit as packaged between 1 ~ 30C." 2. Observation on February 3, 2022, at 3:10 PM, showed a camper being used as a temporary testing site (TTS) in the parking lot of 6028 S Ridgeline Drive Ogden, UT 84405. Observation of the testing area showed a mobile cart located inside the camper being used as a testing table with opened and unopened boxes of CareStart COVID-19 Antigen test kits. 3. Interview with laboratory management on February 3, 2022, at 3:15 PM, confirmed the TTS was performing COVID-19 antigen testing under the CLIA # 46D1054222. 4. No documentation was available for room temperature monitoring within the camper where testing was performed. 5. Interview with the testing personnel and laboratory management on February 3, 2022, at 3:20 PM, confirmed the laboratory failed to monitor and document the room temperature for storage of CareStart COVID-19</p>

Antigen test kits. 6. Email correspondence on March 18, 2022, at 1:38 PM, with laboratory management, confirmed 15,968 COVID-19 antigen tests have been resulted since January 21, 2021.