Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0426602	01/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Northshore Clinical Laboratories,	4751 N Kedzie Ave, Chicago, IL	

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	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: I. Based on review of the manufacturer package insert, interview with the laboratory site supervisor, testing person, and observation of the test facility on 12/29/21 at 2:00 PM, The laboratory failed to follow the manufacturer package insert and failed to maintain training and competency documents when performing COVID-19 testing with the GenBody COVID-19 Ag test system for the detection of the SARS-CoV-2 antigen. Findings 1. The lab was performing rapid COVID Antigen testing with the GenBody COVID-19 Ag test system. 2. The lab was a pop up COVID test site called NOVA located at 2132 Wisconsin Ave NW Washington, DC 20007. Centers for Medicare & Medicaid Services (CMS) Philadelphia Branch location representative contacted the person who handles permits for NOVA on January 3, 2022 at 9 AM who confirmed that the GenBody COVID-19 AG rapid test performed at NOVA DC location falls under NORTHSHORE CLINICAL LABORATORIES, INC, CLIA# 14D0426602. 3.The lab did not have State licensure at the time of the complaint survey. 4. Observation of the lab at 2:00 PM on 12/29/21 showed patients in a long line waiting to be tested outside the lab. Inside there were two patients waiting for COVID results and one patient swabbing their own nostril to have testing performed. 5. The lab had one testing person performing COVID testing. 6. The lab was collecting two nasopharyngeal swabs. One swab to be tested onsite and one swab for send out to be tested at Northshore Clinical Laboratories. 7. The patients swabbed each nostril three times with separate swabs and handed the swabs to the testing person. 8. The testing person would then add one swab to the tube of extraction solution to be tested in house with the GenBody COVID-19 Ag test system. After

	mixing the sample in the tube of extraction solution. The testing person would add drops from the tube to the test cartridge. The second swab was added to a tube of media and bagged up for send out to Northshore Clinical Laboratories. 9. The testing person would then tell the patient to wait seven minutes for results from the GenBody COVID-19 Ag test performed in house. A timer was set for seven minutes. 10. The manufacturer package insert states the patient nasopharyngeal swab sample must be mixed eight to ten times with the extraction solution. Add four drops of the patient sample mixed with the extraction solution to the cartridge sample well and incubate the cartridge for 15-20 minutes read results. The package insert state to maintain interpretation time as false negative and false positive results can occur. 11. Once the test was completed the sample cartridge was placed in a trash can that was not red lined and labeled for hazardous waste. 12. The testing person stated during the interview on 12/29/21 at 2:00 PM that the way she performed the GenBody COVID-19 Ag test was the way she was trained. 13. Documentation of training was not on site during the time of the complaint survey. 14. The lab site supervisor confirmed on 12 /29/21 at 2:00 PM that training nor competency documents were available. II. Based on review of the manufacturer package insert, interview with the laboratory site supervisor, testing person, and observation of the test facility on 12/29/21 at 2:00 PM, The laboratory failed to follow the manufacture package insert and failed to document room temperature and humidity when performing COVID-19 testing with the GenBody COVID-19 Ag test system for the detection of the SARS-CoV-2 antigen. Findings: 1. The lab failed to document room temperature and humidity levels according to the manufacturer package insert. 2. The manufacturer package insert states to bring the test kit and extraction solution to room temperature 15-30 degrees Celsius prior to testing. The package insert states that humidity may decrease reagent stability. 3. The lab did not have logs documenting the room temperature and humidity levels during the time of the complaint survey. 4. The lab site supervisor confirmed on 12/29/21 at 2:00 PM that the logs documenting the room temperature and humidity levels were not available. III. Based on review of the manufacturer package insert, interview with the laboratory site supervisor, testing person, and observation of the test facility on 12/29/21 at 2:00 PM, the laboratory failed to follow the manufacturer package insert and failed to document lot numbers and expiration dates of the test kits and reagents when performing COVID-19 testing with the GenBody COVID-19 Ag test system for the detection of the SARS-CoV-2 antigen. Findings: 1. The lab failed to document the lot numbers and expiration dates of the GenBody COVID-19 Ag test kits and all reagents. 2. The manufacturer package insert states to maintain expiration dates of the test kit.