Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D0456332	06/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Services Pc	1931 West A Street, North Platte, NE	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interviews, the Survey Team determined the laboratory failed to meet the specified requirements for gynecologic cytology proficiency testing (PT) examination in 2019 and 2020. The laboratory failed to administer the PT as required by the proficiency test provider's instructions (refer to D2015).
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during

the PT event.

This STANDARD is not met as evidenced by:
Based on review of cytology proficiency test (PT) records and interviews it was determined the laboratory failed to administer the PT examination as required by the proficiency test provider's laboratory proctor instructions. Findings Include: 1. The Survey Team reviewed the COLLEGE OF AMERICAN PATHOLOGISTS (CAP) PAP PROFICIENCY TEST (PT) PROCTOR PACKET INSTRUCTIONS which stated: -"Monitor the test environment to make sure there is no communication among examinees regarding the result form, the challenge interpretation menu, or the test challenges." -"Distribute the kit instructions, an individual result form, and the matching Challenge Interpretive Menu and set up challenges to the examinee." -"Instruct the examinee to read the kit instructions carefully." -"Remind the examinee not to communicate with any individual regarding the challenges, the interpretations, or any aspect of the task until the testing event has been completed." -"Record the examinees start time in the area located on the individual result form." -"Observe the time and collect all test materials from the examinee after 2 hours, whether or not he or she has completed the test." -"Record the examinees stop time on the result form. Have the examinee sign in the area marked 'Examinee signature'. Sign your name by 'Proctor signature.'" -"Fax the result form immediately after the examinee is done. Do not wait until the end of the test event to fax the result form." 2. During an interview on June 14, 2021 at 3:55 PM Laboratory Director/Technical Supervisor A stated the following, when asked about the laboratory's PT proctor and PT testing activities: -"The slides from the PT were split into two sets of five slides by the proctor and given to the pathologists simultaneously to be reviewed." The pathologists included the Technical Supervisor and the Laboratory Director. -"When either was finished with the set of five slides we would give the slides to the proctor as the courier and the proctor would transfer the slides to the other test taker who was in a different room." 3. During an interview on June 14, 2021 at 3:30 PM Technical Supervisor B stated: -The PT slide set "was simultaneously reviewed five at a time and the proctor would hold the five slides and pass the slides between the two of us who were in different rooms, we did this in order to be efficient with time and saw the proctor as a safe harbor for the slides." 4. The survey team reviewed the CMS-approved GYN Proficiency Testing Result Forms from 2019 and 2020 and observed simultaneous testing start and stop times for the two Technical Supervisors and delayed fax times for three of three PT participants as follows: a. PT test result forms from slide set #34071, for the PT event on September 9, 2019 include: -Result Form for Cytotechnologist: 2019 Set #34071: Start Time: 08:07 AM Stop Time: 09:15 AM Fax Time: 11:20 AM -Result Form for Laboratory Director/Technical Supervisor A: 2019 Set #34071: Start Time: 09:42 AM Stop Time: 10:05 AM Fax Time: 11:21 AM -Result Form for Technical Supervisor B: 2019 Set #34071: Start Time: 09:44 AM Stop Time: 10:01 AM Fax Time: 11:22 AM b. Test result forms from slide set #36683, for the PT event on September 8, 2020 include: -Result Form for Cytotechnologist: 2020 Set #36683: Start Time: 08:12 AM Stop Time: 09:03 AM Fax Time: 10:36 AM -Result Form for Laboratory Director/Technical Supervisor A: 2020 Set #36683: Start Time: 09:17 AM Stop Time: 09:39 AM Fax Time: 10:37 AM -Result Form for Technical Supervisor B: 2020 Set #36683: Start Time: 09:16 AM Stop Time: 09:34 AM Fax Time: 10:38 AM 5. The laboratory failed to administer the PT examination as required by the proficiency test provider's laboratory proctor instructions. a. The Proctor failed to "collect all test materials (set of challenges, result form, Challenge Interpretation Menu, kit instructions) from the examinee after two hours, whether or not he or she has completed the test." b. The Proctor failed to "Fax

