Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2199101	02/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Nomi Health Miami Dade Llc	3075 Nw 107 Ave, Doral, FL	

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	A complaint survey for #2022000744 was conducted on 02/11/2022 to 02/15/2022 at Nomi Health Miami Dade at the testing site listed as Miami International Airport at 2100 NW 42nd Ave Concourse H, Miami FL 33126. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Condition was not met: D8100 - 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: Based on observation, record review and interview, the laboratory failed to follow the manufacturers guidelines to ensure same lots were used for COVID-19 (Coronovirus Disease 2019) testing with Abbott ID NOW COVID-19 test kit (ID NOW). The laboratory failed to follow manufacturers instructions to open the pouch test packages just before use and failed to use a timer with BinaxNOW COVID-19 Ag card kit (BinaxNOW). Findings included: Review of the ID NOW COVID-19 PRODUCT INSERT in the section for "PRECAUTIONS" stated, "Do not mix components from different kit lots or from other ID NOW assays". In the section for "REAGENTS AND MATERIALS" stated: "Materials Provided- BASE -Test Bases: Orange plastic components containing two reaction tubes of lyophilized reagents for the target amplification of SARS-CoV-2 RNA (Severe Acute Respiratory Syndrome Coronavirus Ribonucleic Acid) and an internal control. RCVR -Sample Receivers: Blue plastic components containing 2.5mL of elution buffer. CARTRDG -Transfer Cartridges: White plastic components used to transfer 2x 100uL of sample extract from the Sample Receiver to the Test Base." During an observation on 02/11/2022 at 11:30 AM revealed, a bucket of BinaxNOW antigen foil packets cut open and sitting

	out. Testing personnel A pulled out one of the already cut open packages from the bucket and used it on a patient for specimen collection. During an observation on 02 /11/2022 at 11:45 AM revealed, the technician was not using a timer or a clock to indicate when the BinaxNOW card needed to be read. The BinaxNOW cards did not have a written time when the test started to perform the reading within 15 minutes. During an observation on 02/11/2022 at 12:45 PM, the laboratory had a shelf with boxes of ID NOW kit components to include the BASE and RCVR CARTRDG with different lot numbers. A technician pulled two different lots from the BASE and RCVR CARTRDG to begin the ID Now COVID-19 testing. The laboratory had open boxes of ID NOW kits with different lots around the laboratory. There was no designation of what lots were in use and not in use. Review of BinaxNOW Card product insert states, "Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open. Materials required but not provided: clock timer or stopwatch. Read result in the window 15 mins after closing the card. In order to ensure performance, it is important to read the results promptly at 15 mins and not before." During an interview with the Laboratory Director (LD) on 02/15/2022 at 01: 05 PM, she stated, the laboratory performed 47 BinaxNOW and 40 ID NOW tests for COVID-19 from 02/11/2022 - 02/15/2022.
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 observation, record review and interview, the laboratory failed to follow the manufacturers guidelines to ensure the same lots were in use for COVID-19 (Coronavirus Disease 2019) testing with ID Now test kits. The laboratory failed to ensure foil card test packages were opened just before use and that a timer was used with the BinaxNOW COVID-19 Ag card kits. (See D - 8201)
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 observation, record review and interview, the laboratory failed to follow the manufacturers guidelines to ensure same lots were used for COVID-19 (Coronovirus Disease 2019) testing with Abbott ID NOW COVID-19 test kit (ID NOW). The

	laboratory failed to follow manufacturers instructions to open the pouch test packages just before use and failed to use a timer with BinaxNOW COVID-19 Ag card kit (BinaxNOW). Findings included: Review of the ID NOW COVID-19 PRODUCT INSERT in the section for "PRECAUTIONS" stated, "Do not mix components from different kit lots or from other ID NOW assays". In the section for "REAGENTS AND MATERIALS" stated: "Materials Provided- BASE -Test Bases: Orange plastic components containing two reaction tubes of lyophilized reagents for the target amplification of SARS-CoV-2 RNA (Severe Acute Respiratory Syndrome Coronavirus Ribonucleic Acid) and an internal control. RCVR -Sample Receivers: Blue plastic components containing 2.5mL of elution buffer. CARTRDG -Transfer Cartridges: White plastic components used to transfer 2x 100uL of sample extract from the Sample Receiver to the Test Base." During an observation on 02/11/2022 at 11:30 AM revealed, a bucket of BinaxNOW antigen foil packets cut open and sitting out. Testing personnel A pulled out one of the already cut open packages from the bucket and used it on a patient for specimen collection. During an observation on 02 /11/2022 at 11:45 AM revealed, the technician was not using a timer or a clock to indicate when the BinaxNOW card needed to be read. The BinaxNOW cards did not have a written time when the test started to perform the reading within 15 minutes. During an observation on 02/11/2022 at 12:45 PM, the laboratory had a shelf with boxes of ID NOW kit components to include the BASE and RCVR CARTRDG with different lot numbers. A technician pulled two different lots from the BASE and RCVR CARTRDG to begin the ID Now COVID-19 testing. The laboratory had open boxes of ID NOW kits with different lots around the laboratory. There was no designation of what lots were in use and not in use. Review of BinaxNOW Card product insert states, "Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open. Materials required but not provided: clock timer or stopwatch. Read result in the window 15 mins after closing the card. In order to ensure performance, it is important to read the results promptly at 15 mins and not before." During an interview with the Laboratory Director (LD) on 02/15/2022 at 01: 05 PM, she stated, the laboratory performed 47 BinaxNOW and 40 ID NOW tests for COVID-19 from 02/11/2022 - 02/15/2022.