Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0231879	05/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cmg, Village Family Physicians	4830 Rucker Road, Moneta, 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 CMG, Village Family Physicians on May 29, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observations, a review of procedures, and interviews, the laboratory failed to follow established safety protocols that prohibited eating and storage of food and beverages in the laboratory as observed on the date of the survey May 29, 2025. Findings include: 1. During a tour of the laboratory on 5/29/25 at 11:00 AM, the inspector observed food items (salad dressing, coffee creamer, lunch containers, and soft drink beverages) stored in a dorm sized refrigerator under a table in the laboratory. The inspector inquired regarding the presence of the food and beverages stored in the laboratory refrigerator. The Laboratory Site Manager stated on 5/29/25 at 11 AM: "The staff wanted an area to put break and lunch items and we discussed designating that refrigerator as a clean area." 2. Review of the laboratory procedure manual revealed a policy (Titled: CMG Laboratory Safety, Universal Precautions, Bloodbourne Pathogen Standard for all Testing Personnel and Staff, CMG.01.16.311) that stated: "The following are prohibited in the clinical laboratory: eating, drinking, smoking, application of cosmetics, and handling of contact lenses." 3. While gathering additional records for review on 5/29/25 at 12 noon the inspector noted one testing personnel seated eating from a plate of food at the table in the laboratory. The inspector noted that the personnel was within inches of a biohazard trash receptacle

	and adjacent to a specimen/reagent storage refrigerator. The inspector noted that the entrance door directly behind the lunch plate was a route for specimen delivery to the laboratory and specimen processing. The inspector inquired regarding protocols for eating in the laboratory. The Laboratory Site Manager stated on 5/29/25 at 12 noon, "We did discuss having a clean area for the staff at the table where they would not be required to wear PPE but our organization's protocol is to not eat in the laboratory. I will plan to huddle with the staff to review safety and we will remind staff to use the break rooms or offices to eat and store food." 4. An exit interview with the Medical Laboratory Technician, Laboratory Site Manager, and Laboratory Director on 5/29/25 at 1:30 PM confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of temperature logs, lack of documentation, procedure manual, and interviews, the laboratory failed to monitor the daily temperatures for room, two refrigerators, two freezers, and relative humidity percent (RH%) to ensure proper operating conditions, storage of reagents, specimens, and test kits according to policy for fourteen (14) of twenty-two (22) operational days in July 2024. Findings include: 1. Review of the laboratory temperature logs during the review timeframe of 5/26/23 to 5/29/25 revealed no record monitoring temperatures and RH% on the following 14 days in July 2024: 7/9, 7/11, 7/15-7/19, 7/22-7/26, and 7/29-7/30. The temperature log identified ambient, humidity, small and large refrigerator, small and large freezer to be documented daily. 2. The inspector requested to review environmental monitoring records documenting humidity, ambient, refrigerators and freezers' temperatures for the 14 days outlined above. No additional records were available for review. 3. Review of the laboratory's procedure manual revealed a policy (Titled: CMG Laboratory Quality Assurance Policy) that stated, "to ensure proper operating conditions and storage of reagents, specimens, and test kits per manufacturer's requirements, environmental assessments should be documented each day of operation". 4. An exit interview with the Medical Laboratory Technician, Laboratory Site Manager, and Laboratory Director on 5/29/25 at 1:30 PM confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)

	(3)-- (a)(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 (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(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 proficiency testing (PT) records, analyzer calibration records, policies/procedures, lack of documentation, and interviews, the laboratory failed to perform hematology calibration procedures according to their policy for Complete Blood Count (CBC) patient testing after replacement of critical Abbott Emerald analyzer components on April 7, 2025. Findings include: 1. Review of the laboratory's 2025 American Proficiency Institute PT records revealed a Performance Review and Corrective Action Document for their 2025 Hematology Event 1 unsatisfactory scores for White Blood Cell 67% and Monocyte 40% (dated as reviewed/accepted by the laboratory director on 5/16/25). 2. Review of the laboratory's Abbott Emerald hematology instrument calibration documentation for calendar year 2025 revealed calibrations dated 1/20/25 and 5/6/25. 3. Review of the laboratory's Emerald service records revealed that an Abbott field service representative performed a service call on 4/7/25 and replaced the O-ring and WBC Counting Head and repaired the FCMIG Optics, Detector, Measurement and Reading Flow Cell. The service representative's report also noted replacement parts for leaks, drips, bubbles. The inspector requested to review a calibration performed on 4/7/25 after the major maintenance outlined above. No calibration record was available for review. The Medical Laboratory Technician (MLT) stated on 5/29/25 at 1 PM, "I called for field service as part of the corrective action for an unsatisfactory PT event but we did not calibrate until a month after the service work. We continued to have the issues." 4. Review of the laboratory's procedure manual revealed a policy (Titled: CMG: CBC Abbott Emerald Analyzer, CMG 01.15.558) that stated "calibration frequency includes when the instrument requires a major system component to be replaced." 5. An exit interview with the Medical Laboratory Technician, Laboratory Site Manager, and Laboratory Director on 5/29/25 at 1:30 PM confirmed the above findings.