Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0664200	11/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Fisher Titus Medical Center Pathology	272 Benedict Ave, Norwalk, OH	

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
D0000	A focus survey was completed on November 19, 2021. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: Cytology- 42 CFR 493.1221 Laboratory Director- 42 CFR 493.1441 Technical Supervisor- 42 CFR 493.1447
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 it was determined the laboratory failed to establish policies and procedures for the evaluation and comparison of three annual statistics (refer to D5629); failed to follow policies and procedures for the establishment of individual workload limits and failed to reassess workload limits at least every six months (refer to D5633 and D5637); failed to maintain records of the total number of slides examined and the total number of hours spent examining slides (refer to D5645); failed to establish written policies and procedures to document the workload limit (refer to D5647); failed to establish policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results (refer to D5657); and failed to follow written policies and procedures to ensure that amended test reports stated the basis of correction (refer to D5659).
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 and interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics. 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 cytology cases examined -Number of specimens processed by specimen type -Number of patient cases reported by diagnosis, including the number reported as unsatisfactory 2. During an interview on November 18, 2021 at 12:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Operations Director.
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 records and interview it was determined that the laboratory failed to follow written policies and procedures to ensure that maximum workload limits were established for five of five Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The laboratory failed to follow the policy CYTOLOGY WORKLOAD LIMIT POLICY which stated: "Workload limits are established by pathologist." 2. The Survey Team requested and the laboratory failed to provide individual maximum workload limits for five of five Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E 3. During an interview on November 18, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Operations Director.
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 laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure maximum workload limits for five of five Technical Supervisors were reassessed at least every six months and adjusted as necessary in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how the laboratory would reassess the workload limit of the Technical Supervisors at least every six months and adjust when necessary. 2. The Survey Team requested and the laboratory failed to provide workload limit reassessments for five of five Technical Supervisors at least every six months in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E 3. During an interview on November 18, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Operations Director.
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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure the laboratory would maintain records of the total number of slides examined and the total number of hours spent examining slides during each 24-hour period for five of five Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how records would be maintained of the total number of slides examined and the total number of hours spent examining slides during each 24-hour period for five of five Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E 2. During an interview on November 18, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Operations Director.
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 records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for five of five Technical Supervisors who performed screening of cytology specimens in 2019, 2020 and to the date of the survey in 2021. 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 Technical Supervisors who performed screening of cytology specimens. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for five of five Technical Supervisors who performed screening of cytology specimens in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E 3. During an interview on November 18, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director /Technical Supervisor A and Operations Director.
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, cytology test reports, cytology slide preparations and interview it was determined that the laboratory failed to establish written policies and procedures to ensure unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report five of five nongynecologic cytology slide preparations from July 2018 through August 2021 as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory for evaluation. 2. The laboratory failed to identify five of five nongynecologic cytology slide preparations from July 2018 through August 2021 as being unsatisfactory for evaluation. Cases include: -07-XP-18-0000055 -07-XP-20-0000006 (A) -07-XP-20-0000102 (A) -07-XP-21-0000080 -07-XP-21-0000176 3. During an interview on November 18, 2021 at 3:00 PM the Laboratory Director/Technical Supervisor A and Operations Director confirmed that written policies and procedures were not established prior to the date of the survey.
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 the review of laboratory policies and procedures and interview it was determined that 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 November 18, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Operations Director.
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, laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures to ensure corrected test reports indicated the basis for the correction on the test report. Four of five corrected test reports from October 7, 2021 to October 13, 2021 failed to state the basis for the correction. Findings include: 1. The laboratory failed to follow the procedure AMENDED/ADDENDUM REPORTING which stated: "4. Enter in the diagnostic correlation flag, and the reason for the amendment." 2. The Survey Team reviewed five amended test reports from October 7, 2021 to October 13, 2021. Four of five test reports failed to state the basis for correction. Test reports include: -07-XP-21-0000053 -07-XP-21-0000149 -07-XP-21-0000152 -07-XP-21-0000179 3. During an interview on November 18, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Operations Director.
