Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0264812	(X3) Date Survey Completed 02/14/2024
Name of Provider or Supplier Urological Associates Of Savannah, Pc	**Street Address, City, State** 230 East Derenne Avenue, Savannah, GA	
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of 22 laboratory policies and procedures, laboratory records and interview the laboratory failed to follow one written policy and procedure. Findings include: 1. The laboratory failed to follow the procedure URINE CYTOLOGY WORKLOAD LIMIT, which stated: "To ensure compliance with regulatory requirements, there will be a time log placed by the microscope to be completed by the screener." 2. The Survey Team requested and the laboratory failed to provide records titled URINE CYTOLOGY SCREENER TIME LOG from 2022, 2023 and January 1, 2024 to the date of the survey in 2024 for one of one Technical Supervisors. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor and Laboratory Supervisor.
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 22 laboratory policies and procedures and interview the laboratory failed to establish 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 step-by-step process for reporting nongynecologic cytology test results into the laboratory information system (LIS). 2. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor and Laboratory Supervisor.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of 22 laboratory policies and procedures and interview the laboratory failed to ensure that 20 of 22 written policies and procedures were approved, signed and dated by the current Laboratory Director. Findings include: 1. The Laboratory Director failed to sign and date 20 of 22 laboratory policies and procedures to indicate approval. Procedures include: -LAB DIRECTOR HIGH COMPLEXITY CLINICAL LABORATORY -CLINICAL CONSULTANT HIGH COMPLEXITY CLINICAL LABORATORY -TECHNICAL SUPERVISOR HIGH COMPLEXITY CLINICAL LABORATORY -GENERAL SUPERVISOR HIGH COMPLEXITY CLINICAL LABORATORY -TESTING PERSONNEL JOB DESCRIPTION HIGH COMPLEXITY CLINICAL LABORATORY -TESTING PERSONNEL MANAGEMENT HIGH COMPLEXITY LABORATORY -LABORATORY INFORMATION SYSTEM (LIS) -CRITICAL VALUE POLICY -ESTABLISHMENT/VERIFICATION OF PERFORMANCE SPECIFICATION -OSHA GUIDELINES: LABORATORY SAFETY -FIRE PLAN -EXPOSURE CONTROL PLAN - BLOODBORNE PATHOGENS -CHEMICAL SPILL -HANDWASHING -VOLUNTARY REPORTING OF DEVICE-RELATED ADVERSE EVENTS TO THE FDA -INCIDENT MANAGEMENT REPORTING -INCIDENT MANAGEMENT -HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT -DOCUMENT CONTROL & RECORD RETENTION -RECORD RETENTION 2. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor and Laboratory Supervisor.

D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, observation and interview the laboratory failed to establish and follow a maintenance protocol for one of one microscopes used by the Laboratory Director/Technical Supervisor to examine cytology specimen slides. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's maintenance protocol for the Laboratory Director/Technical Supervisor's microscope. Microscope includes: -BX40CYF (serial number 5L02300) 2. During an observation of the Laboratory Director/Technical Supervisor's microscope on February 12, 2024 at 3:15 PM, there was an adhesive sticker on the microscope that stated maintenance was due May 2023. a. The laboratory failed to perform maintenance on the microscope since May 2022. 3. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director /Technical Supervisor and Laboratory Supervisor.
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, lack of statistical records and interview the laboratory failed to establish and follow written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics. The laboratory failed to document three 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 the evaluation and comparison of three of three nongynecologic cytology statistics. Statistics include: -Number of nongynecologic cytology cases examined -Number of nongynecologic

	specimens processed by specimen type -Number of nongynecologic cases reported by diagnosis, including the number reported as unsatisfactory 2. The Survey Team requested and the laboratory failed to provide records of the three required annual statistics for 2022 and 2023. 3. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor and Laboratory Supervisor.
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 the laboratory failed to follow written policies and procedures to establish an individual maximum workload limit for each Technical Supervisor who performed primary screening of cytology specimens. The Technical Supervisor failed to establish an individual maximum workload limit for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the procedure URINE CYTOLOGY WORKLOAD LIMIT, which stated: "Workload limits for each individual who performs primary screening of cytology slides must be established by the Technical Supervisor based on each screener's documented performance." 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor established an individual maximum workload limit for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor and Laboratory Supervisor.
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 the laboratory failed to 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 cytology specimens. The Technical Supervisor failed to reassess a maximum workload limit for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the procedure URINE CYTOLOGY WORKLOAD LIMIT, which stated: "Workload limits for each individual who performs primary screening of cytology slides must be established by the Technical Supervisor based on each screener's documented performance. This limit is to be re-evaluated every six months as

	specified in the "Quality Assessment Review Form Urine Cytology Screener Performance Evaluation."" 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor reassessed a maximum workload limit for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisor includes: -Laboratory Director /Technical Supervisor 3. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor and Laboratory Supervisor.
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 the laboratory failed to follow written policies and procedures to ensure records were available to document the workload limit for one of one Technical Supervisors who performed primary screening of cytology specimens in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the procedure URINE CYTOLOGY WORKLOAD LIMIT, which stated: "Workload limits for each individual who performs primary screening of cytology slides must be established by the Technical Supervisor based on each screener's documented performance. This limit is to be re-evaluated every six months as specified in the "Quality Assessment Review Form Urine Cytology Screener Performance Evaluation."" 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for one of one Technical Supervisors who performed primary screening of cytology specimens in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor and Laboratory Supervisor.
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 the laboratory failed to establish written policies and procedures to ensure unsatisfactory nongynecologic cytology 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 unsatisfactory nongynecologic cytology slide preparations were identified and reported as

