Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2199811	(X3) Date Survey Completed 03/08/2022
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
D0000	Complaint surveys were performed at the following temporary testing sites (TTS): January 31, 2022 at 10:00 AM at 740 S 100 E, Bountiful, UT 84010 January 31, 2022 at 12:00 PM at 4300 S 1300 E, Millcreek, UT 84117 February 1, 2022 at 9:00 AM at 8000 S Redwood Rd, West Jordan, UT 84088 February 1, 2022 at 10:30 AM at 3345 E Richardson Flat Rd, Park City, UT 84098 February 2, 2022 at 12:00 PM at 5405 W 3100 S, West Valley City, UT 84120 February 3, 2022 at 12:15 PM at 1190 E 2500 N, Logan, UT 84341 Testing personnel at all TTS confirmed the COVID-19 rapid antigen testing was being performed under Nomi Health Lab Services, LLC, CLIA #46D2199811. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiency: 42 C.F.R. 493.1771 Condition: Inspection Requirements
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Complaint surveys were performed at the following temporary testing sites (TTS): January 31, 2022 at 10:00 AM at 740 S 100 E, Bountiful, UT 84010 January 31, 2022 at 12:00 PM at 4300 S 1300 E, Millcreek, UT 84117 February 1, 2022 at 9:00 AM at 8000 S Redwood Rd, West Jordan, UT 84088 February 1, 2022 at 10:30 AM at 3345 E Richardson Flat Rd, Park City, UT 84098 February 2, 2022 at 12:00 PM at 5405 W 3100 S, West Valley City, UT 84120 February 3, 2022 at 12:15 PM at 1190 E 2500 N, Logan, UT 84341 Testing personnel at all temporary testing sites (TTS) confirmed the COVID-19 rapid antigen testing was being performed under Nomi Health Lab Services, LLC, CLIA #46D2199811. Based on review of the GenBody COVID-19 Antigen test kit instructions for use (IFU) at all TTS listed above, observation of

testing performed at the TTS listed above, and interviews with supervisors, management, and testing personnel, the laboratory failed to follow the manufacturer's IFU. Findings include: 1. Review of the GenBody COVID-19 Antigen test kit showed: "Procedural Notes --Allow Test Devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30C) (59-86F) prior to testing. --Do not open the foil pouch until one is ready to perform the test. --Materials required but not provided-Timer. --Label the device with the patient identification or control to be tested. --Place Test Device on a level surface. --For the best performance, swab specimens collected from patients should be tested immediately after collection. The collected swab specimen can be tested for up to 60 minutes following specimen collection --Proper sample collection, storage and transport are essential for correct results. --Store the test kit in a cool, dry place between 2-30 C (35.6-86 F). --Exposure to humidity may decrease the stability of the reagents. The test should be performed immediately after removing the device from the foil pouch. Test devices and swabs should be used immediately upon opening; do not remove Test Devices from the pouch until just before use. --False positive or false negative results can occur if test device is read before 15 minutes or after 20 minutes. --Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled. --The performance of the GenBody COVID-19 Ag was evaluated using the procedures provided in these Instructions for Use (IFU) only. Modifications to these procedures may alter the performance of the test. Step 1. Add the Extraction Solution to the Fill Line indicated on the Extraction Tube (400 L). Step 2. A. Insert the collected specimen swab into the Extraction Solution. B. Mix by squeezing the tube and simultaneously rotating the Swab 8 - 10 times. Remove the swab from the Extraction Tube while pressing the swab against the side of the tube to extract the solution. Caution: Inadequate swab rotation can result in incorrect results. Step 3. Place the Dropper Tip on the Extraction Tube. Step 4. Add 4 drops (~100 L) of the solution to the center of the sample well of the Test Device. Step 5. Read the test result at 15-20 minutes. Test results should not be read after 20 minutes. Caution: False positive or false negative results can occur if test device is read before 15 minutes or after 20 minutes." A. Nomi Health Lab Services, LLC TTS located at 740 S 100 E, Bountiful, UT 84010 1. Observation on January 31, 2022 at 10:00 AM of the collection area showed unopened and opened collection swabs being stored outside in 30 Fahrenheit (F). Review of the storage requirements for the collection swabs showed to store swabs at "1-30 Celsius (C) (33.8-86F)." Observation of the collection cart showed a box filled with collected patient swabs in opened plastic sleeves (pouches) laying directly on top of each other. 2. Interview on January 31, 2022 at 10:08 AM with the collection personnel, "We open the packet, swab both sides of the nasal canal, and put the swab back into the sleeve. The sleeve is left open and put in the box with the rest of the patient swabs. This is a possible patient test contamination." 