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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the analytic phases of cytology testing. The laboratory failed to identify and document failures in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define a quality assessment program to monitor, assess and correct diagnostic interpretation errors identified in 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 2019,

	2020 and to the date of the survey in 2021. 3. During an interview on November 18, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Operations Director.
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 slide preparations and interviews it was determined that 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 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 that written policies and procedures were established to assess, monitor and maintain the competency of the Technical Supervisors performing cytology testing (refer to D6103).
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 slide preparations and interview it was determined that the Laboratory Director failed to ensure quality assessment programs were established to assure the quality of cytology services and identify failures in quality as they occur in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5791 Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide quality assessment programs to assure the quality of cytology services and identify failures in quality as they occur in 2019, 2020 and to the date of the survey in 2021. 2. During an interview on November 18, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Operations Director.
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 polices and procedures, laboratory records, cytology slide examinations and interview it was determined that the Laboratory Director failed to ensure written policies and procedures were established to identify needs for remedial training or continuing education to improve upon diagnostic skills of five of five Technical Supervisors when evaluating nongynecologic specimens from May 2017 to the date of the survey in 2021. Cross refer to D6115 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to identify needs for remedial training or continuing education to improve upon diagnostic skills of five of fiveTechnical Supervisors when evaluating nongynecologic specimens. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E 2. The Survey Team requested and the laboratory failed to provide documentation to identify needs for remedial training or continuing education to improve upon diagnostic skills of five of five Technical Supervisors when evaluating nongynecologic specimens. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E 3. The Survey Team reviewed 722 nongynecologic cytology cases from May 2017 to the date of the survey in 2021. a. The Survey Team identified diagnostic interpretation errors in 36 of 722 cases, confirmed by the Survey Team Pathologist on November 19, 2021. Cases include: -07-XP-17-0000065 (A) -07-XP-18-0000053 -07-XP-18-0000080 -07-XP-20-0000052 -07-XP-20-0000058 -07-XP-21-0000123 -07-XP-21-0000169 -07-XP-20-0000117 -07-XP-19-0000047 -07-XP-20-0000016 -07-XP-20-0000061 -07-XP-20-0000109 -07-XP-21-0000128 -07-XP-21-0000210 -07-XP-21-0000057 -07-XP-18-0000055 -07-XP-21-0000006 (A) -07-XP-20-0000102 (A) -07-XP-21-0000080 -07-XP-21-0000176 -07-XP-18-0000018 (B) -07-XP-20-0000046 (A) -07-XP-20-0000046 (B) -07-XP-18-0000064 -07-XP-20-0000102 (B) -07-XP-20-0000102 (C) -07-XP-20-0000046 (C) -07-XP-20-0000129 (B) -07-XP-19-0000038 -07-XP-19-0000077 -07-XP-21-0000002 (C) -07-XP-21-0000089 -07-XP-21-0000107 -07-XP-21-0000117 -07-XP-21-0000149 -07-XP-21-0000218 b. The laboratory failed to identify the need for remedial training or continuing education to improve upon the diagnostic skills to report the following entities: -Small Cell Carcinoma -Adenocarcinoma -High Grade Urothelial Carcinoma -Squamous Cell Carcinoma -Ductal Carcinoma -Papillary Urothelial Neoplasm -Polyoma Virus -Herpes -Apocrine Metaplastic cells -Unsatisfactory 4. During an interview on November 18, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Operations Director.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of 722 nongynecologic cytology cases/1,212 slides and corresponding final test reports, laboratory policies and procedures and interviews it was determined that the laboratory failed to have a Technical Supervisor who meets the qualification requirements of 493.1451 of this subpart. Technical Supervisor A failed to verify the accuracy of 36 nongynecologic cytology tests (refer to D6115);

	failed to establish and reassess a workload limit for five of five Technical Supervisors (refer to D6130); and failed to ensure that five of five Technical Supervisors documented the number of slides screened and the hours spent screening slides in each 24-hour period (refer to D6133).
