Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2115860	04/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Specialized University Pathologists	8201 Beverly Blvd Ste 405, Los Angeles, CA	

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 the lack of cytology proficiency testing (PT) enrollment records and interview the laboratory failed to enroll in an approved PT program for gynecologic examination. Refer to D2001.
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on the lack of cytology PT enrollment records and interview the laboratory failed to enroll in a CMS-approved cytology PT program for gynecologic examination

	for 2022 and 2023. Findings include: 1. The Survey Team requested and the laboratory failed to enroll in a CMS-approved cytology PT program for 2022 and 2023. 2. During an interview on April 17, 2024 at 11:00 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Laboratory Manager.
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 the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisors (refer to D5209); failed to test staining materials for intended reactivity of the Papanicolaou stain used for the gynecologic and nongynecologic cytology specimen slides for each day of use (refer to D5473); failed to establish and follow written policies and procedures for a program to compare all gynecologic cytology reports with a diagnosis of high grade squamous intraepithelial lesion (HSIL) or malignancy with available histopathology (refer to D5623); failed to establish and follow written policies and procedures to review prior gynecologic cases and identify cases with a more significant lesion (refer to D5625); failed to establish and follow written policies and procedures for an annual statistical evaluation of the required laboratory statistics (refer to D5629); failed establish and follow unsatisfactory cytology slide preparations were identified and reported as unsatisfactory (refer to D5655); failed to establish and follow written policies and procedures to ensure corrected final test reports indicated the basis for correction on the corrected final test report (refer to D5959); and failed to indicate the address of the laboratory where the test was performed (refer to D5805).
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 competency assessment records and interview the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisors. The laboratory failed to assess the competency of three of three Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process for assessing the competency of the Technical Supervisors who performed cytology testing on gynecologic and nongynecologic patient specimens. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for the cytology duties performed by three of three Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the

	survey in 2024. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C 3. During an interview on April 17, 2024 at 11:00 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Laboratory Manager.
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 quality control records and interview the laboratory failed to test staining materials for intended reactivity of the Papanicolaou stain used for the gynecologic and nongynecologic cytology specimen slides for each day of use in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide laboratory records documenting that the characteristics of the Papanicolaou stain used for gynecologic cytology slide preparations was assessed each day of use in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. 2. The Survey Team requested and the laboratory failed to provide laboratory records documenting that the characteristics of the Papanicolaou stain used for nongynecologic cytology slide preparations was assessed each day of use in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. 3. During an interview on April 17, 2024 at 11:00 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Laboratory Manager. .
D5623	CYTOLOGY CFR(s): 493.1274(c)(2) (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) (2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview the laboratory failed to establish and follow written policies and procedures for a program to compare all gynecologic cytology reports with a diagnosis of HSIL or other malignant neoplasms with available histopathology. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasms with available histopathology to

	determine the cause of any discrepancies. 2. During an interview on April 17, 2024 at 11:00 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Laboratory Manager.
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, interview and lack of laboratory records the laboratory failed to establish and follow written policies and procedures to ensure the search and review of prior negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy was performed. The laboratory failed to document the search for prior negative gynecologic specimens for 35 of 35 HSIL or malignant specimens from 2022, 2023 and January 1, 2024 to the date of the survey 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for the search and review of all prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy reported by the laboratory. a. During an interview on April 15, 2024 at 3:30 PM with the Laboratory Manager, the Laboratory Manager stated there was not a specific procedure or policy for this facility and that the search and review of the HSIL gynecologic specimens was performed at Facility B (CLIA# 05D211580). 2. The Survey Team requested and the laboratory failed to provide records of the search and review of prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy reported by the laboratory. The laboratory failed to document the search for prior negative gynecologic specimens for 35 of 35 HSIL or malignant specimens from 2022, 2023 and January 1, 2024 to the date of the survey 2024 3. During an interview on April 17, 2024 at 11:00 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Laboratory Manager.
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 interviews the laboratory failed to establish and follow written policies and procedures for an annual statistical evaluation of six of six required gynecologic laboratory statistics. The laboratory failed to document six of six required annual gynecologic statistics for 2022 and 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of six of six required gynecologic statistics. Statistics include: - Cytology cases examined; - Specimens processed by specimen type; - Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); - Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; - Gynecologic cases where cytology and histology are discrepant; and - 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. 2. The Survey Team requested and the laboratory failed to provide six of six annual statistics for 2022 and 2023. Statistics include: - Cytology cases examined; - Specimens processed by specimen type; - Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); - Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; - Gynecologic cases where cytology and histology are discrepant; and - Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as LSIL, HSIL, adenocarcinoma, or other malignant neoplasms. 3. During an interview on April 15, 2024 at 3:30 PM with the Laboratory Manager, the Laboratory Manager stated there was not a specific policy or procedure for this facility and that the gynecologic cases were combined with Facility B. 4. During an interview on April 17, 2024 at 11:00 AM these findings were confirmed with the Laboratory Director /Technical Supervisor A and the Laboratory Manager.
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, final test reports, cytology slide preparations, interview and confirmation by the Laboratory Director/Technical Supervisor A the laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report one of one nongynecologic test from March - April 2024 as unsatisfactory for evaluation. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. The Survey Team

	requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. a. The laboratory failed to identify one of one nongynecologic test from March - April 2024 as being unsatisfactory for evaluation. Refer to 6115. Test includes: -NG2024-000587 3. During an interview on April 17, 2024 at 11:00 AM these findings were confirmed with the Laboratory Director /Technical Supervisor A and the Laboratory Manager.
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview the laboratory failed to establish and follow written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report gynecologic and 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 gynecologic cytology test results. 2. 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. 3. During an interview on April 17, 2024 at 11:00 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Laboratory Manager.
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 and interview the laboratory failed to establish and follow written policies and procedures to ensure corrected final test reports indicated the basis for correction on the corrected final test report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected final test reports indicated the basis for correction on the corrected final test report. 2. During an interview on April 17, 2024 at 11:00 AM these findings were confirmed with the Laboratory Director /Technical Supervisor A and the Laboratory Manager.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the analytic cytology systems. The laboratory failed to document analytic quality assessment activities during 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the procedure VERIFICATION OF TESTING ACCURACY which stated: "3.2 Peer Review, At least twice a year an internal peer review process is performed by Specialized University Pathologists." a. During an interview on April 15, 2024 at 3:30 PM with the Laboratory Manager, the Laboratory Manager stated that there were no quality assessment activities and the peer review was not performed. 2. The Survey Team requested and the laboratory failed to provide documentation of analytic quality assessment activities during 2022, 2023 and January 1, 2024 to the date of the survey in 2024. a. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to evaluate and monitor the competency of the Technical Supervisors. Refer to D5209. b. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate staining materials for intended reactivity of the Papanicolaou stain used for the gynecologic and nongynecologic cytology specimen slides for each day of use. Refer to D5473. c. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate a program to compare all gynecologic cytology reports with a diagnosis of HSIL or malignancy with available histopathology. Refer to D5623. d. The Survey Team requested and the laboratory failed to provide written polices and procedures for a mechanism to monitor and evaluate the program to review prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of HSIL or malignancy and identify cases with a more significant lesion. Refer to D5625. e. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate an annual statistical evaluation of the required laboratory statistics. Refer to D5629. 3. During an interview on April 17, 2024 at 11: 00 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Laboratory Manager.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of final cytology test reports and interviews 38 of 38 final

	gynecologic test reports from January-March 2024 failed to indicate the address of the laboratory where the test was performed. Findings include: 1. The Survey Team reviewed 38 final gynecologic test reports from January-March 2024. Thirty-eight of 38 final gynecologic test reports failed to indicate the address where the test was performed. Reports include: -C2024-000234 -C2024-000252 -C2024-000263 -C2024-000272 -C2024-000276 -C2024-000280 -C2024-000289 -C2024-000292 -C2024-000296 -C2024-000298 -C2024-000329 -C2024-000362 -C2024-000395 -C2024-000427 -C2024-000446 -C2024-000468 -C2024-000474 -C2024-000493 -C2024-000516 -C2024-000549 -C2024-000554 -C2024-000559 -C2024-000571 -C2024-000616 -C2024-000648 -C2024-000657 -C2024-000662 -C2024-000663 -C2024-000669 -C2024-000692 -C2024-000702 -C2024-000710 -C2024-000728 -C2024-000741 -C2024-000745 -C2024-000758 -C2024-000766 -C2024-000833 2. During an interview on April 15, 2024 at 3:30 PM, the Laboratory Manager stated "the laboratory address was not on any of the gynecologic final test reports." 3. During an interview on April 17, 2024 at 11:00 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Laboratory Manager.
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 and interviews the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to ensure that the laboratory enrolled in an annual gynecologic cytology PT program (refer to D6088); failed to ensure three of three Technical Supervisors had the required morphology training to evaluate and report Hologic ThinPrep Pap Tests (refer to D6102); and failed to provide documentation of competency assessments for three of three Technical Supervisors (refer to D6103).
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the lack of PT enrollment records and interview the Laboratory Director failed to ensure that the laboratory enrolled in an annual gynecologic cytology PT program for 2022 and 2023. Findings include: 1. The Laboratory Director failed to ensure the laboratory was enrolled in an HHS-approved PT program for 2022 and 2023. Refer to D2001.
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 lack of laboratory certification records and interview the Laboratory Director failed to ensure that three of three Technical Supervisors had received the required Hologic ThinPrep Pap Test (TPPT) morphology certification prior to evaluating and reporting Hologic TPPT patient specimens in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Laboratory Director failed to ensure three of three Technical Supervisors received the required morphology certification prior to performing diagnostic evaluations of Hologic TPPT in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C 2. During an interview on April 17, 2024 at 11: 00 AM these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Laboratory Manager.
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, lack of competency assessment records and interview the Laboratory Director failed to ensure written policies and procedures were established and followed to assess, monitor and maintain the competency of the Technical Supervisors performing cytology test procedures and reporting of cytology test results. Findings include: 1. The Laboratory Director failed to provide written policies and procedures to assess the competency of the three of three Technical Supervisors to perform cytology test procedures and reporting of cytology test results, and when necessary, identify methods to improve the skills of the Technical Supervisors. Refer to D5209.
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 242 non-negative gynecologic cases/242 slides from July-December 2022, January-December 2023 and January-March 2024 and

	confirmation by the Laboratory Director/Technical Supervisor A on April 17, 2024, the Technical Supervisor failed to verify the accuracy of one gynecologic cytology test. 1. C2023-000165 01/30/2023 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance SURVEY TEAM DIAGNOSIS: High Grade Squamous Intraepithelial Lesion LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS: High Grade Squamous Intraepithelial Lesion B. Based on the microscopic review of 47 random negative nongynecologic cytology cases/47 slides from March and April 2024 and confirmation by the Laboratory Director/Technical Supervisor A on April 17, 2024, the Technical Supervisor failed to verify the accuracy of one nongynecologic cytology test. 1. NG2024-000587 04/08/2024 Bladder Wash LABORATORY DIAGNOSIS: Negative for High-Grade Urothelial Carcinoma SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory for Interpretation
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.