Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1014741	(X3) Date Survey Completed 06/29/2023
Name of Provider or Supplier Auc Urologists, Llc	**Street Address, City, State** 3600 Sea Mountain Hwy, Little River, SC	

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, cytology specimen slide preparations, and interviews the laboratory failed to establish and follow written policies and procedures for an annual statistical comparison of three of three required nongynecologic statistics (refer to D5629); failed to 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 unsatisfactory slide preparations were identified and reported as unsatisfactory (refer to D5655); and failed to establish and follow written policies and procedures to define the reporting system used for the descriptive nomenclature used to diagnose nongynecologic specimens (refer to D5657).
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 with the Laboratory Director/Technical Supervisor A 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 2021 and 2022. 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 2021 and 2022. 3. During an interview on May 23, 2023 at 11:08 AM these findings were confirmed by Laboratory Director/Technical Supervisor A.
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 laboratory workload establishment records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow written policies and procedures to ensure individual maximum workload limits were established for the Technical Supervisor who performed primary screening of nongynecologic cytology specimen slides. The laboratory failed to provide individual maximum workload limits for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The laboratory failed to follow the policy titled WORKLOAD LIMIT FOR NON-GYNECOLOGICAL CYTOLOGY SCREENING which stated: "Principle: Workload limits on the number of slides to be screened by a primary screener will be in accordance with CLIAA 493.1274(d)" "Purpose: To establish and maintain a maximum workload limit for each individual performing primary screening in cytology (non-gynecological)." 2. The Survey Team requested and the laboratory failed to provide individual maximum workload limits for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Technical Supervisor includes: -Laboratory Director/Technical Supervisor A 3. During an interview on May 23, 2023 at 11:08 AM these findings were confirmed by Laboratory Director /Technical Supervisor A.
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 reassessed workload limit records and interview with the Laboratory Director/Technical Supervisor A 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 Supervisor who performed primary screening of nongynecologic cytology specimen slides. The laboratory failed to provide reassessed maximum workload limits for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The laboratory failed to follow the policy titled WORKLOAD LIMIT FOR NON-GYNECOLOGICAL CYTOLOGY SCREENING which stated: "Procedure: The workload log will be reviewed monthly by the laboratory director. At this time any necessary adjustments to workload limits will be made." 2. The Survey Team requested and the laboratory failed to provide reassessed maximum workload limits for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Technical Supervisor includes: -Laboratory Director /Technical Supervisor A 3. During an interview on May 23, 2023 at 11:08 AM these findings were confirmed by Laboratory Director/Technical Supervisor A.
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 establishment records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow written policies and procedures to ensure records were available to document the workload limit for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The laboratory failed to follow the policy titled WORKLOAD LIMIT FOR NON-GYNECOLOGICAL CYTOLOGY SCREENING which stated: "Principle: Workload limits on the number of slides to be screened by a primary screener will be in accordance with CLIAA 493.1274(d)" "Purpose: To establish and maintain a maximum workload limit for each individual performing primary screening in cytology (non-gynecological)." 2. The Survey Team requested and the laboratory failed to provide records of individual maximum workload limits for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Technical Supervisor includes: -Laboratory Director/Technical Supervisor A 3. During an interview on May 23, 2023 at 11:08 AM these findings were confirmed by Laboratory Director/Technical Supervisor A.
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/Technical Supervisor A the laboratory failed to establish and follow 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 May 23, 2023 at 11:08 AM these findings were confirmed by Laboratory Director /Technical Supervisor A.
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 with the Laboratory Director/Technical Supervisor A the laboratory failed to establish and follow 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 May 23, 2023 at 11:08 AM these findings were confirmed by Laboratory Director/Technical Supervisor A.
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, cytology specimen slide preparations and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems with diagnostic interpretation errors in nongynecologic cytology testing. The laboratory failed to identify and document failures of the cytology analytic systems in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to

