Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1072337	04/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Minuteclinic Diagnostic Of Il, Pllc (Clinic 08760)	3333 Central St, Evanston, 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: Based on review of laboratory's testing menu; manufacturer's instruction; laboratory records; surveyor observation; and interviews with the testing person and nurse manager, the laboratory failed to follow the manufacturer's instructions for performing its SARS-CoV-2 Ag tests. Findings: 1. On April 15, 2021 at 9:15 AM, review of the laboratory's testing menu revealed that the laboratory performs SARS-CoV-2 Ag testing using the LumiraDX waived test kit and analyzer. 2. Instructions for test performance include the following: a. While rotating the swab, insert less than one inch into the first nostril until resistance is me at turbinates. b. Rotate the swab several times against the nasal wall. c. Remove and repeat this process by using the same swab into the second nostril. d. Place and soak the patient swab in the Extraction Buffer for 10 seconds and the stir well by rotating the swab against the side of the vial 5 times. e. After swabbing, process the swab in the Extraction Vial. DO NOT PLACE THE SWAB BACK INTO THE SWAB PACKAGING SLEEVE AFTER SAMPLE COLLECTION. f. Remove the patient swab while squeezing the middle of the Extraction Vial to remove the liquid from the swab. g. Firmly attach the clear or purple Dropper lid and gently invert the extraction vial 5 times. h. Apply the extracted sample from the Extraction Vial onto the sample application area of the inserted test strip. i. The result will be displayed be displayed as a positive or negative SARS-CoV-2 Ag on the instrument's screen. 3. On April 15, 2021 at 9:30 AM, the surveyor reviewed the following records: a. Training documents b. Competency Assessment records c. Temperature Charts d. Quality Control records 4. On April 15, 2021 at 9:40 AM, the surveyor observed that client testing is performed in kiosks in the parking lot

	of the MinuteClinic. 5. On April 15, 2021 at 9:40 AM, the surveyor asked the testing person if she could observe her collecting a patient' specimen. The testing person told the surveyor that verbal instructions for collecting the specimen are given to the client. Then, the client collects his own nasal swab. 6. On April 15, 2021 at 9:45 AM, the surveyor asked for the client's permission to observe him collecting his nasal specimen. The client told the inspector that he had already collected his specimen while sitting in his car. 7. The surveyor observed that same client walking up to the kiosk with his uncovered nasal swab, exposed to the elements, in hand; testing personnel accepting the swab and inserting the swab into the buffer vial; and testing and reporting SARS CoV-2 Ag results of that specimen. 8. On March 15, 2021 at 9:50 AM, the surveyor asked the testing person if she should have rejected the specimen. The testing person told the surveyor "probably." She said, "usually, after the client swabs their nostrils, I have them place their swab back into the sleeve the swab was taken from." 9. On March 15, 2021 at 10:00 AM, the nursing manager confirmed the surveyor's findings.