Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0231191	(X3) Date Survey Completed 08/30/2024
Name of Provider or Supplier Kenbridge Family Medicine	**Street Address, City, State** 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 August 30, 2024 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 and includes the Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of manufacturer's operation manual, procedures, hematology analyzer maintenance logs, instrument calibration records, lack of documentation, and interviews, the laboratory failed to: 1. document performance of twice annual hematology instrument preventative maintenance in calendar year 2023-**REPEAT DEFICIENCY, cross reference D5429; and 2. perform instrument calibration procedures for Complete Blood Count every six months according to their procedure during the twenty-two months reviewed (timeframe: 10/23/22 to 8/30/24), cross reference D5437.
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 a review of manufacturer's operation manual, procedures, hematology analyzer maintenance logs, lack of documentation, and interview, the laboratory failed to document performance of required twice annual instrument preventative maintenance in calendar year 2023. **REPEAT DEFICIENCY Findings include: 1. Review of the Abbott Emerald Operations Manual revealed manufacturer's instructions to "perform Lubricating Syringe Pistons maintenance procedure twice annually" (under heading: Preventative Maintenance). 2. Review of the laboratory procedure manual revealed a procedure (titled: Cell Dyn Emerald Laboratory Procedure -Maintenance) that outlined, "perform semi-annually grease/lubrication of pistons". 3. Review of the laboratory's Emerald hematology maintenance logs for calendar year 2023 revealed one record of the semi annual maintenance outlined above (recorded as performed on 5/3/23). The inspector requested to review additional documentation of the piston syringe maintenance in 2023. No records were available. 4. An exit interview with the technical consultant on 8/30/24 at 2:30 PM confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of procedures, instrument calibration records, lack of documentation, and interview, the laboratory failed to perform instrument calibration procedures for Complete Blood Count (CBC) every six (6) months according to their procedure during the twenty-two (22) months reviewed (timeframe: 10/23/22 to 8/30/24). Findings include: 1. Review of the laboratory's procedure manual revealed a policy titled: Laboratory QC and Calibrations - General Procedures. Under subheading Hematology, the policy stated: "Calibrations will be performed every six months or more frequently as needed." 2. Review of the laboratory's Abbott Emerald instrument calibration documentation from 10/23/22 to the date of the inspection on 8/30/24, a total of 22 months, revealed that CBC calibrations were performed on: 2/28/23, 8/11/23, and 7/22/24. The inspector noted an eleven month time span between the August 2023 calibration and the single calibration performed to date in 2024 (July). The inspector requested to review additional hematology calibration records for calendar

	year 2024. No additional documentation was available for review. 3. An exit interview with technical consultant on 8/30/24 at 2:30 PM confirmed the above findings.