	define an effective quality assessment program to monitor, assess and correct diagnostic interpretation errors identified in nongynecologic cytology testing. 2. The Survey Team requested and the laboratory failed to provide documentation of any problems identified in the accuracy of reporting nongynecologic cytology test results in 2021, 2022 and to the date of the survey in 2023. (Refer to D6103) a. During an interview on May 23, 2023 at 11:08 AM the Survey Team asked the Laboratory Director/Technical Supervisor A how the results of the internal proficiency program for urine cytology are graded. The Laboratory Director/Technical Supervisor A stated "I grade my own and there were never any issues." 3. The laboratory failed to verify the accuracy of 71 nongynecologic cytology tests. (Refer to D6115)
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, cytology specimen slide preparations and interviews 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, who also functions as Technical Supervisor A, failed to ensure that quality control programs were established and followed to assure the quality of laboratory services and identify failures in quality as they occur (refer to D6093); failed to ensure quality assessment programs were established and followed to assure the quality of laboratory services and identify failures in quality as they occur (refer to D6094); and failed to establish and follow written policies and procedures to identify diagnostic discrepancies and failed to follow written policies and procedures to monitor and assess the competency of the Technical Supervisor performing nongynecologic cytology testing (refer to D6103).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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, lack of laboratory records and interview the Laboratory Director, who also functions as Technical Supervisor A, failed to ensure that quality control programs were established and maintained to assure the quality of nongynecologic cytology testing and identify failures in quality as they occur. The Laboratory Director, who also functions as Technical Supervisor A, failed to provide records of an established quality control program in cytology in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assure the quality of cytology testing and identify failures in quality as they occur. 2. The Survey Team requested and the Laboratory Director failed to provide records of an established quality control program in cytology in 2021, 2022

	and to the date of the survey in 2023. 3. During an interview on May 23, 2023 at 11: 08 AM these findings were confirmed by Laboratory Director/Technical Supervisor A.
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, cytology specimen slide preparations and interview the Laboratory Director, who also functions as Technical Supervisor A, failed to follow written policies and procedures to ensure the accuracy of diagnostic interpretations and identify needs for remedial training to improve skills in reporting urinary cytology. The Laboratory Director, who also functions as Technical Supervisor A, failed to identify five of five diagnostic errors as part of their urine cytology quality assurance (QA) program from December 2022 through February 2023. Findings include: 1. The Laboratory Director failed to follow the procedure IN HOUSE PROFICIENCY PROGRAM FOR URINE CYTOLOGY which stated: "Quality Assurance will be responsible for reviewing results and determining that the results are acceptable or unacceptable." 2. The Survey Team reviewed records titled MONTHLY QA PROFICIENCY FOR URINE CYTOLOGY from December 2022 through February 2023. a. The records did not indicate whether the results were acceptable or unacceptable. b. During an interview on May 23, 2023 at 11:08 AM these findings were confirmed by the Laboratory Director who stated "I grade my own and there were never any issues." 3. The Survey Team reviewed seven cytology specimen slide preparations and the corresponding final cytology test reports that were also selected by the laboratory as part of their internal QA proficiency program. The Laboratory Director failed to identify five of five diagnostic errors in the seven urine cytology tests from December 2022 through February 2023. Cases include: -GC23-0027 01/06/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. LABORATORY DIRECTOR QA REVIEW DIAGNOSIS: Benign SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma -GC23-0355 02/23/2023 Catheterized Urine LABORATORY DIAGNOSIS: Atypical urothelial cells LABORATORY DIRECTOR QA REVIEW DIAGNOSIS: Scattered clusters of atypical cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma -GC23-0275 02/09/2023 Voided Urine LABORATORY DIAGNOSIS: Rare atypical urothelial cells LABORATORY DIRECTOR QA REVIEW DIAGNOSIS: Rare atypical cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma -GC23-0127 01/31/2023 Voided Urine LABORATORY DIAGNOSIS: Atypical urothelial cells LABORATORY DIRECTOR QA REVIEW DIAGNOSIS: Atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma -GC22-2132 12/01/2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. LABORATORY DIRECTOR QA REVIEW DIAGNOSIS: Benign SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical urothelial cells 4. The Laboratory Director failed to provide any additional written policies or procedures to assure the quality of nongynecologic cytology services and identify failures in quality as they occur in 2021, 2022 and to the date of the survey in 2023. 5. The Laboratory Director failed to provide any

