Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0264744	(X3) Date Survey Completed 09/24/2018
Name of Provider or Supplier Savannah Primary Care Associates, Llc	**Street Address, City, State** 4451 Paulsen Street, 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 September 24, 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	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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. 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 endocrinology analyzer and the Beckman DxC 600 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 (LJ) charts revealed control values for most analytes fall within plus or minus 1 standard deviation (SD) of the mean. Review of LJ charts, statistics calculated from results obtained by the laboratory and results of control values

	obtained during testing of controls on the Beckman Access 2 endocrinology analyzer revealed the standard deviation calculated on testing performed in their laboratory is much lower for most analytes than the standard deviation used to determine acceptability of controls. Review also revealed the laboratory has not adjusted their QC ranges to reflect the standard deviation obtained by their laboratory. This caused acceptable ranges of plus or minus 2 standard deviations from the mean to be too broad. 2. Review of Levey Jennings charts revealed control values for most analytes fall within plus or minus 1 standard deviation from the mean. Review of LJ charts, Beckman Coulter UniCel DxC Synchron control assay sheets and results of control values obtained during testing of controls on the Beckman DxC 600 chemistry analyze revealed the laboratory uses an assigned standard deviation and has not adjusted their QC ranges to reflect the standard deviation obtained by their laboratory. Review of control values obtained by the laboratory revealed the standard deviation calculated on testing in their laboratory is much lower than the values used to determine acceptability of patient results. This caused acceptable ranges of plus or minus 2 standard deviations from the mean to be too broad. . 3. Interview with the technical consultant and laboratory director (see CMS 209) on September 24, 2018 at 4:30 pm in the laboratory confirmed the laboratory does not use the standard deviation calculated from testing performed in their laboratory to set the 2 SD ranges on LJ charts , most control values fall within plus or minus 1 standard deviation (SD) of the mean and using the SD values showing on the LJ charts causes the acceptable ranges of controls to be too broad .