Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0231191	10/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Kenbridge Family Medicine	306 East 6th Avenue, Kenbridge, 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 Kenbridge Family Medicine on 10/20/22 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: A. Based on a tour of the patient testing room, manufacturer's instructions for use (IFU), lack of documentation and interviews, the lab failed to document and monitor the room temperature in the patient testing room for the BD Veritor Rapid Detection of SARS-CoV-2 (COVID-19) test kits and analyzer from 01/01/21 up to the date of survey on 10/20/22. Findings include: 1. Tour of the facility and interview with testing personnel on 10/20/21 at approximately 10:15 AM revealed a separate room in the adjoining facility used to perform COVID-19 test procedures. The room offered an easy access for patients to drive up and receive care and testing procedures. The surveyor asked how patients are processed for COVID-19 test procedures. They stated, "the test kits and analyzer is kept here in this room. We test patients in their cars, bring the swab in and label the cassette with patient information. We then go back to the main office and log that patient's test results into our electronic medical record." 2. Review of the BD Veritor Rapid Detection of SARS-CoV-2 (COVID-19) test kits and analyzer IFU revealed the following statement, "Storage- Kits may be stored at 2-30 degrees Celsius. Reagents and devices must be a room temperature (15-

	30 degrees Celsius) when used for testing." The inspector asked the testing personnel how they monitor the room temperature of the patient testing room in the adjoining building to ensure the kits and analyzer are maintained within the manufacturer's requirements on 10/20/22 at approximately 11:00 AM. They stated they do not monitor the separate room. 3. An exit interview with the technical consultant on 10/20 /22 at approximately 1215 confirmed the findings. B. Based on the review of manufacturer's instructions for use (IFU), lack of documentation and interviews, the lab failed to document the performance of the external positive and negative controls for the BD Veritor Rapid Detection of SARS-CoV-2 (COVID-19) test kits from 01/01 /21 up to the date of survey on 10/20/22. Findings include: 1. Review of the BD Veritor COVID-19 IFU revealed the following statements, "positive and negative controls swabs are supplied with each kit. BD recommends controls be run once for: each new kit lot, each new operator, and as required by internal quality control procedures and in accordance with local, state and federal regulation or accreditation requirements." 2. In an interview with the testing personnel on 10/20/21 at approximately 10:15 AM, the inspector asked how the lab performs and documents the positive and negative control swabs for each new kit lot. They stated, "I don't do that part, I think the other testing personnel does that part." The inspector requested to review documentation of the above-specified quality control procedures for each new kit lot received from 01/01/21 up to the date of the survey on 10/20/22. The documentation was not available for review. 3. An exit interview with the technical consultant on 10/20/22 at approximately 1215 confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the review of maintenance logs, manufacturer's operation manual, lack of documentation and interview with technical consultant, the lab failed to perform the semi-annual maintenance on the Abbott Cell Dyn Emerald hematology analyzer from 07/22/21 up to the date of survey on 10/20/22. Findings include: 1. Review of the maintenance logs for the Abbott Cell Dyn Emerald analyzer (installed on 05/21/21) revealed the date of 07/22/21 as performance of the semi-annual maintenance (piston syringe lubrication). The maintenance logs lacked documentation of additional performance of the semi-annual maintenance after 07/22/21. The inspector requested to review additional documentation of the aforementioned maintenance. No other documentation was available for review. 2. Review of the Abbott Emerald Operations Manual revealed manufacturer's instructions to "perform Lubricating Syringe Pistons maintenance procedure twice annually". 3. An exit interview with the technical consultant on 10/20/22 at approximately 1215 confirmed the findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview with the the technical consultant (TC), the TC failed to perform and document the annual competency assessments for three of three TP in 2021. Findings include: 1. Review of the CMS-209 form revealed there were a total of three TP performing patient testing. 2. Review of the TP records revealed a lack of documentation by the TC of performance and review of the annual competency assessments for the following: TP A- 2021, TP B- 2021, and TP C- 2021. See attached TP code sheet. 3. An exit interview with the TC on 10/20/22 at approximately 1215 confirmed the findings.