Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D1076651	03/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Iowa Clinic Pathology Laboratory, The	5950 University Avenue, West Des Moines, IA	

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 review of annual gynecologic cytology proficiency test (PT) program instructions, annual gynecologic cytology PT participation records and interviews the laboratory failed to meet the specified requirements for gynecologic cytology PT examination in 2022, 2023 and 2024. The laboratory failed to administer the annual gynecologic cytology PT as required by the PT program's instructions in 2022, 2023 and 2024 (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 annual gynecologic cytology PT program instructions, annual gynecologic cytology PT participation records and interviews the laboratory failed to administer and document the PT examination as required by the PT provider's laboratory proctor instructions in 2022, 2023 and 2024. Findings Include: 1. The laboratory failed to follow the COLLEGE OF AMERICAN PATHOLOGISTS PAP PT PROCTOR PACKET INSTRUCTIONS which stated: "Record each examinee's start time in the area located on the individual test form." "Record the examinee's end time and collect all test materials from them after 2 hours, whether or not he or she has completed the test." a. During an interview on March 12, 2024 at 9:25 AM, the Histotechnician stated the examinee's recorded their own start and end time. The Histotechnician further stated the examinee's took the proficiency test separately. b. The Survey Team reviewed records titled GYNECOLOGIC CYTOLOGY PAP PT INDIVIDUAL RESULT FORM for 2022 and 2023. c. Two of two Technical Supervisor's started the proficiency test and ended the proficiency test at the same date and time in 2022. -Technical Supervisor A -Kit #35063248, Slideset #34456 Ten slides Test date: 02/22/2022 Start time: 08:30 AM Stop time: 09:00 AM -Technical Supervisor B -Kit #35063247, Slideset #34456 Ten slides Test date: 02/22/2022 Start time: 08:30 AM Stop time: 09:00 AM d. Technical Supervisor B started the proficiency test at the same time Technical Supervisor A ended the proficiency test in 2023. -Technical Supervisor A -Kit #36144162, Slideset #37184 Ten slides Test date: 02/21/2023 Start time: 11:20 AM Stop time: 11:30 AM -Technical Supervisor B -Kit #36144163, Slideset #37184 Ten slides Test date: 02/21/2023 Start time: 11:30 AM Stop time: 11:40 AM e. During an interview on March 12, 2024 at 9:25 AM, the Survey Team asked the Histotechnician if the COLLEGE OF AMERICAN PATHOLOGISTS GYNECOLOGIC CYTOLOGY PROFICIENCY TESTING PROGRAM KIT INSTRUCTIONS were reviewed with the examinee's. The Histotechnician stated "clearly they have done it before. They don't need any instructions." . 2. The laboratory failed to follow the COLLEGE OF AMERICAN PATHOLOGISTS PAP PT PROCTOR PACKET INSTRUCTIONS which stated: "Fax the result form immediately after the examinee is done. Do not wait until the end of the PAP PT event to fax the result form(s)." a. The Survey Team reviewed records titled GYNECOLOGIC CYTOLOGY PAP PT INDIVIDUAL RESULTS FORM for 2022. -Technical Supervisor A -Kit #35063248, Slideset #34456 Ten slides Test date: 02/22/2022 Start time: 08:30 AM Stop time: 09:00 AM Fax confirmation date and time: 02/23/2022 7:53 AM -Technical Supervisor B -Kit #35063247, Slideset #34456 Ten slides Test date: 02/22/2022 Start time: 08:30 AM Stop time: 09:00 AM Fax confirmation date and time: no fax confirmation -Cytotechnologist -Kit #35063249, Slideset #34456 Ten slides Test date: 02/22/2022 Start time: 07:45 AM Stop time: 08: 15 AM Fax confirmation date and time: 02/22/2022 8:59 AM b. The Survey Team reviewed records titled GYNECOLOGIC CYTOLOGY PAP PT INDIVIDUAL RESULTS FORM for 2023 -Technical Supervisor A -Kit #36144162, Slideset #37184 Ten slides Test date: 02/21/2023 Start time: 11:20 AM Stop time: 11:30 AM Fax confirmation date and time: 02/21/2023 11:49 AM -Technical Supervisor B -Kit #36144163, Slideset #37184 Ten slides Test date: 02/21/2023 Start time: 11:30 AM Stop time: 11:40 AM Fax confirmation date and time: 02/21/2023 11:53 AM -Cytotechnologist -Kit #36144164, Slideset #37184 Ten slides Test date: 02/21/2023 Start time: 08:00 AM Stop time: 08:32 AM Fax confirmation date and time: 02/21

