Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0947936	03/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Pathology Llp Dba	801 Clarksville Street, Suite C, Paris, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to assess the competency of Technical Supervisors (refer to D5209); failed to ensure that preventive maintenance was performed as specified by the manufacturers (refer to D5429); failed to test staining materials for stain characteristics (refer to D5473); failed to identify one of twelve prior negative cases as having a more significant lesion and failed to document the review of one of twelve prior negative cases (refer to D5625); failed to establish written policies and procedures to establish and reassess individual workload limits (refer to D5633, D5637); failed to establish written policies and procedures to prorate the workload limit when examining slides in less than an eight hour day (refer to D5641); failed to document the total number of slides screened and total number of hours spent examining slides in each 24-hour period (refer to D5645); failed to establish written policies and procedures to ensure records were available to document workload limits (refer to D5647); and failed to follow policies and procedures to ensure that unsatisfactory cytology slide preparations were identified and reported as unsatisfactory (refer to D5655). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.
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 and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of two of two 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 describe the laboratory's process for assessing the competency of two of two Technical Supervisors. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 2. During an interview on March 24, 2021 at 12:45 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and the Laboratory Supervisor.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. 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 ensure that the required maintenance for one of one Shandon Varistain XY cytology stainer and one of one ELMI CM-6MTcentrifuge was performed as specified by the manufacturers 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 preventive maintenance records for one of one Shandon Varistain XY cytology stainer. 2. The Survey Team requested and the laboratory failed to provide preventive maintenance records for one of one ELMI CM-6MT centrifuge. 3. During interviews on March 23, 2021 at 1:20 PM and March 24, 2021 at 12:45 PM these findings were confirmed by the Laboratory Supervisor.
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: A. Based on lack of laboratory records and interviews it was determined that the laboratory failed to test Papanicolaou staining materials for intended reactivity for two of two nongynecologic stain processes to ensure predictable staining characteristics for each day of use 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 stain assessment records for two of two nongynecologic stain processes for 2019, 2020 and to the date of the survey in 2021. Stain processes include: -"Non-gyn stain (Other than bronchs)" -"Non-gyn stain (Bronchs)" 2. During an interview on March 24, 2021 at 12: 45 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and the Laboratory Supervisor. B. Based on review of laboratory records and interviews it was determined that the laboratory failed to test Papanicolaou staining materials for the gynecologic stain process for intended reactivity to ensure predictable staining characteristics for four of 64 days of use from August to December 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide stain assessment records for the gynecologic stain process for four of 64 days of use from August to December 2020. Dates include: -August 14, 2020 -October 9, 2020 -December 29, 2020 -December 31, 2020 2. During interviews on March 23, 2021 at 10:20 AM and March 24, 2021 at 12:45 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A.
D5625	CYTOLOGY CFR(s): 493.1274(c)(3) (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)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, microscopic review of gynecologic specimen slides and laboratory records it was determined that the laboratory failed to follow written policies and procedures to identify one of twelve previous negative gynecologic cases as having a more significant lesion. The laboratory failed to document a review for one of twelve previous negative gynecologic cases. Findings include: 1. The laboratory failed to follow the procedure titled GYNECOLOGIC RETROSPECTIVE SLIDE REVIEW which stated "When a pap smear or a gyn histology is diagnosed as being HSIL, AIS, adenocarcinoma, or other malignant neoplasm, the laboratory will review all previous negative paps available in the laboratory within the previous 5 years." 2. The Survey Team reviewed twelve previous negative gynecologic cases from ten current cases of HSIL from January 2019 through August 2020. a. On March 24, 2021 the Survey Team identified and Technical Supervisor A confirmed that the laboratory failed to identify one of twelve prior negative gynecologic cases as having a more significant lesion than was originally reported. Prior negative case includes: -GC15-02339 3. The Survey Team reviewed records titled FIVE YEAR RETROSPECTIVE REVIEW OF NEGATIVE PAPS ON PATIENTS WITH A CURRENT DIAGNOSIS OF HIGH GRADE /MALIGNANT from January 2019 through August 2020. a. On March 24, 2021 the Survey Team identified and Technical Supervisor A confirmed that one of twelve previous negative gynecologic cases from the ten HSIL cases had no documented review by the laboratory. Prior Negative Case Includes: -GC18-00560
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 interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established by the Laboratory Director/Technical Supervisor A for two of two 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 ensure that individual maximum workload limits were established for each Technical Supervisor who performed screening of cytology specimens. 2. The Survey Team requested and the laboratory failed to provide documentation that a maximum workload limit was established for two of two Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During interviews on March 23, 2021 at 10: 20 AM and March 24, 2021 at 12:45 PM these findings were confirmed by the 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 laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to reassess a maximum workload limit at least every six months for two of two Technical Supervisors in 2019, 2020 and to the date of the survey 2021. Cross refer to D5633 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to reassess a maximum workload limit at least every six months for two of two Technical Supervisors in 2019, 2020 and to the date of the survey 2021. 2. The Survey Team requested and the laboratory failed to provide records of a workload reassessment at least every six months for two of two Technical Supervisors in 2019, 2020 and to the date of the survey. 3. During interviews on March 23, 2021 at 10:20 AM and March 24, 2021 at 12:45 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A.
