Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0904391	10/19/2022
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
D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews, the laboratory failed to establish policies and procedures to assess the competency of the Technical Supervisors (refer to D 5209); failed to follow written policies and procedures for the evaluation of one of three annual statistics (refer to D 5629); failed to establish written policies and procedures for the establishment of individual workload limits, and failed to reassess workload limits at least every six months (refer to D 5633 and D 5637); failed to establish written policies and procedures to ensure that workload limits would be prorated when examining slides in less than eight hours (refer to D 5641); failed to establish written policies and procedures to ensure the laboratory maintained records of the total number of slides examined per 24-hour period and the hours spent examining slides (refer to D 5645); failed to establish written policies and procedures to document the workload limit (refer to D 5647) and failed to establish written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory (refer to D 5655).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory competency assessment records and interview with the Laboratory Director, the laboratory failed to establish written policies and procedures to assess the competency of the Technical Supervisors. The laboratory failed to assess the competency of the three of three Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to assess the competency of the Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for the three of three Technical Supervisors during 2020, 2021 and to the date of the survey in 2022. Technical Supervisors Include: - Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 3. During an interview on October 19, 2022 at 11:15 AM, the Laboratory Director confirmed these findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of preanalytic quality assessment records and interview with the Laboratory Director, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the preanalytic systems. The laboratory failed to document preanalytic quality assessment activities during 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing program to monitor, assess and correct problems identified in the preanalytic laboratory systems. 2. The Survey Team requested and the laboratory failed to provide documentation of preanalytic laboratory quality assessment activities during 2020, 2021 and to the date of the survey in 2022. 3. During an interview on October 19, 2022 at 11:15 AM, the Laboratory Director confirmed these findings.
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, statistical records and interview with the Laboratory Director, the laboratory failed to follow written policies and procedures for the evaluation and comparison of one of three nongynecologic statistics. The laboratory failed to document one of three required annual nongynecologic statistics for 2020 and 2021. Findings include: 1. The laboratory failed to follow the written procedure ANNUAL STATISTICS which stated: "The UASA lab technician will calculate the statistics annually for the number of cases and define them by the specimen type and diagnosis." 2. The Survey Team requested and the laboratory failed to provide one of three required annual nongynecologic statistics for 2020 and 2021. Statistic includes: - Number of patient cases reported by diagnosis, including the number reported as unsatisfactory 3. During an interview on October 19, 2022 at 11:15 AM, the Laboratory Director confirmed these findings.
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 Laboratory Director, the laboratory failed to establish written policies and procedures to ensure individual maximum workload limits were established for the Technical Supervisors who performed primary screening of non-gynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the Technical Supervisor established individual maximum workload limits for the Technical Supervisors who performed primary screening of non-gynecologic cytology specimens. 2. During an interview on October 19, 2022 at 11:15 AM, the Laboratory Director confirmed these findings.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director, the laboratory failed to establish written policies and procedures to reassess and adjust, when necessary, a maximum workload limit at least every six months for the Technical Supervisors who performed primary screening of non-gynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisors' workload limits would be reassessed at least every six months

	and adjusted when necessary. 2. During an interview on October 19, 2022 at 11:15 AM, the Laboratory Director confirmed these findings.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload limit records and interview with the Laboratory Director, the laboratory failed to establish written policies and procedures to ensure that the workload limits for the Technical Supervisors would be prorated when examining cytology slides in less than an eight-hour work day. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limits for the Technical Supervisors when examining non-gynecologic cytology slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for three of three Technical Supervisors when examining slides in less than an eight-hour work day. Technical Supervisors include: - Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 3. During an interview on October 19, 2022 at 11:15 AM, the Laboratory Director confirmed these findings.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload records and interview with the Laboratory Director, the laboratory failed to follow written policies and procedures to ensure records would be maintained of the total number of slides examined and the total number of hours spent examining slides. Cross refer to D6133 Findings include: 1. The laboratory failed to follow the written procedure WORKLOAD LIMITS which stated: "Workloads will be recorded manually on daily workload sheet." 2. During an interview on October 19, 2022 at 11:15 AM, the Laboratory Director confirmed these findings.
D5647	CYTOLOGY CFR(s): 493.1274(d)(4)

	(d) Workload limits.The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory workload limit records and interview with the Laboratory Director, the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for three of three Technical Supervisors who performed primary screening of non-gynecologic cytology specimens during 2020, 2021 and through the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limit for the Technical Supervisors who performed primary screening of non-gynecologic cytology specimens. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for three of three Technical Supervisors who performed primary screening of non-gynecologic cytology specimens during 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 3. During an interview on October 19, 2022 at 11:15 AM, the Laboratory Director confirmed these findings.
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director, the laboratory failed to establish written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory slide preparations were identified and reported as unsatisfactory for evaluation. 2. During an interview on October 19, 2022 at 11:15 AM, the Laboratory Director confirmed these findings.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on the microscopic review of 273 negative nongynecologic cytology cases/273 slides from January 2022 through August 2022, the Technical Supervisor failed to

	verify the accuracy of one non-gynecologic cytology test. 1. UH05722 3/3/22 Voided Urine LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM DIAGNOSIS: High Grade Urothelial Carcinoma
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on review of laboratory polices and procedures, lack of workload limit records and interview with the Laboratory Director, the Technical Supervisor failed to establish an individual workload limit and failed to reassess workload limits at least every six months for three of three Technical Supervisors performing primary slide examinations in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5633 and D5637 Findings include: 1. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor established a maximum workload limit for three of three Technical Supervisors who performed primary slide examinations in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 2. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor reassessed a workload limit at least every six months for three of three Technical Supervisors who performed primary slide examinations in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 3. During an interview on October 19, 2022 at 11:15 AM, the Laboratory Director confirmed these findings.
D6133	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6) In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides. This STANDARD is not met as evidenced by: Based on review of laboratory polices and procedures, lack of laboratory workload records and interview with the Laboratory Director, three of three Technical Supervisors performing primary screening of cytology specimen slides failed to document the number of slides screened and the number of hours devoted to screening slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide records of the total number of slides screened for three of three Technical Supervisors devoted to screening cytology specimen slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 2. The Survey Team requested and the laboratory failed to provide records of the total number of

	hours three of three Technical Supervisors devoted to screening cytology specimen slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 2. During an interview on October 19, 2022 at 11:15 AM, the Laboratory Director confirmed these findings.
D9999	By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.