Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0226413	09/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Midlothian Family Practice Villiage	13332 Midlothian Turnpike, Midlothian, VA	

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
D0000	An announced CLIA Recertification survey was conducted at the Midlothian Family Practice-Village Office on 09/21/22 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
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 a tour, review of manufacturer's instructions for use (IFU), maintenance logs, and lack of documentation, and interviews, the laboratory failed to document performance of required monthly calibration checks for the Quidel Sofia 2 analyzer utilized for COVID-19 testing for seven of twenty-one months reviewed. Dates of record review include 01/01/21 up to date of survey, 09/21/22. Findings include: 1. An entrance interview with the technical consultant (TC) on 09/21/22 at approximately 09:10 AM revealed the facility performed COVID-19 testing. A tour of the exam room designated for patient testing on 09/21/22 at approximately 09:15 AM revealed one Quidel Sofia 2 analyzer in use for COVID-19 testing. 2. Review of the Quidel Sofia 2 SARS Antigen IFU revealed the following statement: Quality Control: "The Calibration Check is a required function that checks the Sofia 2 optics and calculations systems using a specific calibration cassette. The Calibration Check should be performed every 30 days." 3. Review of the Quidel Sofia analyzer maintenance log book revealed lack of documentation of calibration checks for the following months: April, May and June 2021, February, April, June and July 2022.

	Total of seven months. The inspector requested documentation for the above-specified months. The documentation was not available for review. 4. An exit interview with TC on 09/21/22 at approximately 10:30 AM confirmed the findings.