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: Cross refer to D5645 Based on review of laboratory policies and procedures, lack of laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure the workload limit for two of two Technical Supervisors when examining slides in less than an 8-hour workday and with duties other than slide examination, would be prorated to determine the number of slides that may be examined. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to determine how to prorate the workload limit for two of two Technical Supervisors when time was spent on duties other than slide examination or when examining slides in less than an 8-hour day. 2. The Survey Team requested and the laboratory failed to provide documentation of the number of slides that could be examined when time was spent on duties other than slide examination or when examining slides in less than an 8-hour day for two of two Technical Supervisor's. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During interviews on March 23, 2021 at 10: 20 AM and March 24, 2021 at 12:45 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A.
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, laboratory records and interviews 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 and the total number of hours spent evaluating slides during each 24-hour period for two of two Technical Supervisors. 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 and the total number of hours spent evaluating slides during each 24-hour period. 2. The Survey Team requested and the laboratory failed to provide records of the total number of nongynecologic slides and the total number of hours spent evaluating nongynecologic slides during each 24-hour period for two of two Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During interviews on March 23, 2021 at 10:20 AM and March 24, 2021 at 12:45 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A who stated "We didn't know that nongynecologic slides had to be counted but I looked it up and found that they did."
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 interviews it was determined that the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for two of two Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5633 and D5637 Findings include: 1. The Survey Team requested and the laboratory failed to provide records of established workload limits for two of two Technical Supervisors in 2019, 2020, and to the date of the survey in 2021. 2. During interviews on March 23, 2021 at 10:20 AM and March 24, 2021 at 12:45 PM these findings were confirmed by the 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, microscopic review of gynecologic cytology specimen slide preparations and corresponding laboratory records it was determined that the laboratory failed to follow written policies and procedures to ensure that unsatisfactory gynecologic cytology cases were identified and reported as unsatisfactory. The laboratory failed to microscopically identify two of two gynecologic cytology cases in December 2020 as being "Unsatisfactory for Evaluation." Findings include: 1. The laboratory failed to follow the written procedure titled SPECIMEN ADEQUACY CRITERIA which stated "3. Unsatisfactory for evaluation...The cellular component of the smear covers less than 10% of the slide." 2. The laboratory failed to identify and report two of two gynecologic cytology cases in December 2020 as being "Unsatisfactory for Evaluation." Cases include: -GC20-02610 -GC20-02692 2. On March 24, 2021 the Laboratory Director/Technical Supervisor A reviewed the cases and confirmed these findings.
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, microscopic review of glass 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 fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079); and failed to establish written policies and procedures to assess the competency of personnel who perform preanalytic, analytic and postanalytic cytology test procedures (refer to D6103). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, specimen slide preparations and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5429, D5473, D5625, D5633, D5637, D5641, D5645, D5647 and D5655
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of two of two Technical Supervisors and three of three personnel who performed preanalytic cytology test procedures in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5209 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to assess, monitor, and maintain the competency of personnel who performed preanalytic cytology test procedures. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for three of three personnel who

	performed preanalytic cytology test procedures in 2019, 2020, and to the date of the survey in 2021. Personnel include: -Laboratory Supervisor -Histotechnician A -Histotechnician B 3. During an interview on March 24, 2021 at 12:45 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and the Laboratory Supervisor.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: A. Based on the microscopic review of 247 random negative gynecologic cases/slides and the corresponding final test reports from December 2020 through January 2021 and confirmation by Technical Supervisor A on March 24, 2021 it was determined that the Technical Supervisor failed to verify the accuracy of two gynecologic cytology tests. 1. GC20-02610 12/10/2020 ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Unsatisfactory for Evaluation due to Scant Cellularity and Obscuring Blood TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory for Evaluation 2. GC20-02692 12/21/2020 ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Unsatisfactory for Evaluation due to Scant Cellularity and Obscuring Blood and Inflammation TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory for Evaluation due to Obscuring Blood and Inflammation B. Based on the microscopic review of 20 random nongynecologic cases/72 slides and the corresponding final test reports from December 2020 and confirmation by Technical Supervisor A on March 24, 2021 it was determined that the Technical Supervisor failed to verify the accuracy of one nongynecologic cytology test. 1. RC20-00660 12/09/2020 Carinal Lavage LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM DIAGNOSIS: Suspicious for Carcinoma TECHNICAL SUPERVISOR A DIAGNOSIS: Suspicious for 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 lack of laboratory records and interviews it was determined that Technical Supervisor A failed to establish individual workload limits and to reassess workload limits at least every six months for two of two Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Cross Refer to D5633 and D5637
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 review of laboratory policies and procedures, laboratory records and interviews it was determined that two of two Technical Supervisors failed to document the total number of slides screened and the total number of hours spent examining slides during each 24-hour period in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5645
D9999	By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.