Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0333745	12/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Southwest General Health Center	18697 Bagley Road, Laboratory Services, Cleveland, 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 December 9, 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 that the laboratory failed to establish written policies and procedures for the establishment of individual workload limits and failed to reassess workload limits at least every six months (refer to D5633 and D5637); failed to establish written policies and procedures to ensure that workload limits would be prorated when examining slides in less than eight hours (refer to D5641); failed to establish written policies and procedures to ensure the laboratory maintained records of the total number of slides examined and the total number of hours spent examining slides per 24-hour period (refer to D5645); failed to establish written policies and procedures to document the workload limit for each individual (refer to D5647); failed to establish written policies and procedures to ensure corrected test reports indicated the basis for the correction on the test report (refer to D5659); and failed to maintain records of the date the peer review of nongynecologic cases was performed (refer to D5787).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

	CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to assess the diagnostic competency of the Technical Supervisors. The laboratory failed to assess the diagnostic competency of six of six 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 assess the diagnostic competency of the Technical Supervisors. a. The Survey Team reviewed the procedure PERSONNEL that stated: "The laboratory director ensures the professional competency of Pathologists who provide interpretive services to the anatomic Pathology laboratory." b. The procedure failed to detail the criteria used to assess the diagnostic competency of the Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation that assessed the diagnostic competency of six of six Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F 3. During an interview on December 7, 2021 at 4:00 PM, these findings were confirmed with the Manager of Regulatory Compliance. 4. During an interview on December 8, 2021 at 4: 00 PM, these findings were confirmed with Technical Supervisor C and Technical Supervisor E.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of laboratory records and interviews it was determined that the laboratory failed to test staining materials for intended reactivity of the Papanicolaou stain for each day of use in 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the Papanicolaou stain used for staining nongynecologic cytology slides was assessed each day of use in 2020 and to the date of the survey in 2021. 2. During an interview on December 6, 2021 at 2:45 PM, Staff A stated that prepared smears received in the laboratory and cerebrospinal fluid slides were stained with the Papanicolaou stain. 3. During an interview on December 7, 2021 at 9:45 AM, these findings were confirmed with the Manager of Regulatory Compliance. 4. During an interview on December 8, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C and Technical Supervisor E.

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 laboratory records 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. The laboratory failed to document three of three required annual statistics for 2019 and 2020. 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. The Survey Team requested and the laboratory failed to provide records of the three required annual statistics for 2019 and 2020. 3. During an interview on December 6, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C and the Manager of Regulatory Compliance.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure individual maximum workload limits were established for the Technical Supervisors who performed examinations of cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the Technical Supervisor established individual maximum workload limits for the Technical Supervisors who performed examinations of cytology specimens. 2. During an interview on December 6, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C and the Manager of Regulatory Compliance.
D5637	CYTOLOGY

	CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to reassess and adjust when necessary a maximum workload limit at least every six months for the Technical Supervisors. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor's workload limits would be reassessed at least every six months and adjusted when necessary. 2. During an interview on December 6, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C and the Manager of Regulatory Compliance.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limits for six of six Technical Supervisors would be prorated when examining slides in less than eight hours. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limits for the Technical Supervisors when examining slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for six of six Technical Supervisors when examining slides in less than eight hours. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F 3. During an interview on December 6, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C and the Manager of Regulatory Compliance.
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 that the laboratory maintained records of the total number of slides examined and the total number of hours the Technical Supervisors spent examining slides per 24-hour period. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained records of the total number of slides examined and total number of hours the Technical Supervisors spent examining slides. 2. During an interview on December 6, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C and the Manager of Regulatory Compliance.
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 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 six of six 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 the 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 six of six Technical Supervisors who performed screening of cytology specimens in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F 3. During an interview on December 6, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C and the Manager of Regulatory Compliance.
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 establish written policies and procedures to ensure corrected test reports indicated the basis for the correction on the test report. One of two corrected test reports from April 2019 through September 2020

	failed to state the basis for the correction. 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 the correction on the test report. 2. The Survey Team reviewed two corrected test reports from April 2019 through September 2020. One of two test reports failed to state the basis for correction. Test report includes: -NG-19-0000411 3. During an interview on December 6, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C and the Manager of Regulatory Compliance.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of laboratory records and interview it was determined that the laboratory failed to maintain records of the date the peer review of nongynecologic cases was performed for 21 of 21 cases from November through the date of the survey in 2021. Findings include: 1. The Survey Team reviewed laboratory records titled DAILY AP INTERNAL REVIEW from November through the date of the survey in 2021. The records failed to document the date the peer review of nongynecologic cases was performed for 21 of 21 cases. Cases include: -NG-21-0001032 -NG-21-0001036 -NG-21-0001049 -NG-21-0001058 -NG-21-0001069 -NG-21-0001077 -NG-21-0001078 -NG-21-0001084 -NG-21-0001091 -NG-21-0001104 -NG-21-0001099 -NG-21-0001119 -NG-21-0001123 -NG-21-0001130 -NG-21-0001138 -NG-21-0001142 -NG-21-0001144 -NG-21-0001153 -NG-21-0001157 -NG-21-0001165 -NG-21-0001161 2. During an interview on December 7, 2021 at 9:45 AM, the Manager of Regulatory Compliance stated that the date on the records was the date the case was entered into the record and not the date the review was performed.
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, interviews, review of laboratory records and specimen slides 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 of the analytic systems in 2019, 2020 and 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

