Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 14D2048976	**(X3) Date Survey Completed** 06/30/2022
Name of Provider or Supplier Woodridge Clinic Lemont	**Street Address, City, State** 15884 W 127th St, Ste H, Lemont, 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 lack of documentation, direct observation, interview with Lab Director (LD), Office Receptionist 1 (OR 1), and Testing Personnel (TP 1), the laboratory failed to provide training documentation for performing SARS-CoV-2 testing following manufacturers' instructions for four of four testing personnel. Findings Include: 1. On 05/25/2022 at 12:00 pm, interview with Office Receptionist 1 (OR 1) revealed a total of four laboratory Testing Personnel (TP) at the Woodridge Clinic Lemont. 2. On 05/25/2022 at 12:15 pm, direct observation revealed one SARS-CoV-2 test kit in use: Celltrion DiaTrust COVID - 19 Ag Rapid Test 3. Review of the Celltrion DiaTrust COVID - 19 Ag Rapid Test Instructions for Use (IFU) states: F. All operators using your product must be appropriately trained in performing and interpreting the results of your product. Use appropriate personal protective equipment when handling this kit, and use your product in accordance with the labeling. 4. The laboratory failed to provide training documentation of the Celltrion DiaTrust COVID - 19 Ag Rapid Test for TP 1, TP 2, TP 3, and TP 4 upon request. 5. On 05/25/2022 at 12:15 pm, interview with the Lab Director and TP 1 confirmed the laboratory personnel did not have access to training documentation of the Celltrion DiaTrust COVID-19 Ag Rapid Test.