Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0689728	05/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Calvert Internal Medicine Group	985 Prince Frederick Boulevard Suite 201, Prince Frederick, MD	

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
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 annual competency evaluations and interview with the technical consultant (TC), the laboratory did not evaluate the TC for duties performed as the TC. Findings: 1. A review of competency testing records from 2019 to 2021 showed that there was no competency assessment performed on the TC in 2019 and 2020. 2. During an interview on 05/19/2022 at 3:00 PM, the TC confirmed that competency reviews were not performed and documented on the TC for their role as TC.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on procedure manual, laboratory reagent package insert, and patient log record review and interview with the technical consultant (TC), the laboratory did not follow the manufacturer's instructions for performing bacteriology testing. Findings: 1. The laboratory is performing presumptive identification of group A streptococcus on

	throat cultures, using "HardyDisk Bacitracin Differentiation Disks" which are impregnated with low levels of Bacitracin. 2. During an interview at 10:15 AM on the day of the survey, the TC stated that the laboratory evaluates the culture plates at 24 and 48 hours after inoculation. 3. A review of the laboratory's "Throat Culture Log" from 05/02/2022 to 05/10/2022 showed that 3 of 16 patients' throat culture plates were innoculated on 05/06/2022 and interpreted after 3 days' incubation on 05/09/2022; and 4. 13 of 16 patients' throat culture plates were interpreted 2 days after innoculation. 5. The laboratory's "Strep Group A Screen" procedure instructs testing personnel to "Incubate the plates in ambient air at 35-37C for 48 hours." 6. Review of the package insert for the "HardyDisk Bacitracin Differentiation Disks" showed that culture plates must be incubated "for 18-24 hours at 35C" before being read or interpreted. 7. During an interview on 05/19/2022 at 3:00 PM the TC confirmed that the laboratory did not follow the manufacturer's instructions for performing throat cultures.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: A. Based on review of the standard operating procedure (SOP) manual, quality assessment (QA) plan, corrective action logs, and interview with the technical consultant (TC), the laboratory director (LD) did not provide written instructions to ensure that all the required information was gathered, reviewed, documented, and assessed to evaluate the appropriate remedial actions to be taken and corrective actions to be implemented. Findings: 1. Section C of Part 1 of the QA plan lists a ten step process to be used in the monitoring and evaluation of unusual values, discrepancies, apparent errors that need investigation, and corrective actions to be taken. 2. The QA plan included a worksheet titled "Deviation from SOP" which included documentation of the description of the issue, reasons for deviation, and actions taken. 3. Review of the monthly QA records from January through December 2020 and July through December 2021 showed that the worksheet was used to document 20% of the problems encountered in the laboratory. The other problems were documented on a plain piece of paper. The ten steps listed in the QA plan were not part of the documentation of the errors and problems investigated. 4. During the survey on 05/19/2022 at 3:00 PM, the TC confirmed that the investigations that were documented failed to include the steps written in section C of Part 1 QA plan. B. Based on review of the QA plan, "QA Calendar", and interview with the TC, the LD did not ensure that the QA plan included instructions for each of the tasks listed on the QA Calendar to ensure that all the required information was gathered, reviewed, documented, and assessed to evaluate the quality of the laboratory services. Findings: 1. Part 2 of the QA plan states what should be reviewed and documented as part of the QA review. The "QA Calendar" lists what is to be reviewed and documented on a monthly basis. These documents are included with the monthly QA review with the LD. 2. When interviewed, the TC provided worksheets for the tasks listed on the "QA Calendar." These worksheets were not part of the approved QA plan and did not include all the documentation of the criteria listed in Part 2 of the QA plan. 3. During

	the survey on 05/19/2022 at 3:00 PM, the TC confirmed that the QA plan did not include all of the approved monthly QA Calendar worksheets and the documentation of the criteria listed in Part 2 of the QA plan. C. Based on review of the Individualized Quality Control Plan (IQCP) and interview with the TC, the LD did not ensure that the IQCP included supporting data and quality control (QC) frequency and remedial actions to be taken for failures as part of the risk assessment. Findings: 1. The IQCP did not include the supporting data for making the assessment, e.g., package insert, documentation of successful proficiency testing results, and documentation of successful quality control results. The IQCP did not include policies and procedures for QC frequency and remedial actions to be taken when there is a QC failure. 2. During the survey on 05/19/2022 at 3:00 PM, the TC confirmed that the IQCP did not have supporting documentation and QC requirements.
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 competency testing record review and interview with the technical consultant (TC), the TC did not evaluate the competency of all testing personnel and assure that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. Findings: 1. The laboratory currently has 2 testing personnel listed on the "Laboratory Personnel Report (CLIA)" (CMS-209). 2. A review of competency testing records from 2019 to 2021 showed that there were no competency assessments performed on 2 of 2 testing personnel in 2020. 3. During an interview on 05/19/2022 at 3:00 PM, the TC confirmed that competency reviews were not performed and documented on all testing personnel in the laboratory.