	additional records to assure the quality of nongynecologic cytology services and to identify failures in reporting nongyecologic urine cytology tests as they occurred in 2021, 2022 and to the date of the survey in 2023. (Refer to D5791) 6. During an interview on May 23, 2023 at 11:08 AM the Laboratory Director/Technical Supervisor A stated that nongynecologic cytology specimen slide preparations and final test reports were not sent for outside consultation, in an effort to check the accuracy of diagnostic interpretations, unless requested by an outside provider.
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: A. Based on review of laboratory polices and procedures, laboratory records, cytology specimen slide preparations and interview the Laboratory Director, who also functions as Technical Supervisor A, failed to establish and follow written policies and procedures to ensure the competency of the Technical Supervisor to accurately report diagnostic interpretations. The Laboratory Director, who also functions as Technical Supervisor A, failed to identify and document needs for remedial training to improve upon the diagnostic skills of one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to ensure the competency of the Technical Supervisor to report urinary cytology specimens, to identify the Technical Supervisor's need for remedial training and to improve upon the Technical Supervisor's diagnostic skills to identify and report the following diagnostic entities: (Refer to D6115) -High grade urothelial carcinoma -Suspicious for high grade urothelial carcinoma -Atypical urothelial cells -Polyoma virus 2. The Survey Team requested and the Laboratory Director failed to provide documentation of the need for remedial training to improve upon diagnostic skills for one of one Technical Supervisor when reporting urine cytology specimens in 2021, 2022 and to the date of the survey in 2023. Technical Supervisor includes: -Technical Supervisor A 3. During an interview on May 23, 2023 at 11:08 AM these findings were confirmed by Laboratory Director/Technical Supervisor A. B. Based on review of laboratory policies and procedures, lack of competency assessment records and interview the Laboratory Director, who also functions as Technical Supervisor A, failed to follow written policies and procedures to assess and monitor the competency of the Technical Supervisor who conducted analytic and postanalytic phases of cytology testing. The Laboratory Director, who also functions as Technical Supervisor A, failed to provide documentation of a competency assessment for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Laboratory Director failed to follow the policy titled PERSONNEL COMPETENCY which stated: "All technical personnel will demonstrate competency during a 90 day probationary period...These competency assessments will then be reassessed every six months." 2. The Survey Team requested and the Laboratory Director failed to provide documentation of a competency assessment for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Technical Supervisor includes: -

	Laboratory Director/Technical Supervisor A 3. During an interview on May 23, 2023 at 11:08 AM these findings were confirmed by Laboratory Director/Technical Supervisor A. C. Based on review of laboratory policies and procedures, lack of competency assessment records and interview the Laboratory Director failed to follow written policies and procedures to assess, monitor and maintain the competency of the Histotechnicians who conducted preanalytic phases of cytology testing. The Laboratory Director failed to provide documentation of a competency assessment for two of two Histotechnicians in 2022 and to the date of the survey in 2023. 1. The Laboratory Director failed to follow the policy titled PERSONNEL COMPETENCY which stated: "All technical personnel will demonstrate competency during a 90 day probationary period...These competency assessments will then be reassessed every six months." 2. The Laboratory Director failed to provide documentation of a competency assessment for two of two Histotechnicians in 2022 and to the date of the survey in 2023. Histotechnicians include: -Histotechnician A -Histotechnician B 3. During an interview on May 23, 2023 at 11:08 AM these findings were confirmed by Laboratory Director/Technical Supervisor A.
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: A. Based on microscopic review of 1,060 random negative nongynecologic cases/1, 060 slides and the corresponding final cytology test reports from October 2022 through May 2023 and confirmation by the Survey Team Pathologist on June 16, 2023 the Laboratory Director, who also functions as Technical Supervisor A, failed to verify the accuracy of 35 nongynecologic cytology tests. 1. GC23-0870 05/04/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 2. GC23-0857 04/27/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 3. GC23-0813 04/24/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 4. GC23-0680 04/03/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 5. GC23-0329 02/20/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 6. GC22-2076 11/27 /2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 7. GC22-2007 11/14/2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 8. GC22-1857 10/20/2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 9. GC22-1854 10/20/2022 Bladder wash LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 10. GC22-1702 09/29/2022 Voided Urine

LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 11. GC23-0643 03/30/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 12. GC23-0604 03/27/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 13. GC23-0233 02/08/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 14. GC23-0134 01/31/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 15. GC23-0038 01/09/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 16. GC23-0029 01/06/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 17. GC23-0027 01/06/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 18. GC22-2334 12/30/2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 19. GC22-2286 12/20/2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 20. GC22-2280 08/12/2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 21. GC22-2227 12/13/2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 22. GC22-1911 10/28/2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 23. GC22-1886 10/25/2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 24. GC22-1858 10/20/2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 25. GC23-0316 02/16/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical urothelial cells, polyoma virus identified 26. GC23-0276 02/09/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical urothelial cells, polyoma virus identified 27. GC23-0229 02/08/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical urothelial cells, polyoma virus identified 28. GC23-0122 01/31/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical urothelial cells, polyoma virus identified 29. GC22-2014 11/14/2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical urothelial cells, polyoma virus identified 30. GC22-1890 10/26/2022 Voided

Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical urothelial cells, polyoma virus identified 31. GC23-0340 02/20/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for high grade urothelial carcinoma, polyoma virus identified 32. GC23-0334 02/20/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for high grade urothelial carcinoma, polyoma virus identified 33. GC23-0284 02/13/2023 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for high grade urothelial carcinoma, polyoma virus identified 34. GC22-1920 10/31/2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for high grade urothelial carcinoma, polyoma virus identified 35. GC22-1720 10/05/2022 Voided Urine LABORATORY DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for high grade urothelial carcinoma, polyoma virus identified B. Based on microscopic review of 166 random non-negative nongynecologic cases/166 slides and the corresponding final cytology test reports from October 2022 through May 2023 and confirmation by the Survey Team Pathologist on June 16, 2023 the Laboratory Director, who also functions as Technical Supervisor A, failed to verify the accuracy of 11 nongynecologic cytology tests. 1. GC23-0936 05/11/2023 Voided Urine LABORATORY DIAGNOSIS: Atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 2. GC23-0769 04/17/2023 Voided Urine LABORATORY DIAGNOSIS: Mildly atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 3. GC23-0600 03/23/2023 Voided Urine LABORATORY DIAGNOSIS: Atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 4. GC23-0355 02/23/2023 Catheterized Urine LABORATORY DIAGNOSIS: Atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 5. GC23-0286 02/15/2023 Voided Urine LABORATORY DIAGNOSIS: Rare clusters of mildly atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 6. GC23-0275 02/09/2023 Voided Urine LABORATORY DIAGNOSIS: Rare atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 7. GC23-0127 01/31/2023 Voided Urine LABORATORY DIAGNOSIS: Atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 8. GC23-0040 01/09/2023 Voided Urine LABORATORY DIAGNOSIS: Rare atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 9. GC22-2146 12/02/2022 Voided Urine LABORATORY DIAGNOSIS: Rare clusters of mildly atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 10. GC22-1898 10/26/2022 Voided Urine LABORATORY DIAGNOSIS: Atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 11. GC22-1809 10/13/2022 Voided Urine LABORATORY DIAGNOSIS: Atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma C. Based on microscopic review of 52 focused nongynecologic cases/52 slides and the corresponding final cytology test reports from June 2018 through May 2023 and confirmation by the Survey Team Pathologist on June 16, 2023 the Laboratory Director, who also functions as Technical Supervisor A, failed to verify the accuracy of 25 nongynecologic cytology tests. The 25 focused cases identified with diagnostic discrepancies were from eight patients diagnosed with

