Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1102253	08/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Urology, Llc	13555 W Mcdowell Rd, Suite 302, Goodyear, AZ	

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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of patient test requisitions and interview with the facility personnel, the laboratory's test requisition failed to include the time of collection. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Microbiology, with an approximate annual test volume of 45,000. The laboratory performs a Laboratory Developed Test (LDT), Infectious Disease Detection by Real-Time PCR, on the Thermo Fisher Quant Studio 12K Flex analyzer. The laboratory began patient testing on June 20, 2020. 2. The test requisitions for Specimen ID 212640512 and 220410201 reviewed during the survey conducted on August 2, 2022 failed to include the time of specimen collection. 3. The facility personnel confirmed that the patients' test requisitions reviewed during the survey failed to include the time of specimen collection.

D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of established performance specification documentation for the Laboratory Developed Test (LDT), Infectious Disease Detection by Real-Time PCR, used to test patient urine specimens and interview with the facility personnel, the laboratory failed to demonstrate the effects of the patients' clinical conditions, disease states, and medications as interfering substances that may effect the analytical specificity of the test system. Findings include. 1. During the survey conducted on August 2, 2022, no documentation was included in the establishment of performance specifications for the 'Infectious Disease Detection by Real-Time PCR' test indicating if the patients' clinical conditions, disease states, and any common medications may effect and/or inhibit the analytical specificity of the test system. 2. The facility personnel interviewed on August 2, 2022 at 12:50pm acknowledged that there was no specific analysis performed that included the effects of the patients' clinical conditions, disease states and common medications as possible interfering substances that may effect analytical specificity of the test system. 3. The laboratory began patient testing using the LDT referenced above on June 20, 2020 with an approximate annual test volume of 45,000.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration records from the Thermo Fisher Quant Studio 12K Flex analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration procedures as established by the laboratory. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Microbiology, with

	an approximate annual test volume of 45,000. The laboratory performs a Laboratory Developed Test (LDT), Infectious Disease Detection by Real-Time PCR, on the Thermo Fisher Quant Studio 12K Flex analyzer. The laboratory began patient testing on June 20, 2020. 2. The laboratory's established calibration procedure performed on the Thermo Fisher Quant Studio 12K Flex analyzer requires a semi-annual calibration to include a Regions of Interest (ROI) calibration, Uniformity calibration, Dye calibration and Utilization calibration. 3. No documentation was presented for review during the survey conducted on August 2, 2022 to indicate the laboratory performed and documented the calibration procedures listed above semi-annually on the analyzer indicated above. Calibration records reviewed during the survey indicated the analyzer was calibrated in June 2020 and was not calibrated again until June 2021. 4. The facility personnel interviewed on 8/02/22 at 1:25pm confirmed the laboratory failed to perform the semi-annual calibration procedures listed above during December 2020.