Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0670414	05/21/2024
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on lack of proficiency testing (PT) records for 2023/2024 and interview with the general supervisor (GS) and laboratory director (LD), the laboratory failed to enroll in an approved PT program for FISH testing (Refer to D2001)
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) for 2023 and 2024, and interview with the

	general supervisor (GS) and laboratory director (LD), the laboratory failed to enroll in an approved PT program for the laboratory's fluorescence in situ hybridization (FISH) testing. Findings: 1. Review of 2023 and 2024 PT records showed no enrollment in an approved PT program for the analyte: FISH. 2. Interview with the GS and LD on May 7, 2024 at 12:00 PM confirmed the laboratory failed to enroll in an approved PT program for FISH.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency testing records for 2023 and to date May 7, 2024 and interview with the the general supervisor (GS) and laboratory director (LD), the laboratory failed to maintain a copy of records for proficiency testing (PT), including the signed attestation statement and raw data for a minimum of two years. Findings: 1. Review of 2023 and to date May 7, 2024 showed the laboratory failed to provide a signed attestation for the API Hematology/Coagulation events 1, 2 and 3 for 2023 and event 1 for 2024. 2. Review of 2023 and to date May 7, 2024 showed the laboratory failed to provide raw data for the API Hematology/Coagulation events 1, 2, and 3 for 2023 and event 1 for 2024. 3. Interview with the GS and LD on May 7, 2024 at 12:00 PM confirmed the laboratory failed to maintain a copy of all records for PT, including the signed attestation statements and raw data for a minimum of two years.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the performance verification procedure for the Sciteck AutoUA analyzer and interview with the general supervisor (GS) and laboratory director (LD), the laboratory failed to verify and document the manufacturer's reference intervals prior to reporting patient test results. Findings: 1. Review of the performance verification procedures for the Sciteck AutoUA analyzer showed the laboratory failed

	to verify and document that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: glucose, bilirubin, ketone, specific gravity, chloride, blood, pH, protein, urobilinogen, nitrite, leukocyte, and creatinine. 3. Interview with the GS and LD on May 7, 2024 at 11:30 AM confirmed the laboratory failed to verify document manufacturer's reference intervals prior to reporting patient test results.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of maintenance documentation and interview with the technical supervisor (TS) #1, the laboratory failed to perform and document function checks for the laboratory's pipettes and centrifuges 2023 and to date May 7, 2024. Findings: 1. Review of maintenance documentation showed the laboratory failed to perform and document the function checks for the following pipettes: Serial number SH42210 due January 2024 Serial number RH19807 due January 2024 2. Lack of maintenance documentation showed the laboratory failed to perform and document function checks for the following centrifuges: Megafuge ST Plus series Thermo Scientific MySpin 12 3. Interview with the GS on May 7, 2024 at 12:00 PM confirmed the laboratory failed to perform and document function checks for the laboratory's pipettes and centrifuges.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records for 2023 and to date May 7, 2024 for the Sciteck AutoUA and interview with the general supervisor (GS), the laboratory failed to include two control materials of different concentrations for six of twelve analytes on 22 days in January 2023. Findings: 1. Review of QC log for January 2023 showed only one level of QC was performed for the following analytes: hemoglobin, bilirubin, pH, leukocyte esterase, urobilinogen, and nitrite for the days January 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24, 25, 26, 27, 30 and 31. 2. Interview with the GS on May 7, 2024 at 11:00 AM, confirmed the laboratory failed to include two control materials of different concentrations.

D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the quality control records for 2023 and 2024 for Sciteck AutoUA and interview with the general supervisor (GS), the laboratory failed to verify the quality control (QC) met the manufacturer's criteria for acceptability before reporting patient test results. Findings: 1. Review of the QC logs for Sciteck AutoUA for 2023 and to date May 7, 2024, the laboratory did not have the manufacturer's target concentration (package inserts) ranges for the QC logs available. 2. Interview with the GS on May 7, 2024 at 11:30 confirmed the laboratory failed to document and verify the quality control (QC) met the manufacturer's criteria for acceptability before reporting patient test results.
D5653	CYTOLOGY CFR(s): 493.1274(e)(3) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(3) All nongynecologic preparations are reviewed by a technical supervisor. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review. This STANDARD is not met as evidenced by: Based on review of patient report and interview with the general supervisor (GS), confirmed the laboratory failed to document review of nongynecologic preparations by the technical supervisor (TS) with signature. Findings: 1. Review of the patient report showed there was no documentation of review done by the TS #2 with signature or in the electronic medical record. 2. Interview with the GS on May 7, 2024 at 12:00 PM confirmed the laboratory failed to document review of nongynecologic preparations with signature.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by:

