

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0421160	<b>(X3) Date Survey Completed</b>  05/25/2022
<b>Name of Provider or Supplier</b>  Woodridge Clinic	<b>Street Address, City, State</b>  7530 S Woodward Ave, Woodridge, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, direct observation, interview with Testing Personnel (TP 1), the laboratory failed to provide training documentation for performing SARS-CoV-2 testing following manufacturers' instructions for two of two testing personnel. Findings Include: 1. On 05/25/2022 at 9:39 am, interview with (TP 1) revealed a total of two laboratory Testing Personnel (TP) at the Woodridge Clinic in Woodridge. 2. On 05/25/2022 at 9:45 am, direct observation revealed two SARS-CoV-2 test kits in use: Accula Test SARS-CoV-2 Sienna COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) 3. Review of the Accula Test SARS-CoV-2 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 authorized labeling. 4. Review of the Sienna COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) 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. 5. The laboratory failed to provide training documentation of the Accula Test SARS-CoV-2 and the Sienna COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) for TP 1 and TP 2 upon request. 6. On 05/25/2022 at 10:20 am, interview with TP 1 confirmed the laboratory personnel did not have access to training documentation of the Accula Test SARS-CoV-2 or the Sienna COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) kits.</p>