	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. The laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for comparing nongynecologic cytology reports with the corresponding histopathology report and determining the causes for discrepancies. a. During an interview on December 7, 2021 at 10:45 AM, Technical Supervisor C stated that the laboratory compared all cytology reports with the corresponding histopathology reports. If there was a discrepancy the cytology and histopathology slides were reviewed to determine the cause of the discrepancy. Technical Supervisor C used a checkmark on a piece of paper that listed the case accession numbers to indicate agreement with the original diagnosis. If there was a disagreement with the original diagnosis the case would be reviewed by two additional Technical Supervisors. b. The Survey Team reviewed 14 nongynecologic cytology cases with a discrepant histopathology report. The laboratory failed to identify and document the reason for the discrepancy for the 14 discrepant cases per their policy. Cases include: -NG-20-0000079 -NG-20-0000148 -NG-20-0000250 -NG-20-0000462 -NG-20-0000468 -NG-20-0000489 -NG-20-0000570 -NG-20-0000608 -NG-20-0000631 -NG-20-0000754 -NG-20-0000804 -NG-20-0000880 -NG-20-0000933 -NG-20-0001031 c. The laboratory failed to identify three of the 14 cases as having a more significant lesion than originally reported. Cases include: -NG-20-0000462 -NG-20-0000468 -NG-20-0000250 (A) 4. During an interview on December 7, 2021 at 4:00 PM, these findings were confirmed with the Manager of Regulatory Compliance. 5. During an interview on December 8, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C and Technical Supervisor E.
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, specimen slides 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 control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur (refer to D6093); 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).
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, laboratory records and interviews it was determined that the Laboratory Director failed to ensure that quality control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur. Cross refer to D5473, D5629 Findings include: 1. The Laboratory Director failed to ensure the laboratory tested staining materials for intended reactivity of the Papanicolaou stain. 2. The Laboratory Director failed to ensure written policies and procedures were established for an annual statistical evaluation of three of three required laboratory statistics, and failed to ensure the laboratory documented the three required annual statistics.
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, specimen slides 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 records of an established quality assessment program and failed to identify failures in quality as they occur in 2019, 2020 and to the date of the survey in 2021.
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, specimen slides and interviews 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 six of six Technical Supervisors when evaluating nongynecologic specimens from 2019, 2020 and to the date of the survey in 2021. Cross refer to D5209, D6115 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to assess the diagnostic competency of the Technical Supervisors. The laboratory failed to assess the diagnostic competency of six of six Technical

