Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660617	05/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Pathology Laboratories Inc	1111 W 34th Street Suite 100, Austin, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of sixteen laboratory procedures and interview it was determined that the Facility A laboratory (CLIA #45D06660617) failed to have two written policies and procedures. Findings include: 1. The Survey Team requested and the Facility A laboratory failed to provide a written policy or procedure to describe the laboratory's slide storage and retention process. 2. The Survey Team requested and the Facility A laboratory failed to provide a written policy or procedure to describe the laboratory's gynecologic and non-gynecologic cytology Proficiency Testing programs. a. The procedure titled SOP: CAP INTERLABORATORY COMPARISON PROGRAM -

	AUS250578SOP was established by Facility B (CLIA #45D0505003) and was not established by or available in Facility A. b. The procedure titled SOP: PROFICIENCY TESTING FOR NEW HIRES - AUS250579SOP was established by Facility B and was not established by or available in Facility A. 3. These findings were confirmed by Technical Supervisor C and Staff A during interviews on 05/25 /2018 at 11:00 AM.
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 Hologic THINPREP 2000 SYSTEM OPERATOR'S MANUAL, review of certification records for the Hologic ThinPrep Pap Test, laboratory reports and interviews it was determined that the Facility A laboratory failed to ensure that one of fifteen Technical Supervisors had received the appropriate training to evaluate gynecologic specimens using the Hologic ThinPrep Pap Test, according to the manufacturer's instructions. Findings include: 1. The Hologic THINPREP 2000 SYSTEM OPERATOR'S MANUAL, CYTYC Part Number 70354-001, states "the evaluation of microscopic slides produced with the THINPREP 2000 System should be performed only by cytotechnologists and pathologists who have been trained to evaluate THINPREP prepared slides by CYTYC Corporation or by organizations or individuals designated by CYTYC Corporation." a. The Survey Team requested and the Facility A laboratory failed to provide morphology training records for one of fifteen Technical Supervisors who performed diagnostic interpretations on Hologic ThinPrep Pap Tests. There were no training records for: - Technical Supervisor N 2. The Survey Team reviewed 20 final Hologic ThinPrep Pap Test reports from 2017. Technical Supervisor N performed the diagnostic interpretations on the 20 ThinPrep Pap Tests without receiving the required morphology training. Accession numbers of the ThinPrep PapTests include: ZG182315, ZG182324, ZG182342, ZG182351, ZG182370, ZG182398, ZG182431, ZG182511, ZG182567, ZG182576, ZG182629, ZG197480, ZG197739, ZG197873, ZG204181, ZG204271, ZG204305, ZG214188, ZG214221, ZG214553 3. These findings were confirmed during an interview on 5/24/2018 at 2:00 PM with Staff A and Technical Supervisor C.
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 interviews it was determined that the Facility A laboratory failed to establish written policies and procedures to ensure that the cytology diagnosis and the histopathology diagnosis were compared to determine the causes of any discrepancies. Findings include: 1. The Survey Team requested and the Facility A laboratory failed to provide written policies and procedures to describe the laboratory's process to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. a. During an interview on 05/22/2018 at 10:15 AM with Technical Supervisor C and Staff A, Staff A stated that the comparison of cytology reports and corresponding histopathology reports was performed at Facility B. b. The Survey Team requested procedure titled SOP: CYTO/HISTO CORRELATION - AUS250690SOP from Staff A. The procedure was located at Facility B and was not established by or available in Facility A. 2. These findings were confirmed by the Facility A Laboratory Director /Technical Supervisor A during an interview on 05/22/2018 at 3:00 PM.
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 and interviews it was determined that the Facility A laboratory failed to establish written policies and procedures to ensure that the search and review of prior negative gynecologic specimens received within the previous five years, for each patient with a current High Grade Lesion (HSIL) or Malignancy was performed. Findings include: 1. The Survey Team requested and the Facility A 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. a. During an interview on 05/22/2018 at 10:15 AM with Technical Supervisor C and Staff A, Staff A stated that the search and review of previous negative gynecologic slides was performed at Facility B. b. The Survey Team requested procedure titled SOP RETROSPECTIVE RE-SCREENING - AUS250689SOP from Staff A. The procedure was located at Facility B and was not established by or available in Facility A. 2. These findings were confirmed by the Facility A Laboratory Director/Technical Supervisor A during an interview on 05/22 /2018 at 3:00 PM.
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, laboratory records and interviews it was determined that the Facility A laboratory failed to establish written policies and procedures for the evaluation and comparison of six of six laboratory statistics, and failed to document six of six required annual statistics for 2016 and 2017. Findings include: 1. The Survey Team requested and the Facility A laboratory failed to provide written policies and procedures to describe the laboratory's process for an annual statistical evaluation of six of six required annual statistics. 2. The Survey Team requested and the laboratory failed to provide records of the six of six required annual statistics for 2016 and 2017. 3. During an interview on 05/22/2018 at 10:15 AM with Technical Supervisor C and Staff A, Staff A stated that the evaluation and review of laboratory statistics was performed at Facility B. Staff A stated that the statistical data that was compiled included cases reported at other facilities. 4. These findings were confirmed by the Facility A Laboratory Director/Technical Supervisor A during an interview on 05/22/2018 at 3:00 PM.
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 it was determined that the laboratory failed to establish written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process to ensure that corrected reports indicated the basis for the correction. 2. The Survey Team requested procedure titled SOP: CHANGE AFTER RELEASE: CORRECTED AND AMENDED REPORT - AUS250663SOP from Staff A. The procedure was located at Facility B and was not established by or available in Facility A. 3. These findings were confirmed during an interview with Technical Supervisor C and Staff A on 05/25/2018 at 11:00 AM.
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 it was determined that the Facility A laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Facility A Laboratory Director (who was also Technical Supervisor A) 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 ensure that one of fifteen Technical Supervisors had received appropriate training to evaluate gynecologic specimens using the Hologic ThinPrep Pap Test (refer to 6102). 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, and interviews it was determined that the Facility A 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 D5403, D5623, D5625, D5629 and D5659
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 review of the Hologic THINPREP 2000 SYSTEM OPERATOR'S MANUAL, review of certification records, laboratory reports and interviews it was

	determined that the Facility A Laboratory Director failed to ensure appropriate training according to the manufacturer's instructions. One of fifteen Technical Supervisors had not received the appropriate training to evaluate the Hologic ThinPrep Pap Test. Cross Refer to 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 review of 415 gynecologic cases (419 slides) from February through May 2018 and confirmation by the Survey Team Pathologist on May 25, 2018 it was determined that the Technical Supervisor failed to verify the accuracy of one gynecologic test. 1. ZT987431 02/21/2018 Imaged ThinPrep Pap Test FACILITY A LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion/Reactive SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion
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.