Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0188598	03/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Keystone Urology Specialists	2106 Harrisburg Pike Suite 200, Lancaster, PA	

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 and follow written policies and procedures for the establishment, reassessment and documentation of individual workload limits (refer to D5633, D5637 and D5647); failed to establish and follow written policies and procedures to ensure that workload limits would be prorated when examining slides in less than eight hours (refer to D5641); failed to establish and follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined and the total number of hours spent examining slides per 24-hour period (refer to D5645); and failed to establish and follow written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. (refer to D5655).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with Technical Supervisor A it was determined the laboratory failed to establish and follow written policies and procedures for the collection, labeling, storage and preservation, and transportation of nongynecologic specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the collection, labeling, storage and preservation, and transportation of nongynecologic specimens. 2. During an interview on March 18, 2024 at 1:30 PM, Technical Supervisor A confirmed these findings.
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 8 laboratory policies and procedures and interview with Technical Supervisor A the laboratory failed to establish and follow written policies and procedures for one laboratory test process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory microscopic examination on nongynecologic slides to include the detection of inadequately prepared slides. 2. During an interview on March 18, 2024 at 11:30 AM, Technical Supervisor A 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, laboratory statistical records and interview with Technical Supervisor A the laboratory failed to establish and follow written policies and procedures for an annual statistical evaluation of three of three required nongynecologic laboratory statistics. The laboratory failed to document one of three required annual nongynecologic statistics for 2022 and 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of three of three required nongynecologic statistics. Statistics include: -The number of cytology cases examined -The number of cases processed by specimen type -The number of cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) 2. The Survey Team requested and the laboratory failed to provide one of three required annual nongynecologic cytology statistics for 2022 and 2023. Statistic includes: -The number of cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) 3. During an interview on March 18, 2024 at 1:30 PM, Technical Supervisor A 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, lack of workload limit records and interview with Technical Supervisor A the laboratory failed to establish and follow written policies and procedures to establish an individual maximum workload limit for each Technical Supervisor who performed primary screening of nongynecologic cytology specimens. The Technical Supervisor failed to establish an individual maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor would establish maximum workload limits for each Technical Supervisor who performed primary screening of nongynecologic cytology specimens. 2. The Survey Team requested and the laboratory failed to provide documentation that the laboratory Technical Supervisor established an individual maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During an interview on March 18, 2024 at 9:30 AM, Technical Supervisor A 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, lack of workload limit reassessment records and interview with the Technical Supervisor A the laboratory failed to establish and follow 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 nongynecologic cytology specimens. The Technical Supervisor failed to reassess a maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor would reassess a maximum workload limit for the Technical Supervisors at least every six months and adjust when necessary. 2. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor reassessed a maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During an interview on March 18, 2024 at 9:30 AM, Technical Supervisor A 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 records and interview with Technical Supervisor A the laboratory failed to establish and follow written policies and procedures to ensure that workload limits for the Technical Supervisors would be prorated when examining 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 workload limits for the Technical Supervisors when examining slides in less than an eight-hour day, or with duties other than examining cytology specimen slides. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for two of two Technical Supervisors when examining slides in less than eight hours. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During an interview on March 18, 2024 at 9:30 AM, Technical Supervisor A 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 Technical Supvisor A the laboratory failed to establish and follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined by each individual per 24-hour period and the number of hours individuals spent examining slides per 24-hour period. Findings include: 1. The Survey Team requested and the laboratory failed to provide policies and procedures to ensure that the laboratory maintained records of the total number of slides examined by each individual per 24-hour period and the number of hours individuals spent examining slides per 24-hour period. 2. The Survey Team requested and the laboratory failed to provide records of the total number of slides examined by each individual per 24 hour period and the number of hours each individual spent examining slides for two of two Technical Supervisors in 2022, 2023 and to the date of the survey in 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During an interview on March 18, 2024 at 9:30 AM, Technical Supervisor A 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 workload limit records and interview with Technical Supervisor A the laboratory failed to establish and follow written policies and procedures to ensure records were available to document the workload limit for two of two Technical Supervisors who performed primary screening of nongynecologic cytology specimens in 2022, 2023 and January 2024 to the date of the survey in 2024. 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 nongynecologic cytology specimens. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for two of two Technical Supervisors who performed primary screening of nongynecologic cytology specimens in 2022, 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During an interview on March 18, 2024 at 9:30 AM, Technical Supervisor A 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, final test reports, specimen slides and confirmation by Technical Supervisor A the laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory nongynecologic patient specimens were identified and reported as unsatisfactory. The laboratory failed to identify and report three of three nongynecologic tests from June 2023 through March 2024 as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. The laboratory failed to identify three of three nongynecologic patient specimens from June 2023 through March 2024 as being unsatisfactory for evaluation. Cases include: C23-400 C24-31 C24-35 3. During an interview on March 18, 2024 at 1:30 PM, Technical Supervisor A confirmed these findings.
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 final cytology test reports and interview with Technical Supervisor A twenty of 20 final cytology test reports from August 1, 2023 to August 7, 2023 failed to indicate the test performed. Findings include: 1. The Survey Team reviewed 20 final cytology test reports titled "Surgical Pathology Report" from August 1, 2023 to August 7, 2023. Twenty of 20 final cytology test reports failed to indicate the test performed. 2023 test reports include: -C23-448 thru C23-467 2. During an interview on March 18, 2024 at 1:30 PM, Technical Supervisor A 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 520 random negative nongynecologic cytology cases/520 slides from June 2023 through March 2024 and confirmation by Technical