	Supervisors in 2019, 2020 and to the date of the survey in 2021. 2. 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 the Technical Supervisors when evaluating nongynecologic specimens. 3. The Survey Team requested and the laboratory failed to provide documentation to identify needs for remedial training or continuing education to improve upon the diagnostic skills of six of six Technical Supervisors when evaluating nongynecologic specimens. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F 4. The Survey Team reviewed 406 nongynecologic cytology cases from January 2020 through November 2021. a. The Survey Team Pathologist confirmed on December 9, 2021 diagnostic interpretation errors on 15 of 406 cases. Cases include: -NG-21-0000541 -NG-21-0000878 -NG-21-0000383 -NG-21-0000557 -NG-21-0000607 -NG-21-0000847 -NG-21-0000655 -NG-21-0000561 -NG-21-0000800 -NG-21-0000900 -NG-21-0000901 (A) -NG-21-0000901 (B) -NG-20-0000462 -NG-20-0000468 -NG-20-0000250 (A) b. The laboratory failed to identify the need for remedial training or continuing education to improve upon the diagnostic skills to recognize and report the following entities: -Adenocarcinoma -Squamous Cell Carcinoma -Non-Small Cell Carcinoma -Suspicious for Squamous Cell Carcinoma -Suspicious for Carcinoma -Suspicious for Malignancy -Suspicious for High Grade Urothelial Carcinoma -Non-Diagnostic 5. During an interview on December 7, 2021 at 4:00 PM, these findings were confirmed with the Manager of Regulatory Compliance. 6. During an interview on December 8, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C and Technical Supervisor E.
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 406 nongynecologic cytology cases/1213 slides and corresponding final test reports, laboratory policies and procedures and interview it was determined that the laboratory failed to have a Technical Supervisor who meets the qualification requirements of 493.1451 of this subpart. The Technical Supervisor failed to verify the accuracy of 15 nongynecologic cytology tests (refer to D6115); failed to establish and reassess a workload limit for six of six Technical Supervisors (refer to D6130); and failed to ensure that six of six 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 312 negative nongynecologic cytology cases /921 slides from April through November 2021 and confirmation by the Survey Team Pathologist on December 9, 2021 it was determined that the Technical Supervisor failed to verify the accuracy of seven nongynecologic cytology tests. 1. NG-21-0000541 06/08/21 Pericardial Fluid LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells, Favor Adenocarcinoma 2. NG-21-0000878 09/22/21 Ascites LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells, Adenocarcinoma 3. NG-21-0000383 04 /23/21 Renal Pelvis Wash, Left LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 4. NG-21-0000557 06/14/21 Pleural Fluid, Left LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for Malignancy 5. NG-21-0000607 06/30 /21 Lung Biopsy, Right LABORATORY DIAGNOSIS: No Malignant Cells Identified SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for Squamous Cell Carcinoma 6. NG-21-0000847 09/15/21 Pleural Fluid LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for Carcinoma 7. NG-21-0000655 07/15 /21 Aspiration Right Breast LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: Non-Diagnostic. No Ductal Cells Present B. Based on the microscopic review of 80 non-negative nongynecologic cytology cases/265 slides from April through October 2021 and confirmation by the Survey Team Pathologist on December 9, 2021 it was determined that the Technical Supervisor failed to verify the accuracy of five nongynecologic cytology tests. 1. NG-21-0000561 06/11/21 Left Neck Fine Needle Aspiration LABORATORY DIAGNOSIS: Atypical Cells Present SURVEY TEAM PATHOLOGIST DIAGNOSIS: Squamous Cell Carcinoma 2. NG-21-0000880 09/23/21 Pancreatic Mass, FNB LABORATORY DIAGNOSIS: Atypical Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: Adenocarcinoma 3. NG-21-0000900 09/28/21 Pleural Fluid, Left LABORATORY DIAGNOSIS: Scant Atypical Epithelial Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: Malignant. Adenocarcinoma 4. NG-21-0000901 (A) 09/28/21 Right Upper Lobe Bronchial Mass Brush LABORATORY DIAGNOSIS: Atypical Epithelial Cells Present SURVEY TEAM PATHOLOGIST DIAGNOSIS: Malignant. Non-Small Cell Carcinoma, Favor Adenocarcinoma 5. NG-21-0000901 (B) 09/28/21 Bronchial Washings LABORATORY DIAGNOSIS: Atypical Epithelial Cells Present SURVEY TEAM PATHOLOGIST DIAGNOSIS: Malignant. Non-Small Cell Carcinoma, Favor Adenocarcinoma C. Based on the microscopic review of nine focused negative nongynecologic cytology cases/20 slides from January 2020 through November 2020 and confirmation by the Survey Team Pathologist on December 9, 2021 it was determined that the Technical Supervisor failed to verify the accuracy of three nongynecologic cytology tests. 1. NG-20-0000462 06/26/20 Pleural Fluid, Right LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells, Adenocarcinoma 2. NG-20-0000468 06/29/20 Pleural Fluid, Left LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM PATHOLOGIST DIAGNOSIS: Positive for Malignant Cells, Adenocarcinoma 3. NG-20-0000250 (A) 04/02/20 Bronchial Wash LABORATORY DIAGNOSIS: No Malignant Cells Identified SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for Squamous Cell 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 the Technical Supervisor failed to establish individual workload limits and to reassess the workload limits at least every six months for six of six Technical Supervisor performing primary slide examinations in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the Technical Supervisor failed to provide documentation that the Technical Supervisor established a maximum workload limit for six of six Technical Supervisors who performed primary screening in 2019, 2020 and to the date of the survey in 2021 Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F 2. The Survey Team requested and the Technical Supervisor failed to provide records of a workload reassessment at least every six months for six of six Technical Supervisor who performed primary screening in 2019, 2020 and January 2021 to the date of the survey on July 19, 2021. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F 3. During an interview on December 6, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C and the Manager of Regulatory Compliance.
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 six of six 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 and the total number of hours six of six 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: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F 2. During an interview on December 6, 2021 at 4:00 PM, these findings were confirmed with Technical Supervisor C and the Manager of Regulatory Compliance.
D9999	By agreement between ASCT Services, Inc. and CMS, information provided for

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