

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2061427	<b>(X3) Date Survey Completed</b> 09/29/2021
<b>Name of Provider or Supplier</b> Midlothian Family Practice Westchester	<b>Street Address, City, State</b> 15769 Westchester Main Street, Midlothian, 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 announced CLIA recertification survey was conducted at Midlothian Family Practice Westchester on September 29, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. 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 review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification Form (CMS 116), Food and Drug Administration (FDA) Emergency Use Authorization (EUA), manufacturer's instructions for use (IFU), lack of documentation, and interviews, the laboratory failed to provide documentation of required training for the use and interpretation of results for the Quidel Sofia SARS Antigen FIA testing system during the timeframe of December 2020 to the date of the inspection, September 29, 2021. Findings include: 1. During a pre-survey review on 09/27/21, the inspector noted that the laboratory director indicated on the submitted CMS 116 form COVID-19 testing utilizing Quidel Sofia SARS Antigen test cassettes. During the survey entrance interview with the technical consultant (TC) on 09/29/21 at approximately 1 PM, it was revealed that the office began performing rapid COVID-19 antigen testing with Quidel Sofia test system in December 2020. 2. Review of the FDA's issued EUA (dated 05/08/20) revealed a Quidel Sofia SARS Antigen FIA manufacturer's IFU with the following statement: "Conditions of Authorization for Laboratory and Patient Care Setting: All operators using your</p>

product must be trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use the product in accordance with the authorized labeling." 3. During a tour of the rapid COVID-19 testing exam room (adjacent to the main laboratory) at approximately 2:00 PM, the inspector reviewed the Sofia COVID-19 antigen test system maintenance and temperature logs, and requested to review testing personnel training records for the timeframe of when patient testing went live in December 2020 up to 9/29/21. No training documentation was available for review. The TC stated at approximately 2:30 PM: "The providers and their nurses perform the COVID-19 testing. There are approximately 10 testing personnel operating the Sofia and reporting rapid antigen test results. I do not have their training records for you to review today". 4. In an exit interview with the TC, at approximately 3:00 PM, the above findings were confirmed.