current abnormal cytology tests from October 2022 through May 2023 by the Survey Team Pathologist. Patient 1 current case: GC23-0931 05/11/2023 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical urothelial cells Patient 1 focused cases: 1. GC22-0559 03/09/2022 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: Rare atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 2. GC21-0468 02/22/2021 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 3. GC20-2751 11/19/2020 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 4. GC20-1848 08/12/2020 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 5. GC20-0931 04/22/2020 Voided Urine TECHNICAL SUPERVISOR B DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 6. GC19-3472 01/06/2020 Voided Urine TECHNICAL SUPERVISOR B DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 7. GC19-2390 08/28/2019 Voided Urine TECHNICAL SUPERVISOR B DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 8. GC19-0089 01/10/2019 Voided Urine TECHNICAL SUPERVISOR B DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 9. GC18-2002 08/01/2018 Voided Urine TECHNICAL SUPERVISOR B DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma Patient 2 current case: GC23-0680 04/03/2023 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma Patient 2 focused cases: 10. GC23-0256 02/08/2023 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 11. GC22-1719 10/05/2022 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma 12. GC21-2378 10/05/2021 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: Atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 13. GC20-2716 11/16/2020 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 14. GC20-1420 06/16/2020 Voided Urine TECHNICAL SUPERVISOR B DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 15. GC19-0947 04/01/2019 Voided Urine TECHNICAL SUPERVISOR B DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma Patient 3 current case: GC23-0813 04/24/2023 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma Patient 3 focused cases: 16. GC22-1769 10/10/2022 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: Rare clusters of atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS:

	High grade urothelial carcinoma 17. GC22-0760 03/29/2022 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 18. GC21-2054 08/31/2021 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: Rare clusters of atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 19. GC20-0153 01 /21/2020 Voided Urine TECHNICAL SUPERVISOR B DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma 20. GC19-1968 07/16/2019 Voided Urine TECHNICAL SUPERVISOR B DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma Patient 4 current case: GC23-0604 03/27/2023 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma Patient 4 focused case: 21. GC21-1083 04/28/2021 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma with squamous differentiation Patient 5 current case: GC23-0086 01/24/2023 Voided Urine FACILITY B DIAGNOSIS: Atypical urothelial cells, cannot further evaluate due to cellular degeneration Patient 5 focused case: 22. GC22-0109 01/13/2022 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: Rare atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma Patient 6 current case: GC22-2014 11/14/2022 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical urothelial cells, polyoma virus identified Patient 6 focused case: 23. GC21-0319 02/05/2021 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for high grade urothelial carcinoma, polyoma virus identified Patient 7 current case: GC22-2132 12 /01/2022 Voided Urine TECHNICAL SUPERVISOR A DIAGNOSIS: No atypia or malignant cells are present. SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical urothelial cells Patient 7 focused case: 24. GC18-1713 06/28/2018 Voided Urine TECHNICAL SUPERVISOR B DIAGNOSIS: Few atypical urothelial cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: High grade urothelial carcinoma Patient 8 current case: GC23-0096 01/25/2023 Voided Urine FACILITY B DIAGNOSIS: Atypical urothelial cells, cannot further evaluate due to cellular degeneration Patient 8 focused case: 25. GC18-2394 09/19/2018 Voided Urine TECHNICAL SUPERVISOR B DIAGNOSIS: Atypical urothelial cells SURVEY TEAM PATHOLOGIST 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 written policies and procedures, lack of laboratory workload establishment records and interview the Laboratory Director, who also functions as Technical Supervisor A, failed to establish individual workload limits and to reassess

	the workload limits at least every six months for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Cross refer to D5633 and D5637 Findings include: 1. The Survey Team requested and Technical Supervisor A failed to provide documentation that Technical Supervisor A established a maximum workload limit for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. (Refer to D5633) Technical Supervisor includes: -Technical Supervisor A 2. The Survey Team requested and Technical Supervisor failed to provide records of a workload reassessment at least every six months for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. (Refer to D5637) Technical Supervisor includes: -Technical Supervisor A 3. During an interview on May 23, 2023 at 8:53 AM these findings were confirmed by the Laboratory Director/Technical Supervisor A.
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.