	the result form immediately after the examinee is done. Do not wait until the end of the test event to fax the result form" as indicated in the CAP instructions.
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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of Technical Supervisors who performed cytology testing and reporting of test results. The laboratory failed 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 assess the competency of the Technical Supervisors who performed cytology testing. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for two of two 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 3. During an interview on June 16, 2021 at 8: 30 AM Technical Supervisor B confirmed these findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the BD SUREPATH IMPLEMENTATION GUIDE, certification records for the BD SurePath Pap Test and interview it was determined the laboratory failed to ensure Laboratory Director/Technical Supervisor A had received appropriate training to evaluate gynecologic specimens using the BD SurePath Pap Test according to manufacturer's instructions, for 2020 and to date of the survey in 2021.. Findings include: 1. The BD SUREPATH IMPLEMENTATION GUIDE states "BD Surepath Morphology Training" must be completed for cytotechnologists and pathologists who evaluate BD SurePath prepared slides. 2. The Survey Team requested and the laboratory failed to provide morphology training records for Laboratory Director /Technical Supervisor A who performed diagnostic interpretations on BD SurePath Pap Tests for 2020 and to date of the survey in 2021. 3. During an interview on June 16, 2021 at 8:30 AM Technical Supervisor B confirmed these findings.
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, laboratory records, specimen slides and interview it was determined the laboratory failed to follow written policies and procedures to ensure the review of prior negative gynecologic specimens received within the previous five years for each patient with a current High Grade Lesion (HSIL) or malignancy detected errors in the performance of cytology examinations. The laboratory failed to identify one of six prior negative specimens as having a more significant lesion than initially reported. Findings include: 1. The laboratory failed to follow the policy QUALITY ASSURANCE - QUALITY CONTROL RETROREVIEWS which stated: -"If the review shows more than a two step discrepancy, the slide is given to the original cytotechnologist for review." 2. The Survey Team reviewed records and corresponding slides from five patients with a current HSIL, from February 2020 through December 2020. a. The Survey Team identified and Technical Supervisor B confirmed on June 16, 2021 that one of six prior negative cases from the five patients had a significant lesion of more than two steps than was originally reported. Case includes: -X18-001526 3. During an interview on June 16, 2021 at 8:30 AM Technical Supervisor B confirmed these findings.
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 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 one of one 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 reassess and adjust when necessary a maximum workload limit at least every six months for one of one Technical Supervisors who performed primary evaluations of cytology specimen slides. 2. The Survey Team requested and the laboratory failed to provide records of a workload reassessment at least every six months for one of one Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor B 3. During an interview on June 16, 2021 at 8:30 AM, Technical Supervisor B confirmed these findings.
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 interview it was determined the laboratory failed to establish written policies and procedures to ensure the laboratory maintained records of the total number of hours spent examining nongynecologic slides during each 24-hour period. The laboratory failed to maintain records of the total number of hours spent examining nongynecologic slides during each 24-hour period for Technical Supervisor B 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 the laboratory maintained records of the total number of hours spent in the primary examination of nongynecologic slides during each 24-hour period. 2. The Survey Team requested and the laboratory failed to provide records of the total number of hours Technical Supervisor B spent in the primary examination of nongynecologic slides during each 24-hour period in 2019, 2020 and to the date of the survey in 2021. 3. During an interview on June 16, 2021 at 8:30 AM Technical Supervisor B 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, specimen slides and interviews it was determined 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 compliance with applicable regulations (refer to D6079); failed to ensure testing of samples for the gynecologic cytology PT program in 2019 and 2020 was performed in accordance with 493.801 (refer to D6089); failed to ensure appropriate training according to the manufacturer's instructions (refer to D6102); and failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of two of two Technical Supervisors (refer to D6103).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical

	consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, specimen slides and interviews it was determined that Laboratory Director/Technical Supervisor A 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 D5411, D5625, D5637, D5645.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of PT records and interviews it was determined that Laboratory Director/Technical Supervisor A failed to ensure testing of samples for the gynecologic cytology PT program in 2019 and 2020 was performed in accordance with 493.801, which requires the laboratory to adminster the PT test events as required by the PT provider's instructions. Cross Refer to D2015
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the review of the BD SUREPATH IMPLEMENTATION GUIDE, review of certification records and interview it was determined that Laboratory Director /Technical Supervisor A failed to ensure appropriate training to evaluate BD SurePath specimen slides according to the manufacturer's instructions, for one of two Technical Supervisors. Cross Refer to D5411
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 and interview it was determined that Laboratory Director/Technical Supervisor A failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of two of two Technical Supervisors who performed preanalytic, analytic and postanalytic cytology test procedures in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5209 and D5411
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on the microscopic review of 344 random negative gynecologic cases/slides and the corresponding final test reports from January 2020 and confirmation by Technical Supervisor B on June 16, 2021 it was determined that Technical Supervisor B failed to verify the accuracy of one gynecologic cytology test. 1. X20-00381 1/29 /2020 Surepath Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion (LSIL) TECHNICAL SUPERVISOR B DIAGNOSIS: LSIL
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 polices and procedures, laboratory records and interviews it was determined that Technical Supervisor B failed to reassess workload limits at least every six months for Technical Supervisor B in 2019, 2020 and to the date of the survey in 2021. Cross Refer to 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 interview it was determined that Technical Supervisor B failed to document the total number of hours devoted to 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.