	Based on review of patient test reports and interview with the general supervisor (GS), the laboratory failed to include the name and address of the laboratory location where the FISH test was performed on the patient test report. Findings: 1. Review of the patient test report showed no name and address of the location where the pathologist reads FISH slides offsite. 2. Interview with the GS on May 20, 2024 at 12:00 PM confirmed the laboratory failed to include the name and address of the laboratory location where the FISH test was performed on the patient test report.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of 2023 and 2024 proficiency testing (PT) records, verification procedures, patient reports, procedure manuals, personnel records, lack of training documents, and interviews, the laboratory director failed to provide overall management and direction of the laboratory. The LD failed to ensure that verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method prior to patient testing (Refer to D6086); the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory proficiency testing results (Refer to D6092); the laboratory director failed to ensure test results include pertinent information required for interpretation (Refer to D6098); the laboratory director failed to ensure one of five testing personnel recieved appropriate training prior to testing patient specimens in the laboratory for FISH (Refer to D6102); the laboratory director failed to ensure an approved procedure manual was available to testing personnel performing testing (Refer to D6106).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of verification procedures for the Sciteck AutoUA analyzer and FISH procedure, and interview with the general supervisor (GS) and laboratory director (LD), the LD failed to ensure that verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method prior to patient testing. Findings: 1. Review of the verification procedures for the Sciteck AutoUS analyzer showed no documentation that the verification procedures were adequate, reviewed, and approved by the laboratory director to determine the accuracy, precision, reportable range and reference range verification prior to patient testing. 2. Review of the verification procedures for the FISH analysis showed no documentation that the verification procedures were adequate, reviewed, and approved by the laboratory director to determine the accuracy, precision, reportable range and reference range verification prior to patient

	testing. 3. Interview with the GS and LD on May 7, 2024 at 12:00 PM confirmed the LD failed to ensure that verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method prior to patient testing.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of Wisconsin State Laboratory of Hygiene Proficiency Testing (WSLHPT) proficiency testing (PT) for 2023 and 2024 and interview with the general supervisor (GS) and laboratory director (LD), the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory proficiency testing results. Findings: 1. Review of 2023 PT showed no corrective action plan for WSLHPT Event 2. 2. Review of 2024 PT showed no corrective action plan for WSLHPT Event 1. 3. Interview on May 7, 2024 at 12:00 PM confirmed the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of patient test report, procedure manual and interview with the general supervisor (GS), the laboratory director failed to ensure test results include pertinent information required for interpretation. Findings: 1. Review of the procedure manual showed no approved reference ranges for the laboratory Sciteck AutoUA analyzer for the following analytes: glucose, bilirubin, ketone, specific gravity, chloride, blood, pH, protein, urobilinogen, nitrite, leukocyte, and creatinine. 2. Review of patient report showed no reference ranges (normal range) values are on the patient report for the following analytes: glucose, bilirubin, ketone, specific gravity, chloride, blood, pH, protein, urobilinogen, nitrite, leukocyte, and creatinine. 3. Interview with the GS on May 7, 2024 at 12:00 PM confirmed the laboratory director failed to ensure test results include pertinent information required for interpretation.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on review of personnel records, lack of initial training documents, and interview with the general supervisor (GS), the laboratory director failed to ensure one of five testing personnel (TP) received appropriate training prior to testing patient specimens in the laboratory for fluorescence in situ hybridization (FISH). Findings: 1. Review of personnel records, showed the laboratory could not provide documentation for initial training prior to testing patient specimens for TP #1. 2. Testing Personnel #1 read approximately 285 slides from October 2023 to date May 7, 2024. 3. Interview with the GS on May 7, 2024 at 1:00 PM confirmed the laboratory director failed ensure TP received appropriate training prior to testing patient specimens in the laboratory for FISH.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with the general supervisor (GS) , the laboratory director (LD) failed to ensure an approved procedure manual was available to testing personnel performing testing. Findings: 1. The laboratory did not have documentation to show the laboratory director approved the Sciteck AutoUA analyzer procedure manual for the following analytes; glucose, bilirubin, ketone, specific gravity, chloride, blood, pH, protein, urobilinogen, nitrite, leukocyte, creatinine. 2. The laboratory did not have documentation to show the laboratory director approved the FISH procedure manual. 3. Interview with GS on May 7, 2024 at 12:00 PM confirmed, there was no documentation to show an approved procedure manual was available for testing on the Sciteck AutoUA analyzer and FISH testing.