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 the microscopic review of 518 negative nongynecologic cytology cases /925 slides from May 2017 through November 2021 and confirmation by the Survey Team Pathologist on November 19, 2021 it was determined that Technical Supervisor A failed to verify the accuracy of 20 nongynecologic cytology tests. 1. 07-XP-17-0000065 (A) 07/13/17 Bronchial Brushings, Right Lower Lobe LABORATORY DIAGNOSIS: No Evidence of Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells, Small Cell Carcinoma 2. 07-XP-18-0000053 07/13/18 Ascitic Fluid LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells, Adenocarcinoma 3. 07-XP-18-0000080 10/29/18 Pleural Fluid LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells 4. 07-XP-20-0000052 06 /26/20 Pleural Fluid, Left LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells, Favor Adenocarcinoma 5. 07-XP-20-0000058 07/08/20 Pleural Fluid, Side Not Specified LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells, Favor Adenocarcinoma 6. 07-XP-21-0000123 06/22/21 Ascitic Fluid LABORATORY DIAGNOSIS: No Evidence of Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells, Adenocarcinoma 7. 07-XP-21-0000169 08/09/21 Urine, Voided LABORATORY DIAGNOSIS: No Evidence of Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Urothelial Carcinoma 8. 07-XP-20-0000117 10/30/20 Common Bile Duct, Brushings LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: Highly Suspicious for Adenocarcinoma 9. 07-XP-19-0000047 06/19/19 Esophagus, Brushings LABORATORY DIAGNOSIS: Negative for Malignancy or Dysplasia SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for Malignancy 10. 07-XP-20-0000016 02/21/20 Bronchial Washings LABORATORY DIAGNOSIS: No Evidence of Malignancy Identified SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for Squamous Cell Carcinoma 11. 07-XP-20-0000061 07/07/20 Thoracentesis, Side Not Specified LABORATORY DIAGNOSIS: Negative for Malignance SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for Small Cell Carcinoma 12. 07-XP-20-0000109 10/09/20 Urine, Voided LABORATORY DIAGNOSIS: No Evidence of Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 13. 07-XP-21-0000128 06/28/21 Ascitic Fluid LABORATORY DIAGNOSIS: No Evidence of Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for Malignancy 14. 07-XP-21-0000210 10/07/21 Urine, Cystoscopic Collected LABORATORY DIAGNOSIS: Negative for High Grade Papillary Urothelial

Carcinoma SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 15. 07-XP-21-0000057 05/07/21 Urine, Cystoscopic LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade, Suspicious for Herpes, Positive for Polyoma Virus 16. 07-XP-18-0000055 07/16/18 Ureteral Washings LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Insufficient for Diagnosis 17. 07-XP-21-0000006 (A) 01/20/20 Bronchial Washings, Left Lower Lobe LABORATORY DIAGNOSIS: Negative for Malignance SURVEY TEAM PATHOLOGIST DIAGNOSIS: Insufficient Cellularity 18. 07-XP-20-0000102 (A) 10/27/20 Bladder Washings LABORATORY DIAGNOSIS: Negative for High Grade Papillary Urothelial Neoplasm SURVEY TEAM PATHOLOGIST DIAGNOSIS: Insufficient for Diagnosis 19. 07-XP-21-0000080 05/24/21 Urine, Cystoscopic Collected LABORATORY DIAGNOSIS: No Evidence of Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Insufficient Cellularity 20. 07-XP-21-0000176 08/13 /21 Urine, Cystoscopy LABORATORY DIAGNOSIS: Negative for High Grade Urothelial Neoplasm SURVEY TEAM PATHOLOGIST DIAGNOSIS: Insufficient Cellularity B. Based on the microscopic review of 215 non-negative nongynecologic cytology cases/287 slides from May 2017 through November 2021 and confirmation by the Survey Team Pathologist on November 19, 2021 it was determined that Technical Supervisor A failed to verify the accuracy of 16 nongynecologic cytology tests. 1. 07-XP-18-0000018 (B) 02/21/18 Bronchial Brushings, Right LABORATORY DIAGNOSIS: Positive for Non-Small Cell Carcinoma, Consistent with Squamous Cell Carcinoma SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for Malignant Cells 2. 07-XP-20-0000046 (A) 06/17/20 Bladder Washings LABORATORY DIAGNOSIS: Positive for Papillary Urothelial Neoplasm SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade 3. 