Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473725	09/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Urologic Specialists Of Oklahoma Inc	10901 E 48th St South, Tulsa, OK	

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	The recertification survey was performed on 09/13/2021. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with technical consultant #2 and the laboratory manager at the conclusion of the survey.
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 a review of records, manufacturer's package insert, and interview with technical consultant #2 and the laboratory manager, the laboratory failed to have control procedures that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for Albumin and Total Protein testing. Findings include: (1) On 09/13/2021 at 10:45, the laboratory manager stated the followingto the surveyor: (a) Albumin and Total Protein testing were performed on the Ortho Vitros 350 analyzer; (b) Two levels of Vitros Performance Verifier quality control (QC) materials were performed each day of patient testing for the analytes listed above. (2) The surveyor reviewed the package inserts for the control materials. The manufacturer provided a standard deviation (SD) for the laboratory to utilize for each level of control and analyte; and a range of means

	for the laboratory to use as a guide when establishing their means; (3) The surveyor reviewed QC records for testing performed from 01/01/2021 through 08/01/2021. The review showed the laboratory was using SD's that were greater than the package insert provided SD's for Albumin and Total Protein as follows: (a) Vitros Performance Verifier level 1 (lot #N7648) and level 2 (lot #L7425) (i) Albumin (aa) Level 1 - The package insert SD was 0.090. A SD of 0.700 had been used to evaluate QC results; (bb) Level 2 - The package insert SD was 0.110. A SD of 0.139 had been used to evaluate QC results. (ii) Total Protein (aa) Level 1 - The package insert SD was 0.150. A SD of 0.920 had been used to evaluate QC results. (4) The surveyor reviewed the findings with technical consultant #2 and the laboratory manager. Both stated on 09/13 /2021 at 04:15 pm the laboratory was using SD's beyond the package insert SD's as shown above.