3. Observation on January 31, 2022 at 10:15 AM of the laboratory area located within a mobile storage unit, showed an area with one table, no timers, a box filled with collected patient swabs in opened plastic sleeves (pouches) laying directly on top of each other, boxes of unopened GenBody COVID-19 kits, and extraction solution located in the middle of a roll of duct tape with "hot hands" hand warmers. The temperature the extraction solution was being stored at was 61.7 C (143.1 F). 4. Review of the manufacturer's IFU showed "Allow Test Devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30C) (59-86F) prior to testing." 5. No documentation was available for room temperature monitoring within the mobile storage unit. No timers were available for use. 6. Review of manufacturer's IFU showed "Materials required but not provided-Timer. Read the test result at 15-20 minutes. Test results should not be read after 20 minutes. Caution: False positive or false negative results can occur if test device is read before 15 minutes or after 20 minutes" 7. Interview on January 31, 2022 at 10:20

AM with the testing personnel, "The extraction solution must be warmed up so we keep the reagent warm with hand warmers. We do not monitor the temperature in the unit. We turn the temperature down to 65 F at night." 8. No training documentation was available. Email correspondence with the laboratory director (LD) of the main laboratory (A) on March 4, 2022 at 11:42 AM confirmed no training documentation was completed prior to patient testing. 9. Email correspondence with laboratory director of main lab (A) on March 8, 2022 at 5:49 PM confirmed 85,106 COVID-19 rapid antigen patient tests have been performed since April 13, 2021 at Nomi Health Lab Services, LLC TTS at 740 S 100 E, Bountiful, UT 84010. B. Nomi Health Lab Services, LLC TTS located at 4300 S 1300 E, Millcreek, UT 54117 1. Observation on January 31, 2022 at 12:15 PM of the laboratory area located within a mobile storage unit showed a box containing opened patient collected swabs ready for testing stored in the opened sleeves (pouches) directly on top of each other; a full box of GenBody COVID-19 test kit cassettes removed from the packaging, stored directly on top of each ready for testing; no timers; no temperature documentation; yogurt; a bag of Cheez-Its; and rice cakes sitting directly on the testing table and next to the contaminated test kits. 2. Review of manufacturer's IFU showed, "Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled. Allow Test Devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30C) (59-86F) prior to testing. Store the test kit in a cool, dry place between 2-30 C (35.6-86 F). The test should be performed immediately after removing the device from the foil pouch. Test devices and swabs should be used immediately upon opening; do not remove Test Devices from the pouch until just before use." 3. Interview with the field supervisor on January 31, 2022 at 12:30 PM confirmed "We do not monitor the temperature in the laboratory and turn the heat off at night." 4. Review of the manufacturer's IFU showed, "Materials required but not provided-Timer. Read the test result at 15-20 minutes. Test results should not be read after 20 minutes. Caution: False positive or false negative results can occur if test device is read before 15 minutes or after 20 minutes." 5. Observation of the computer showed the check in time is when the patient pulls up and checks in on the computer with laboratory staff. The collection of the specimen is approximately one to five minutes later dependent on the number of patients in line. 6. Interview with testing personnel on January 31, 2022 at 12:40 PM, "We do not use timers. I add 15 minutes onto the time the patient is checked in." 7. Interview with testing personnel January 31, 2022 at 12:45 PM, "We prep every two hours. We open the kit cassettes and put them in a box." 8. No training documentation was available. Email correspondence with LD of the main laboratory (A) on March 4, 2022 at 11:42 AM confirmed no training documentation was completed prior to patient testing. 9. Email correspondence with LD of main lab (A) on March 8, 2022 at 5:49 PM confirmed 12,528 COVID-19 rapid antigen patient tests have been performed since January 12, 2022 at Nomi Health Lab Services, LLC TTS located at 4300 S 1300 E, Millcreek, UT 54117. C. Nomi Health Lab Services, LLC TTS located at 8000 S Redwood Rd, West Jordan, UT 84088 1. Observation on February 1, 2022 at 9:00 AM of the laboratory area located within a mobile storage unit showed a box containing opened patient collected swabs ready for testing placed directly on top of each other stored in the opened sleeves (pouches); a full box of GenBody COVID-19 test kit cassettes removed from the packaging; no timers; no temperature documentation; and storage of the extraction solution with hand warmers. 2. Review of manufacturer's IFU showed, "Allow Test Devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30C) (59-86F) prior to testing. Store the test kit in a cool, dry place between 2-30 C (35.6-86 F). The test should be performed immediately after removing the device from the foil pouch. Test devices and swabs should be used immediately upon opening; do not remove Test Devices from the pouch until just before use. Materials required but not provided-Timer." 3.

