

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2207798	<b>(X3) Date Survey Completed</b> 03/04/2022
<b>Name of Provider or Supplier</b> Ageless Md Arlington Preventative	<b>Street Address, City, State</b> 2221 N Buchanan St Suite 102, Arlington, VA	
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>D0000</b>	An unannounced Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (Complaint #VA00054123) was conducted at Ageless MD Arlington Preventative Health & Medicine on February 2, 2022 (on-site) to March 4, 2022 by a Medical Facilities Inspector from the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Based on a video conference call, review of documents, emails and interviews, the inspector found the complainant's allegation of not following manufacturer's instructions for interpreting of COVID-19 testing was substantiated. Specific deficiency cited is as follows:
<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 a interview, review of the manufacturer's instruction for use (IFU), and patient clinic note, the facility failed to follow the Quidel Sofia 2 SARS Antigen FIA manufacturer's IFU for sample incubation and interpretation of results for one (1) of 1 patients on January 4, 2022. Findings include: 1. During a video conference call with Testing Personnel A (TP A) on March 1, 2022 at approximately 11:30 AM, TP A stated the laboratory began COVID-19 Antigen testing on November 23, 2022 using the BD Veritor System for the Rapid Detection of SARS CoV-2 and Quidel Sofia 2 SARS Antigen FIA. 2. During an interview with TP A on March 1, 2022 at approximately 12:00 PM, the inspector inquired with TP A the incubation time for COVID-19 Antigen testing utilizing the Quidel Sofia 2. TP A stated the test is read at fifteen (15) minutes and should not read after thirty (30) minutes because the results could be inaccurate. The inspector asked TP A if they had ever reported a patient's test</p>

result after 30 minutes. TP A stated they called Patient A on January 4, 2022 at approximately thirty minutes and informed Patient A their test result was negative. About an hour later when they were discarding the test cassettes, they noticed a "faint" line on Patient A's cassette and called the patient to let them know the result was faintly positive and to be careful until they received their PCR results. 3. Review of the IFU for the Quidel Sofia 2 SARS Antigen FIA kit revealed the following statement: "Warning: Results must not be interpreted past 30 minutes after inoculation. Using the Sofia past this time might result in false results." 4. In an interview with TP A on March 1, 2022 at 11:55 AM, the above findings were confirmed. 5. Review of Patient A's clinic notes for January 4, 2022 (notes received via email on March 3, 2022) revealed the following statements: "PT testing due to confirmed exposure from a COVID-19 positive case...PT was contacted by phone about 30 minutes after testing and provided the negative rapid results. PT was contacted again about an hour later...PT was told that there is a chance of a false negative when someone has these symptoms; especially after a confirmed direct exposure and that the express service they purchased includes calling them in about an hour after their test report has been processed and sent for review in addition to the immediate telephone reporting of the results when they're ready...explained on some rapid test they show a line that varies based on the antigen levels detected and to be cautious to avoid infecting her entire family."