Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0904391	01/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Urology Specialists, Pllc	2260 W Orange Grove Rd, #160, Tucson, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of verification documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of (A) histopathology testing and (B) cytology testing at least twice annually during 2017 and 2018. Findings include: A1. The laboratory performs patient testing under the sub-specialty of Histopathology, with an approximate annual test volume of 95. A2. No documentation was presented for review during the survey conducted on January 25, 2019 to indicate the laboratory verified the accuracy of slide interpretations from biopsy specimens at least twice annually during 2017 and 2018. A3. The facility personnel confirmed that the laboratory failed to document the accuracy of histology slide interpretations made by the laboratory during 2017 and 2018. B1. The laboratory performs patient testing under the sub-specialty of Cytology, with an approximate annual test volume of 1,072. B2. No documentation was presented for review during the survey conducted on January 25, 2019 to indicate the laboratory verified the accuracy of slide interpretations from cytology specimens at least twice annually during 2017 and 2018. B3. The facility personnel confirmed that the laboratory failed to document the accuracy of cytology slide interpretations made by the laboratory during 2017 and 2018.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems

	identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's established Quality Assessment policies and interview with the facility personnel, the laboratory failed to establish policies related to accuracy verification for (A) Histopathology testing and (B) Cytology testing performed by the laboratory. Findings include: A1. The laboratory performs biospy interpretations under the sub-specialty of Histopathology, with an approximate annual test volume of 95. A2. No documentation was presented during the survey to indicate the laboratory had established policies related to the verification of accuracy process for the testing indicated above, including but not limited to, information specific to the frequency of the review, number of cases reviewed, individual or laboratory performing the review and a remedial action plan in the event of a noted discrepancy. A3. The facility personnel confirmed that the laboratory did not have an established policy in place at the time of the survey for the verification of accuracy process for histopathology testing performed by the laboratory. B1. The laboratory performs cytology slide interpretations under the sub-specialty of Cytology, with an approximate annual test volume of 1,072. B2. No documentation was presented during the survey to indicate the laboratory had established policies related to the verification of accuracy process for the testing indicated above, including but not limited to, information specific to the frequency of the review, number of cases reviewed, individual or laboratory performing the review and a remedial action plan in the event of a noted discrepancy. B3. The facility personnel confirmed that the laboratory did not have an established policy in place at the time of the survey for the verification of accuracy process for cytology testing performed by the laboratory.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview with the facility personnel, it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation for three of three required statistics for nongynecologic cytology specimens. Findings include: 1. The laboratory failed to provide a written policy and procedure for an annual statistical laboratory evaluation of three required statistics for the nongynecologic specimens: a) the number of cytology cases examined; b) the number of specimens

	processed by specimen type; and c) the number of patient cases reported by diagnosis, to include unsatisfactory. 2. The facility personnel confirmed that there were no written policies and procedures for documenting and evaluating annual statistics for cytology cases interpreted by the laboratory.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the facility personnel, it was determined that the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established by the Technical Supervisor for two out of two Technical Supervisors when performing primary evaluation of cytology specimen slide evaluations in 2017 and 2018 and to the day of the survey conducted on January 25, 2019. Findings include: 1. No documentation was presented for review during the survey to indicate the laboratory established written policies and procedures to ensure that a maximum workload limit was established by the Technical Supervisor for each Technical Supervisor who performs patient testing under the sub-specialty of Cytology. 2. The facility personnel confirmed that the laboratory did not have established policies and procedures related to workload limits for cytology testing personnel at the time of the survey.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) records and interview with the facility personnel, it was determined that the laboratory failed to document corrective actions taken to resolve problems associated with unsatisfactory test comparison results. Findings include: 1. The laboratory performs Prostate-specific Antigen (PSA) testing on the Qualigen analyzer in the specialty of Chemistry, with an approximate annual test volume of 536. 2. The laboratory's policy titled, PSA Comparisons, states, "Every 6 months we will run 2 assay PSA comparisons against outside laboratories to check the accuracy of our PSA machine. We will document our assay PSA results and results from the outside laboratory. If the results from both laboratories are greater than 1.0 in difference we will re-perform controls to verify the assay PSA machine is working correctly. Those results would be documented in our PSA control log." 3. Review of the PSA comparison documentation that was performed on 1/18/2019 indicated the laboratory's PSA result was 7.0 ng/ml and the outside laboratory's PSA result was 4.9 ng/ml. 4. No documentation of corrective action was presented for review during the survey to indicate the laboratory identified

	the unsatisfactory comparison results and followed its policy to perform the controls again to verify the analyzer was working properly. 5. The facility personnel confirmed that the lab failed to take corrective action for the unsatisfactory PSA test comparison results referenced above.
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 facility personnel, the laboratory failed to include on the test report the (A) units of measurement for the PSA (Prostate-specific Antigen) test and (B) the laboratory address where the testing was performed. Findings include: A1. The laboratory performs PSA testing in the specialty of Chemistry, with an approximate annual test volume of 536. A2. Three out of three PSA test reports reviewed during the survey, patient #105544, 304205 and 429898, were lacking the units of measurement for the PSA test result. The Qualigen test system used by the laboratory for PSA testing issues the test result in ng/mL. A3. The facility personnel confirmed that the PSA test reports reviewed during the survey were missing the units of measurement. B1. The laboratory performs semen testing (presence/absence) under the specialty of Hematology with an approximate annual test volume of 310. B2. Two out of two patient test reports reviewed during the survey (#470809 and 474887) failed to include the laboratory address where the testing was performed. B3. The facility personnel confirmed that the laboratory address where the testing was performed was not indicated on the test reports referenced above.