Interview on February 1, 2022 at 9:15 AM with the field lead, "The laboratory director said to put the swab back in the packaging even though the instructions state otherwise. I questioned why we are not performing the test according to the manufacturer's instructions and was told to do it this way. We are now getting fewer positives." 4. Interview with the field lead on February 1, 2022 at 9:30 AM confirmed the laboratory failed to follow the manufacturer's IFU by not following the step by step process and failed to perform temperature monitoring of the laboratory area. 5. Review of the manufacturer's IFU showed, "Read the test result at 15-20 minutes. Test results should not be read after 20 minutes. Caution: False positive or false negative results can occur if test device is read before 15 minutes or after 20 minutes." 6. Interview with testing personnel on February 1, 2022 at 9:50 AM, "I use the computer based on check in time to figure my 15 minutes. Sometimes it takes longer than 20 minutes." 7. February 1, 2022 at 10:09 AM, review of an email sent to the field lead from management revealed, "Hey (name redacted) personnel identifier A, you know when we're swabbing (rapid) we're "supposed to" put the swab back into the swab package? Personnel identifier A's response-"Correct" "So yesterday (name redacted) personnel identifiers B and C came by, and yes, I was doing resulting differently. We were swabbing then placing the swab into the Extraction tube (the extraction tube had the patient birthday and MRN on it). The guys both said we were doing it wrong and had to change it. I mentioned to them that swabbing someone then putting it back into the swab packaging is kinda (sic) cross contamination, once you break that seal, you lose most of the sample you just swabbed by putting it back in the packaging. We did switch back to how it's supposed to be. Today we decided to over the instructions in the Genbody boxes again." The email showed a picture of the instructions with highlighted step 5-after BOTH nostrils have been swabbed, place the swab into the extraction tube. 8. No training documentation was available. Email correspondence with LD of the main laboratory (A) on March 4, 2022 at 11:42 AM confirmed no training documentation was completed prior to patient testing 9. Email correspondence with LD of main lab (A) on March 8, 2022 at 5:49 PM confirmed 42,821 COVID-19 rapid antigen patient tests have been performed since March 5, 2021 at Nomi Health Lab Services, LLC TTS located at 8000 S Redwood Rd, West Jordan, UT 84088. D. Nomi Health Lab Services, LLC TTS located at 3345 E Richardson Flat Rd, Park City, UT 84098 1. Observation on February 1, 2022 at 10:45 AM showed a large tent open to the outside air where the laboratory area was located. The testing was being completed on a table in the open air with heaters on the ground. The recorded temperature was 9.9 C (50 F). 2. Observation of the testing area showed a box of opened (removed from the packaging) GenBody COVID-19 test kits. 3. Observation showed a van which transported the testing personnel, GenBody COVID-19 test kits and equipment. 4. Observation showed no timers and no temperature documentation. 5. Review of manufacturer's IFU showed, "Allow Test Devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30C) (59-86F) prior to testing. Store the test kit in a cool, dry place between 2-30 C (35.6-86 F). The test should be performed immediately after removing the device from the foil pouch. Test devices and swabs should be used immediately upon opening; do not remove Test Devices from the pouch until just before use. Materials required but not provided-Timer." 6. Interview with testing personnel on February 1, 2022 at 11:05 AM confirmed no temperature monitoring or documentation. Interview with testing personnel stated, "I wait 20 minutes or longer on the test just to be safe. We pick up the test kits in the morning from the warehouse and we sometimes run QC on the kits." 7. No training documentation was available. Email correspondence with LD of the main laboratory (A) on March 4, 2022 at 11:42 AM confirmed no training documentation was completed prior to patient testing. 8. Email correspondence with laboratory director of main laboratory (A) on March 8, 2022 at 5:49 PM confirmed

8,461 COVID-19 rapid antigen patient tests have been performed since January 19, 2021 at Nomi Health Lab Services, LLC TTS located at 3345 E Richardson Flat Rd, Park City, UT 84098. E. Nomi Health Lab Services, LLC TTS located at 5405 W 3100 S, West Valley City, UT 84120 1. Observation on February 2, 2022 at 12:00 PM showed a cart with the unopened collection swabs stored outside exposed to the temperature of 25 F and included collected patient swabs with the sleeves opened. 2. Observation of the laboratory on February 2, 2022 at 12:10 PM located within a mobile storage unit showed no temperature monitoring or documentation; no timers; a box of opened GenBody COVID-19 cassettes (from the packaging) piled in a large box ready for use; and unopened GenBody COVID-19 boxes. 