

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0231158	(X3) Date Survey Completed 11/18/2020
Name of Provider or Supplier Cmg- Burkeville	Street Address, City, State 412 Namozine Street, Burkeville, 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 on-site survey was conducted at the CMG-Burkeville on November 18, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory conducted on October 15, 2020 with off-site record review of documentation and a follow-up phone conference on November 16, 2020. Specific deficiencies cited are as follows:
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the review of Individualized Quality Control Program (IQCP) policy, quality control (QC) test logs, daily patient test logs, lack of documentation, and an interview with the primary testing personnel (TP), the lab failed to perform at least two levels of external QC materials each day of patient testing for the non-waived Abbott iSTAT Chem 8+ cartridges from July 29, 2020 and up to November 17, 2020 while reporting one hundred and fifty-four (154) patients. Findings include: 1. Review of the IQCP policy revealed the lab director signed as approved for the lab to perform external QC procedures (to include TriControls Level 1 and 3) every 30/31 days or with new shipment or lot number for Chem 8+ cartridges as of 11/17/20. An interview with the primary TP on November 18, 2020 at approximately 11 AM revealed the lab began testing patients on 7/29/20. 2. Review the QC test logs for the non-waived Abbott iSTAT Chem 8+ cartridges revealed the laboratory performed external QC</p>

procedures on the following dates: 7/27/20, 8/10/20, 8/28/20, 9/14/20, 10/12/20, 10/13/20, 10/16/20 and 11/09/20. 3. Review of the daily patient test logs revealed the following dates of patient testing: 7/29/20- 4 patients, 8/3/20- 2 patients, 8/4/20- 5 patients, 8/5/20- 3 patients, 8/12/20- 2 patients, 8/14/20- 8 patients, 8/21/20- 3 patients, 8/24/20- 2 patients, 8/25/20- 3 patients, 8/26/20- 6 patients, 8/31/20- 2 patients, 9/2/20- 6 patients, 9/3/20- 2 patients, 9/4/20- 5 patients, 9/9/20- 7 patients, 9/10/20- 4 patients, 9/11/20- 5 patients, 9/15/20- 2 patients, 9/16/20- 2 patients, 9/17/20- 4 patients, 9/22/20- 2 patients, 9/23/20- 6 patients, 9/25/20- 4 patients, 9/28/20- 6 patients, 9/30/20- 5 patients, 10/1/20- 3 patients, 10/2/20- 1 patient, 10/5/20- 4 patients, 10/6/20- 3 patients, 10/7/20- 3 patients, 10/8/20- 2 patients, 10/9/20- 4 patients, 10/15/20- 3 patients, 10/19/20- 1 patient, 10/20/20- 2 patients, 10/21/20- 2 patients, 10/26/20- 2 patients, 10/27/20- 1 patient, 10/28/20- 1 patient, 10/29/20- 2 patients, 11/2/20- 1 patient, 11/4/20- 5 patients, 11/5/20- 3 patients, 11/6/20- 2 patients, 11/11/20- 3 patients and 11/12/20- 6 patients. Total of 154 patients. The inspector requested to review documentation of external QC procedures performed for the aforementioned dates. The documentation was not available for review. 4. In an interview with the primary TP on November 18, 2020 at approximately 11:45 AM, they confirmed that there was lack of documentation of the performance of external QC procedures performed for the aforementioned dates and that the IQCP policy was signed as approved by the lab director on 11/17/20.

D6020

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on the review of Individualized Quality Control Program (IQCP) policy, quality control (QC) test logs, daily patient test logs, lack of documentation, and an interview with the primary testing personnel (TP), the lab director failed to ensure that the IQCP was performed and approved prior to reducing the performance of external QC materials for the non-waived Abbott iSTAT Chem 8+ cartridges from July 29, 2020 and up to November 17, 2020 while reporting one hundred and fifty-four (154) patients. Cross Reference D5447.