

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2199811	(X3) Date Survey Completed 11/18/2022
Name of Provider or Supplier Nomi Health	Street Address, City, State 3696 West 2100 South, Salt Lake City, 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
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 record review of the Abbott BinaxNOW COVID-19 Antigen CARD test system and laboratory Standard Operating Procedure (SOP), and a direct observation of patient testing, the laboratory failed to follow the BinaxNOW COVID-19 Antigen CARD test system instructions for 14 of 14 patient nasal swab samples tested on 11/18/2022. The temporary testing site performed 143 tests on 11/18/2022 and performs approximately 10,000 patient tests per year. The findings included: 1. A record review of the Abbott BinaxNOW COVID-19 Antigen CARD test manufacturer's instructions and the laboratory's SOP for BinaxNOW COVID-19 Antigen test revealed the laboratory failed to follow the instructions for test performance, which required testing personnel to hold the extraction reagent bottle vertically and count six drops of reagent needed to be dispensed to the test card before the patient sample swab was inserted. 2. A direct observation of 14 out of 14 patient samples collected and tested on 11/18/2022, at 8:00 AM through 9:52 AM, revealed the laboratory testing personnel failed to follow the Abbott BinaxNOW COVID-19 Antigen CARD instructions and SOP for patient testing.</p>