Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0670414	03/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Phoenix Urology Of St Joseph, Inc	901 Heartland Rd Ste 1800, Plaza 2, Saint Joseph, MO	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of chemistry procedures and interview with testing personnel #2, the laboratory failed to include a step-by-step procedure for quality control (QC) value ranges entered into the Beckman Coulter Access 2 analyzer. Findings: 1. Review of chemistry procedures showed no step-by-step procedure for determining acceptable QC ranges to be entered into the Beckman Coulter Access 2 analyzer. 2. Interview with testing personnel #2 on March 16, 2021 at 9:00 AM confirmed laboratory failed to establish a step-by-step procedure for chemistry QC.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the microbiology freezer, review of freezer temperature logs for 2020/2021 and interview with testing personnel #1, the laboratory failed to store microbiology reagents and quality control material at manufacturer's required temperatures for 56 of 69 days. Findings: 1. Observation of the microbiology freezer showed two boxes of "UTI Plus Panels" and 2 boxes of UTI positive/negative controls with a manufacturer's acceptable storage temperature of minus 20 degrees Celsius. 2. Review of the laboratory's temperature log showed a defined acceptable range of minus 10 degrees Celsius to minus 30 degrees Celsius. For 56 testing days the laboratory failed to meet the manufacturer's required temperature of minus 20 degrees Celsius. 3. Interview with testing personnel #1 on March 16, 2021 at 10:30 AM confirmed the laboratory failed to store microbiology reagents and controls at acceptable temperatures.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of microbiology quality control (QC) records for 2021 and interview with testing personnel #1, the laboratory failed to perform positive and negative controls each day of patient testing on the BioRad CFX96 Real-Time System for determination of urinary tract infections for 40 of 50 patient testing days. Findings: 1. Review of 2021 microbiology QC records showed the laboratory failed to perform a positive and negative QC each day of patient testing. 2. Interview with the testing personnel #1 on March 16, 2021 at 10:30 AM confirmed, the laboratory did not test a positive and negative control each day of patient testing.
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 2021 chemistry quality control (QC) package inserts, QC logs, and interview with testing personnel #2, the laboratory failed to establish criteria for acceptability of chemistry QC. Findings: 1. Review of chemistry QC level 1, 2 and 3 for Prostate Specific Antigen (PSA) Free, PSA Total and Testosterone showed the following ranges were entered into the Beckman Coulter Access 2 analyzer: PSA Free Level 1, Lot # 85231: 0.107 - 0.227 ng/mL PSA Free Level 2, Lot # 85232: 1.500 - 2.640 ng/mL PSA Free Level 3, Lot # 85233: 9.990 - 17.610 ng/mL PSA Total Level 1, Lot # 85231: 0.220 - 0.340 ng/mL PSA Total Level 2, Lot # 85232: 2.830 - 4.630 ng /mL PSA Total Level 3, Lot # 85233: 19.250 - 31.550 ng/mL Testosterone Level 1, Lot # 85231: Negative 280.190 - 282.010 ng/dL Testosterone Level 2, Lot # 85232: Negative 1023.830 - 1031.170 ng/dL Testosterone Level 3, Lot # 85233: Negative 2294.080 - 2310.920 ng/dL 2. Review of Liquichek Immunoassay Plus Control, Levels 1, 2, and 3 package insert showed the following ranges at 3 standard deviations: PSA Free Level 1, Lot # 85231: 0.127 - 0.207 ng/mL PSA Free Level 2, Lot # 85232: 1.69 - 2.46 ng/mL PSA Free Level 3, Lot # 85233: 11.2 - 16.3 ng/mL PSA Total Level 1, Lot # 85231: 0.222 - 0.338 ng/mL PSA Total Level 2, Lot # 85232: 3.12 - 4.33 ng/mL PSA Total Level 3, Lot # 85233: 21.3 - 29.5 ng/mL Testosterone Level 1, Lot # 85231: 0.725 - 1.10 ng/mL Testosterone Level 2, Lot # 85232: 2.99 - 4.36 ng/mL Testosterone Level 3, Lot # 85233: 6.88 - 9.95 ng/mL 3. Review of testosterone QC level 3 showed 1 of 10 testing days QC was not within acceptable limits. 4. Review of testosterone QC showed analyzer reports ng/dL and package insert measurements is reported in ng/mL. 5. Interview with testing personnel #2 on March 16, 2021 at 9:15 AM confirmed laboratory failed to establish criteria for acceptability of chemistry QC.