	Supervisor A on March 19, 2024 Technical Supervisor A failed to verify the accuracy of three nongynecologic cytology tests. 1. C23-400 07/11/2023 Urine LABORATORY DIAGNOSIS: Rare benign urothelieal cells and inflammatory cells in a background containing erythrocytes an amorphous debris. Negative for High-Grade Urothelial Carcinoma SURVEY TEAM DIAGNOSIS: Unsatisfactory for interpretation, obscuring blood and debris TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory 2. C24-35 02/01/2024 Urine LABORATORY DIAGNOSIS: Sparsely cellular specimen containing a few benign squamous cells and inflammatory cells. Negative for High-Grade Urothelial Carcinoma SURVEY TEAM DIAGNOSIS: Unsatisfactory for interpretation, scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory due to lack of urothelial cells 3. C24-31 02/02/2024 Urine LABORATORY DIAGNOSIS: Hypocellular specimen, rare benign squamous cells. Negative for High-Grade Urothelial Carcinoma SURVEY TEAM DIAGNOSIS: Unsatisfactory for interpretation, scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory due to lack of urothelial cells
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 the lack of workload limit records and interview with Technical Supervisor A the Technical Supervisor failed to establish and reassess a maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The Technical Supervisor failed to provide documentation that the Technical Supervisor established a maximum workload limit for two of two Technical Supervisors who performed primary nongynecologic cytology slide examinations in January through December 2023 and January 2024 to the date of the survey in 2024. Refer to D5633 and D5647 2. The Technical Supervisor failed to provide documentation that the Technical Supervisor reassessed a workload limit at least every six months for two of two Technical Supervisors who performed primary nongynecologic cytology slide examinations in January through December 2023 and January 2024 to the date of the survey in 2024. Refer to D5637 and D5647 3. During an interview on March 18, 2024 at 9:30 AM, Technical Supervisor A 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 interview with Technical Supervisor A and lack of workload records it was determined that Technical Supervisor A and Technical Supervisor B failed to

	maintain records of the total number of slides examined during each 24-hour period and the number of hours spent examining slides in each 24-hour period when performed primary slide examinations in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. During an interview on March 18, 2024 at 9: 30 AM, Technical Supervisor A stated that Technical Supervisor A and Technical Supervisor B did not record the date primary slide examinations were performed, the number of slides examined or the number of hours spent examining slides. Refer to D5645
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.