3. Review of manufacturer's IFU showed, "Allow Test Devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30C) (59-86F) prior to testing. Store the test kit in a cool, dry place between 2-30 C (35.6-86 F). The test should be performed immediately after removing the device from the foil pouch. Test devices and swabs should be used immediately upon opening; do not remove Test Devices from the pouch until just before use. Materials required but not provided - Timer." 4. Review of the manufacturer's IFU showed, "Read the test result at 15-20 minutes. Test results should not be read after 20 minutes. Caution: False positive or false negative results can occur if test device is read before 15 minutes or after 20 minutes." 5. Interview with testing personnel on February 2, 2022 at 12:15 PM, "Now per the field lead we are using our phones to check timing. We set the timer on our phones to 15 minutes from check in." 6. Observation of the computer showed the check in time is when the patient pulls up and checks in on the computer with laboratory staff. The collection of the specimen is performed approximately one to five minutes later dependent on the number of patients in line. 7. No training documentation was available. Email correspondence with LD of the main laboratory (A) on March 4, 2022 at 11:42 AM confirmed no training documentation was completed prior to patient testing 8. Email correspondence with LD of main lab (A) on March 8, 2022 at 5:49 PM confirmed 32,879 COVID-19 rapid antigen patient tests have been performed since April 14, 2021 at Nomi Health Lab Services, LLC TTS located at 5405 W 3100 S, West Valley City, UT 84120. F. Nomi Health Lab Services, LLC TTS located at 1190 E 2500 N, Logan, UT 84341 1. Observation on February 3, 2022 at 12:00 PM of the laboratory located within a mobile storage unit showed no temperature monitoring or documentation and patient collected swabs ready for testing in opened sleeves (pouches). Observation of the laboratory testing area revealed a room temperature reading on the surveyor thermometer of 33.3C (91.9F). 2. Review of the manufacturer's IFU showed, "Read the test result at 15-20 minutes. Test results should not be read after 20 minutes. Caution: False positive or false negative results can occur if test device is read before 15 minutes or after 20 minutes." 3. Observation on February 3, 2022 showed: patient (A) specimen added to the test cassette and timing started at 12:05 PM and resulted at 12:28 PM--total elapsed time of 23 minutes. patient (B) specimen added to the test cassette and timing started at 12:07 PM and resulted at 12:28 PM--total elapsed time of 21 minutes. patient (C) specimen added to the test cassette and timing started at 12:16 PM and resulted at 12:30 PM--total elapsed time of 14 minutes. 4. Review of manufacturer's IFU showed, "Allow Test Devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30C) (59-86F) prior to testing. Store the test kit in a cool, dry place between 2-30 C (35.6-86 F). The test should be performed immediately after removing the device from the foil pouch. Test devices and swabs should be used immediately upon opening; do not remove Test Devices from the pouch until just before use. Materials required but not provided-Timer." 5. Outside temperature was documented at 27 F. 6. Interview on February 3, 2022 at 12:10 PM with the onsite supervisor, "If busy, we put the cart with collection swabs outside." 7. Interview with

	testing personnel on February 3, 2022 at 12:15 PM about the specific timeframe required to read the COVID-19 test revealed, "As long as there is a relative timeframe, we can read the test up to one hour." 8. No training documentation was available for review. Email correspondence with LD of the main laboratory (A) on March 4, 2022 at 11:42 AM confirmed no training documentation was completed prior to patient testing. 9. Email correspondence with the LD of the main laboratory (A) on March 8, 2022 at 5:49 PM confirmed 11,134 COVID-19 rapid antigen patient tests have been performed since January 11, 2022 at Nomi Health Lab Services, LLC TTS located at 1190 E 2500 N, Logan, UT 84341.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on observations made during the survey, review of the GenBody COVID-19 Antigen Test instructions for use, lack of training, lack of temperature records, and interviews with field supervisors, management, and testing personnel, the laboratory is performing testing in a manner that constitutes an imminent and serious risk to public health (Refer to D8201).
D8201	INSPECTION OF COW OR PPMP LABS CFR(s): 493.1775(b) (b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures. This STANDARD is not met as evidenced by: Based on observations at the time of the survey, lack of temperature and storage records, review of the GenBody COVID-19 antigen test kit instructions for use and interviews with field supervisors, management, and testing personnel, the laboratory operated in a manner that constituted a serious risk to public health by failing to follow manufacturer's instructions for use and storage of COVID-19 antigen test kits on (Refer to D1001).