

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0264831	(X3) Date Survey Completed 11/27/2018
Name of Provider or Supplier Bcg Medical Group	Street Address, City, State 340 Eisenhower Dr, Suite 1200, Savannah, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on November 27, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's 2017 and 2018 quality control (QC) records for testing performed on the Beckman Access 2 chemistry/endocrinology analyzer and the Vitros chemistry analyzer, review of the package inserts for controls used to determine analyzer performance and staff interview, the laboratory failed to establish criteria for acceptability of the controls. Findings include: 1. Review of Levey Jennings charts, BioRad Liquicheck Immunoassay Plus Control assay sheets and results of control values obtained during testing of controls on the Beckman Access 2 endocrinology/chemistry analyzer revealed the laboratory uses the 3 standard</p>

deviation range given by the manufacturer on the assay sheet to determine the acceptable range of control values and has not adjusted their QC ranges to reflect the standard deviation obtained by their laboratory. Review of control values obtained by the laboratory also revealed the standard deviation calculated on testing performed in their laboratory is much lower than the values used to determine acceptability of patient results. 2. Review of Levey Jennings charts, Vitros Performance Verifier Control Assay Sheets and results of control values obtained during testing of controls on the Vitros chemistry analyzer revealed the laboratory uses the values assigned for the "range of mean values " to determine control acceptability and has not adjusted their QC ranges to reflect the values obtained by their laboratory. 3. Review of laboratory records also revealed lot numbers and generation of lot numbers of reagents, as well as lot numbers of calibrators and controls for testing performed on the Vitros chemistry analyzer change frequently which will require evaluation of control ranges be re-evaluated frequently. 4. Interview with the technical consultant and testing personnel # 2 (see CMS 209) on November 27, 2018 at 3 pm in the break room confirmed the laboratory changes lot numbers/generation of reagents, lot numbers of calibrators and controls frequently for testing performed on the Vitros Chemistry analyzer and QC values for testing performed on the Vitros and Beckman Access 2 are not reflective of the results obtained by the laboratory.