Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0875358	08/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Midlothian Family Practice Waterford	3000 Watercove Road, 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 Midlothian Family Practice Waterford-Virginia Physicians, INC on August 6, 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 deficiencies cited are as follows:
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: A. Based on a review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour, review of procedures, temperature logs, and lack of documentation, the laboratory failed to document temperature monitoring ensuring Sofia 2 SARS antigen test kits were stored according to the written procedure for seven (7) of 7 months reviewed in calendar year 2021. Findings include: 1. During a pre-survey review on 08/04/21, the inspector noted that the laboratory director (LD) indicated on the submitted CMS 116 form patient COVID-19 testing utilizing Quidel Sofia SARS Antigen test cassettes. 2. During a laboratory tour on 08/06/21 at approximately 10:00 AM, the inspector noted that the Sofia analyzer was in use for COVID-19 testing in the facility's Treatment Room adjacent to the laboratory. The inspector noted one opened box of Sofia Flu+SARS Antigen test cassettes stored in the Treatment Room (kit lot number 706406; twelve of twenty-five cassettes remaining). The inspector noted there was no thermometer or temperature monitoring logs in the Treatment Room. 3. Review of the laboratory's procedures revealed a Sofia 2 Flu + SARS Antigen Procedure (approved by the LD on

	12/29/20) that stated: Warnings and Precautions: "This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Authorization (EUA) for use by laboratories certified under CLIA that meet the requirements to perform high, moderate, or waived complexity tests"; Kit Storage and Stability: "Store the kit at room temperature 59 degrees Fahrenheit (F) to 86 F (15 C to 30 C)." 4. Review of the main laboratory's temperature log book revealed no records for the COVID-19 testing area located in the Treatment Room. The inspector requested to review temperature monitoring for the COVID-19 testing area. No records were available for review. 5. An exit interview with technical consultant (TC) on 08/06/21 at approximately 11:30 PM confirmed the above findings. B. Based on a review of the CMS 116 form, tour, review of procedures, maintenance logs, and lack of documentation, the laboratory failed to document performance of required monthly calibration checks for the Sofia 2 analyzer utilized for COVID-19 testing for four (4) of seven (7) months reviewed in calendar year 2021. Findings include: 1. During a pre-survey review on 08/04/21, the inspector noted that the laboratory director (LD) indicated on the submitted CMS 116 form patient COVID-19 testing utilizing Quidel Sofia SARS Antigen test cassettes. 2. During a laboratory tour on 08/06/21 at approximately 10:00 AM the inspector noted that one (1) Sofia analyzer was in use for COVID-19 testing in the facility's Treatment Room adjacent to the laboratory. 3. Review of the laboratory's procedures revealed a Sofia 2 Flu + SARS Antigen Procedure (approved by the LD on 12/29/20) that stated: 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 is to be performed every 30 days." 4. Review of the Sofia log book revealed the following calibration check's were recorded: 01/08/21, 01/14/21, 01/18/21, 01/25/21, 05/05/21, and 07/14/21. The inspector requested to review calibration checks performed in February, March, April, and June of calendar year 2021. No records were available for review. 5. An exit interview with TC on 08/06/21 at approximately 11:30 PM confirmed the above findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a tour, review of procedures, maintenance logs, lack of documentation, and an interview, the laboratory failed to document function checks of revolutions per minute (RPM) verification for one (1) Unico centrifuge utilized for microscopic urine sediment examinations in calendar year 2020. Findings include: 1. During a tour of the laboratory on 08/06/21 at approximately 10:00 AM the inspector noted 1 Unico centrifuge (Model C856, Serial Number 0607250) in use for microscopic urine sediment specimen processing. 2. Review of the laboratory's procedures revealed the following protocol: Microscopic Examination of Urine - that stated "12 ml of urine should be taken from a freshly mixed urine specimen and centrifuged at 2,000 RPM

	for 5 minutes." 3. Review of the laboratory's centrifuge maintenance documentation revealed the Unico centrifuge was calibrated for 2,000 RPM as outlined above. The maintenance was performed by H and M Sales and Services, INC on 09/12/2019 and 06/10/21. The inspector requested to review documentation of the Unico RPM check for calendar year 2020. No record was available for review. The inspector inquired of the laboratory's centrifuge maintenance protocols. The technical consultant (TC) stated at approximately 11:00 AM: "Our protocol is to have all centrifuge RPM checks done annually but the company failed to come in 2020." 4. An exit interview with TC on 08/06/21 at approximately 11:30 PM confirmed the above findings.