	unsatisfactory. 2. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor and Laboratory Supervisor.
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview the laboratory failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. 2. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor and Laboratory Supervisor.
D5659	CYTOLOGY CFR(s): 493.1274(e)(6) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview the laboratory failed to establish written policies and procedures to ensure corrected test reports indicated the basis for correction on the corrected test report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected test reports indicated the basis for correction on the corrected test report. 2. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor and Laboratory Supervisor.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview the laboratory failed to establish and follow written policies and procedures

	for an ongoing mechanism to monitor, assess and correct problems identified in the analytic cytology systems. The laboratory failed to document analytic quality assessment activities during 2022, 2023 and January 1, 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 for an ongoing program to monitor, assess and correct problems identified in the analytic cytology systems. 2. The Survey Team requested and the laboratory failed to provide documentation of analytic quality assessment activities during 2022, 2023 and January 1, 2024 to the date of the survey in 2024. a. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the diagnostic interpretations of the Laboratory Director/Technical Supervisor. 3. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor and Laboratory Supervisor.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic cytology systems. The laboratory failed to document postanalytic quality assessment activities during 2022, 2023 and January 1, 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 for an ongoing program to monitor, assess and correct problems identified in the postanalytic cytology systems. 2. The Survey Team requested and the laboratory failed to provide documentation of postanalytic quality assessment activities during 2022, 2023 and January 1, 2024 to the date of the survey in 2024. 3. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor and Laboratory Supervisor.
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 laboratory policies and procedures, laboratory records and and interview the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations (refer to D6079); failed to ensure quality assessment programs were established to assure the quality of laboratory services and identify failures in quality

	as they occur (refer to D6094); and failed to ensure the competency of one of one Technical Supervisors (refer to D6103).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations. Findings include: 1. The Laboratory Director failed to provide direction and oversight to ensure all laboratory policies and procedure were approved by the current Laboratory Director. Refer to D5407 2. The Laboratory Director failed to provide direction and oversight to ensure the compilation, documentation and evaluation of annual laboratory statistics. Refer to D5629 3. The Laboratory Director failed to provide direction and oversight to ensure the Technical Supervisors performing evaluation and reporting of cytology specimens had an established workload limit and failed to ensure criteria were established to reassess workload limits every 6 months. Refer to D5633, D5637, D5647, D6130
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview the Laboratory Director failed to ensure quality assessment programs were established to assure the quality of cytology services. The Laboratory Director failed to identify failures in quality as they occur. Findings include: 1. The Laboratory Director failed to ensure the establishment of written policies and procedures for a quality assessment program. 2. The Laboratory Director failed to provide records of an established quality assessment program and failed to identify failures in quality as they occurred in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. a. The Laboratory Director failed to ensure quality assessment programs were established to monitor, assess and correct problems identified in the analytic cytology

	systems. Refer to D5791 b. The Laboratory Director failed to ensure quality assessment programs were established to monitor, assess and correct problems in the postanalytic cytology systems. Refer to D5891
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of competency assessment records and interview the Laboratory Director failed to ensure written policies and procedures were established and followed to assess the competency of the Technical Supervisor. The laboratory failed to assess the competency of one of one Technical Supervisors in 2022, 2023 January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Laboratory Director failed to provide written policies and procedures to describe the process to assess the competency of the Technical Supervisor. 2. The Laboratory Director failed to provide competency assessment records for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisor includes: -Laboratory Director /Technical Supervisor 3. During an interview on February 13, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor and Laboratory Supervisor.
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 288 random negative nongynecologic cytology cases/289 slides from January 2022 through December 2023 and confirmation by the Technical Supervisor on February 13, 2024 the Technical Supervisor failed to verify the accuracy of two nongynecologic cytology tests. 1. UC23-00098 10/06/23 Voided Urine LABORATORY DIAGNOSIS: Negative for High-Grade Urothelial Carcinoma SURVEY TEAM DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma TECHNICAL SUPERVISOR DIAGNOSIS: Suspicious for High-Grade Urothelial Carcinoma 2. UC23-00006 01/11/23 Voided Urine LABORATORY DIAGNOSIS: Negative for High-Grade Urothelial Carcinoma SURVEY TEAM DIAGNOSIS: Negative for High Grade Urothelial Carcinoma Polyoma Virus TECHNICAL SUPERVISOR DIAGNOSIS: Negative for High Grade Urothelial Carcinoma Polyoma Virus
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 the Technical Supervisor failed to establish and reassess a maximum workload limit for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Technical Supervisor failed to provide documentation the Technical Supervisor established a maximum workload limit for one of one Technical Supervisors who performed primary cytology slide examinations in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Refer to D5633 and D5647 2. The Technical Supervisor failed to provide documentation the Technical Supervisor reassessed a workload limit at least every six months for one of one Technical Supervisors who performed primary cytology slide examinations in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Refer to D5637 and D5647
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.