

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1090545	(X3) Date Survey Completed 08/14/2019
Name of Provider or Supplier Cmg Farmville Laboratory	Street Address, City, State 935 South Main Street, Farmville, 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 Farmville Laboratory on August 13-14, 2019 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:
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on a laboratory tour, review of policies and procedures, equipment maintenance records, and interviews, the laboratory failed to follow their Revolutions Per Minute (RPM) calibration protocol for one (1) of two (2) centrifuges located in the specimen processing area during the twenty-two (22) months reviewed. Findings include: 1. During a tour on August 13, 2019 at approximately 2:00 PM, the inspector noted 2 Unico Powerspin centrifuges in specimen processing areas: Unit 1-Clinical Engineering Tag ID 211273- on urinalysis specimen processing bench, Unit 2- Clinical Engineering Tag ID 212075- on blood specimen processing bench. 2. Review of the policy and procedure manual's Quality Assurance (QA) section revealed the following 2 policies: General Lab Equipment Maintenance Policy that stated "All general lab equipment (used to process specimens) will have yearly preventative maintenance and calibrations. This applies to centrifuges, pipettes, microscopes"; Specimen Processing Policy that stated "centrifugation phase for serum or plasma</p>

specimen processing is 10 to 15 minutes at 3200-3500 RPM". 3. Review of the equipment maintenance records (October 2017 to the date of the survey) revealed no RPM calibration documentation for the Unit 2 Unico centrifuge (Tag ID 212075 utilized for blood specimen processing). The inspector requested to review a 3200-3500 RPM calibration verification. No documentation was available for review. 4. In an interview with the technical consultant and laboratory managers at approximately 2:30 PM on 8/14/19, the above findings were confirmed.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a laboratory tour, review of calibration records for the chemistry analyzer and an interview, the laboratory failed to perform calibration verification twice a year for Sodium (Na), Potassium (K), and Chloride (CL) analytes during the twenty-two (22) months reviewed. Findings include: 1. During a tour on August 13, 2019 at approximately 2:00 PM, the inspector noted an Ortho Clinical Vitros 350 in use for patient chemistry testing. 2. Review of the laboratory's Vitros 350 chemistry analyzer calibration records from October 1, 2017 to the date of the survey (22 month timeframe) revealed that Na, K, and CL calibrations were completed with a two (2) point calibration. The inspector requested to review calibration verification documentation for the analytes outlined above. The documentation was not available for review. 3. In an interview with the technical consultant and laboratory managers at approximately 2:30 PM on 8/14/19, the above findings were confirmed.