Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0231879	05/25/2023
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 23, 2023 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:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), procedure and policy manual, personnel files, lack of documentation, and an interview, the laboratory did not follow their policy for annual technical consultant (TC) competency assessments during the review timeframe of August 2021 to the date of the survey on May 23, 2023. Findings include: 1. Review of the CMS 209 revealed that Personnel # 1 serves as TC. (See Personnel Code Sheet.) 2. Review of the laboratory procedure and policy manual revealed a policy (titled: CMG Laboratory Quality Assurance Policy) that outlined a protocol for annual TC competency assessment documentation. The protocol stated, "Competency assessment of the technical consultant should be performed annually by the lab director for the duties assigned". 3. Review of the personnel files revealed no TC competency assessment records during the twenty-one month review timeframe of August 2021 to 5/23/23. 4. An interview with TC and lead testing personnel on 5/23 /23 at approximately 2:30 PM confirmed the above findings.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records (2021 Event 3, 2022 Events 1-3, 2023 Event 1) and an interview, the laboratory director failed to ensure that two (2) chemistry and urinalysis modules' analyte results were submitted timely for scoring on one (1) of five (5) PT events reviewed. Findings include: 1. Review of the laboratory's AAB-Medical Laboratory Evaluation (AAB-MLE) PT records (a total of 5 events) revealed the following: 2023 AAB-MLE 1st Chemistry Event : Direct Bilirubin - challenge sample CHM-01 scored as "no result submitted"; 2023 AAB-MLE 1st Urinalysis Event : RBC and WBC- challenge samples 1-5 scored as result absent (zero). The inspector inquired regarding the above analytes scored as "no results" submitted. The technical consultant (TC) stated on 5/23/23 at approximately 1:30 PM, "The MLE PT company changed the format when merged to AAB-MLE and the staff were unfamiliar with the new result entry process on the first event. We plan to contact the PT program and will document an evaluation of the analytes identified". The lead testing personnel stated at approximately 1:30 PM, "I cannot remember if the urinalysis RBC and WBC challenges were slides or photos" 2. An interview with the TC and lead tech on 5/23/23 at approximately 2:30 PM confirmed the above 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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and an interview, the technical consultant (TC) failed to perform hematology and chemistry competency evaluations for one (1) of three (3) testing personnel (TP) in calendar year 2022. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified a TC and 3 TP qualified to perform/report non-waived patient hematology Complete Blood Count (CBC) and routine chemistry testing. 2. Review of the available personnel files revealed no 2022 Abbott Emerald CBC or Ortho Clinical Vitros 350 chemistry competency evaluation performed/signed by the TC for Personnel # 2. (See Personnel Code Sheet.) The inspector requested to review competency assessment for Personnel # 2. The TC stated on 5/23/23 at approximately 1:30 PM, "The tech was a travel tech and came to help us in 2022. I did not get in to get the competency completed." 3. An interview with the TC and primary testing personnel on 5/23/23 at approximately 2:30 PM confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), procedures, laboratory personnel files, lack of documentation, and an interview, the technical consultant (TC) failed to perform annual Potassium Hydroxide (KOH) / Wet Prep and Urine Sediment Examination competency evaluations for six (6) of seven (7) microscopy testing personnel (TP) in 2022. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified one TC and 7 qualified personnel responsible for patient KOH/Wet Prep and Urine Sediment Examination testing (TP A - G). (See Personnel Code Sheet.) 2. Review of the laboratory's procedure manual revealed a policy that outlined competency assessment that stated, "Evaluating the competency of all testing personnel to ensure staff maintain their competency to perform test procedures and report results promptly, accurately, and proficiently. This will be documented twice per year during the employee's first year and annually thereafter." 3. Review of the laboratory personnel files revealed no microscopy competency assessment documentation for TP A - F in calendar year 2022. The inspector requested to review microscopy competency assessments for the 6 TP outlined above. No documentation was unavailable for review. 4. A follow up interview with the TC and lead tech on 5 /24/23 at approximately 1:40 PM confirmed the above findings.