Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0264063	**(X3) Date Survey Completed** 06/13/2019
Name of Provider or Supplier Urology Specialists Of Georgia	**Street Address, City, State** 5400 Bowman Road, Suite 100, Macon, 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 June 13, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) documents, and staff interview, the Laboratory did not have signed attestation statements for Testosterone (Testo) and Prostate Specific Antigen (PSA) results submitted for evaluation. Findings: 1. Review of the API documents, the laboratory did not have signed attestation statements for the second event of 2017, the first and second event of 2018, and the first event of 2019 for Testo and PSA. 2. Interview with staff #3(CMS 209 form), the office manager, and the operations manger, on June 13, 2019, at approximately 4:00 pm, confirmed that the Laboratory Director, and the testing personnel, had not signed the attestation statements for the aforementioned API testing events.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials

	using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Quality Control(QC) documents for the Beckman Coulter Access 2 (Access2) analyzer, for the analytes Testosterone (Testo) and Prostate Specific Antigen (PSA), the laboratory did not have control procedures that monitor the accuracy and precision of the complete analytic process. Findings: 1. Review of the QC documents for the 2018 and 2019, the laboratory failed to print and review Levy Jennings charts for the analytes Testo and PSA. 2. The laboratory did not have the manufacturer ranges for the BioRad Immunoassay for Testo and PSA. 3. Interview with staff #3,(CMS 209 form), the office manager, and the operations manager, on June 13, 2019, at approximately 4:50pm confirmed that the laboratory failed to print and review Levy Jennings charts for Testo and PSA, and they did not have the manufacturer ranges for the BioRad Immunoassay Control for Testo, and PSA.
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 2018 and 2019 quality control (QC) records for testing performed on the Beckman Coulter Access 2 Immunoassay analyzer (Access 2), review of the package inserts for controls, review of the manufacturer's instructions for use of controls and staff interview, the laboratory failed to establish criteria for acceptability of controls. Findings include: 1. Review of the 2018 & 2019 QC documents for Testosterone(Testo) and Prostate Specific Antigen(PSA) performed on the Access 2, and review of BioRad control assay sheets for the Immunoassay Plus control revealed the laboratory uses the standard deviation (SD) and ranges 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. 2. Review of on-line instructions for Biorad controls listed above and obtained from BioRad at www.myeinserts.com, revealed each laboratory should establish their own acceptable ranges and use the assayed

	ranges as a guide. 3. Interview with staff #3 (see CMS 209), Office Manager and the operations manager, on June 13, 2019 at 4:15 pm in the Laboratory confirmed the laboratory uses the mean and SD ranges from the assay sheets supplied by the manufacturer and those ranges are not indicative of ranges obtained by their laboratory.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Quality Control documents for the Beckman Access 2, and the American Proficiency Institute documents, the Laboratory Director did not provide overall management and direction in accordance with 493.1405 of this subpart. Reference: D2009, D5441, D5469