07-XP-20-0000046 (B) 06/17/20 Bladder Washings LABORATORY DIAGNOSIS: Positive for Papillary Urothelial Neoplasm SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade 4. 07-XP-18-0000064 09/12/18 Fine Needle Aspiration, Right Breast LABORATORY DIAGNOSIS: Suspicious for Ductal Carcinoma SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for Malignant Cells, Apocrine Metaplastic Cells Present 5. 07-XP-20-0000102 (B) 10/27/20 Ureteral Washings, Right LABORATORY DIAGNOSIS: Suspicious for Papillary Urothelial Neoplasm SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade 6. 07-XP-20-0000102 (C) 10/27/20 Ureteral Washings, Right LABORATORY DIAGNOSIS: Suspicious for Papillary Urothelial Neoplasm SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade 7. 07-XP-20-0000046 (C) 06 /17/20 Bladder Washings LABORATORY DIAGNOSIS: Suspicious for Low Grade Papillary Urothelial Neoplasm SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade 8. 07-XP-20-0000129 (B) 11/18/20 Ureteral Washings, Right LABORATORY DIAGNOSIS: Suspicious for Low Grade Papillary Neoplasm SURVEY TEAM PATHOLOGIST DIAGNOSIS: Negative for High Grade 9. 07-XP-19-0000038 05/17/19 Ascitic Fluid LABORATORY DIAGNOSIS: Hypocellular Specimen Showing Rare Atypical Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells, Adenocarcinoma 10. 07-XP-19-0000077 10/16/19 Urine, Cystoscopy LABORATORY DIAGNOSIS: Atypical Urothelial Cells Present SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Urothelial Carcinoma 11. 07-XP-21-0000002 (C) 01/11/21 Bronchial Brushings, Right Middle Lobe LABORATORY DIAGNOSIS: Occasional Atypical Squamous Cells Identified SURVEY TEAM PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells, Favor Squamous Cell Carcinoma 12. 07-XP-21-0000089 06/02/2021 Ascitic Fluid LABORATORY DIAGNOSIS: Atypical Epithelial Cells Present SURVEY TEAM

	PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells, Adenocarcinoma 13. 07-XP-21-0000107 06/16/21 Ascitic Fluid LABORATORY DIAGNOSIS: Atypical Epithelial Cells Present SURVEY TEAM PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells, Adenocarcinoma 14. 07-XP-21-0000117 06/17/21 Urine, Cystoscopy LABORATORY DIAGNOSIS: Atypical Urothelial Cells Present SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Urothelial Carcinoma 15. 07-XP-21-0000149 10/11/21 Urine, Voided LABORATORY DIAGNOSIS: Atypical Epithelial Cells Present SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Urothelial Carcinoma 16. 07-XP-21-0000218 10/19/21 Urine, Voided LABORATORY DIAGNOSIS: Atypical Urothelial Cells Present 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 the lack of laboratory records and interview it was determined that Technical Supervisor A failed to establish individual workload limits and to reassess the workload limits at least every six months for five of five Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. 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 five of five Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E 2. The Survey Team requested and Technical Supervisor A failed to provide records of a workload reassessment at least every six months for five of five Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E 3. During an interview on November 18, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Operations Director.
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 the lack of laboratory records and interview it was determined that five of five Technical Supervisors performing primary screening of cytology specimen slides failed to document the number of slides screened and the number of hours devoted to screening slides during each 24-hour period in 2019, 2020 and to the date of the

	survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide records of the total number of slides screened for five of five Technical Supervisors spent screening cytology specimen slides during each 24-hour period in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E 2. The Survey Team requested and the laboratory failed to provide records of the total number of hours devoted to screening during each 24-hour period in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E 3. During an interview on November 18, 2021 at 3:00 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor A and Operations Director.
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.