Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0935333	07/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
S Tx Urology & Urologic Oncology	9102 Floyd Curl, San Antonio, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing an Individualized Quality Control Plan for its Qualigen Fast Pack System installed in January 2017. The finding were: 1. A review of the laboratory's verification studies revealed the laboratory

	installed a new Qualigen Fast Pack System (serial number 0976) for testing Testosterone and Prostate-specific Antigen in January 2017. 2. A review of the laboratory's quality control records revealed the laboratory failed to have documentation of performing quality control testing each day of patient testing. 3. The laboratory was asked to provide documentation of developing an Individualized Quality Control Plan for the new analyzer. No documentation was provided. 4. The laboratory did provide an Individualized Quality Control Plan for a second analyzer (serial number 0329) which was performed in August 2015. 5. An interview with the office manager on 07/23/2018 at 1045 hours in the break room revealed the laboratory had not developed an Individualized Quality Control Plan for the analyzer installed in January 2017. She stated she was unaware a plan was required to be performed for each instrument. This confirmed the findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory failed to have documentation of performing comparison studies for its two Qualigen Fast Pack Systems in 2017. The findings were: 1. A review of the laboratory's records revealed the laboratory utilized two Qualigen Fast Pack System analyzers (serial numbers 0329 and 0976) were utilized for Testosterone and Prostate-specific Antigen testing in 2017. 2. The laboratory was asked to provide documentation of performing twice annual comparisons for Testosterone and Prostate-specific Antigen with both analyzers in 2017. No documentation was provided. 3. An interview with the office manager on 07/23/2018 at 1045 hours in the break room revealed the laboratory was unaware of the requirement to perform twice annual comparisons between analyzers. This confirmed the findings.