	/2023 09:28 AM c. The Survey Team reviewed records titled GYNECOLOGIC CYTOLOGY PAP PT INDIVIDUAL RESULTS FORM for 2024. -Technical Supervisor A -Kit #37283223, Slideset #34295 Ten slides Test date: 03/04/2024 Start time: 01:00 PM Stop time: 01:15 PM Fax confirmation date and time: 03/04/2024 2: 51 PM 03/04/2024 2:23 PM - fax busy 03/04/2024 2:38 PM - fax busy -Technical Supervisor B -Kit #37283222, Slideset #34295 Ten slides Test date: 03/04/2024 Start time: 01:45 PM Stop time: 02:00 PM Fax confirmation date and time: no fax confirmation -Cytotechnologist -Kit #37283224, Slideset #34295 Ten slides Test date: 03/04/2024 Start time: 08:00 AM Stop time: 08:30 AM Fax confirmation date and time: no fax confirmation 3. During an interview on March 12, 2024 at 2:30 PM, the Laboratory Director/Technical Supervisor A confirmed the records titled GYNECOLOGIC CYTOLOGY PAP PT INDIVIDUAL RESULT FORM were not faxed immediately after the examinee's completed the test and stated the Histotechnician was performing duties in the histology laboratory during the proficiency test. The Laboratory Director/Technical Supervisor A further stated the Laboratory Director/Technical Supervisor A and Technical Supervisor B took the proficiency test separately.
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 follow two written policies and procedures (refer to D5401); failed to establish written policies and procedures for eight laboratory test processes (refer to D5403); failed to ensure six of 47 written policies and procedures were approved, signed and dated by the current Laboratory Director (refer to D5407); failed to establish and follow manufacturer's instructions (refer to D5411 and D5423); failed to ensure the required maintenance for the Hologic ThinPrep Genesis Processors was performed (refer to D5429); failed to test staining materials for intended reactivity of the Diff-Quick stain used to stain nongynecologic cytology slides for each day of use (refer to D5473); failed to establish and follow written policies and procedures for a program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of high grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or malignant neoplasms with available histopathology (refer to D5623); failed to 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 to follow written policies and procedures to ensure corrected final cytology test reports indicated the basis for correction on the corrected final cytology test report (refer to D5659); and failed to maintain records of the date the search and retrospective review was performed for current HSIL or malignant cases (refer to D5787).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of 47 laboratory policies and procedures, lack of laboratory records and interviews the laboratory failed to follow two written policies and procedures. Findings include: 1. The laboratory failed to follow the procedure QUALITY ASSURANCE, which stated: "Daily stain checks performed for gyn and non-gyn slides" a. The Survey Team requested and the laboratory failed to provide records documenting an assessment of the characteristics of the Diff Quick stain used to stain nongynecologic cytology slides for each day of use in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. 2. The laboratory failed to follow the procedure ANNUAL STATISTICAL EVALUATION POLICY, which stated, "The laboratory performs and documents an annual statistical evaluation of the following:" "Number of LSIL+ gynecologic cases where cytology and available histology results are discrepant" "Number of LSIL+ gynecologic cases for which histology results were not available to compare with malignant or pre malignant cytology cases" a. The Survey Team requested and the laboratory failed to provide the following records for 2022 and 2023: -Number of low grade squamous intraepithelial lesion (LSIL)+ gynecologic cases where cytology and available histology results are discrepant -Number of LSIL+ gynecologic cases for which histology results were not available to compare with malignant or pre malignant cytology cases 3. During an interview on March 11, 2024 at 2:30 PM, these findings were confirmed with the Cytotechnologist. 4. During an interview on March 12, 2024 at 2:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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 47 laboratory policies and procedures and interview the laboratory

	failed to establish written policies and procedures for eight laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the collection and submission process for fine needle aspiration (FNA) specimens. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for operating the Tissue-Tek Prisma autostainer and coverslipper. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process to manually coverslip cytology specimen slides. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the use of the Hologic ThinPrep Imaging System. 5. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the staining protocol to stain nongynecologic specimen slides with the Diff-Quick stain. 6. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for cytology PT enrollment and participation of personnel that perform gynecologic cytology testing. 7. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the laboratory followed the cytology PT provider's instructions for the gynecologic proficiency test. 8. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the laboratory maintained duplicates of original final cytology test reports when a correction was made to the original final cytology test report. 9. During an interview on March 13, 2024 at 12:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Pathology Manager, Cytotechnologist and Director of Ancillary Services.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of 47 laboratory policies and procedures and interviews the laboratory failed to ensure six of 47 written policies and procedures were approved, signed and dated by the current Laboratory Director. Findings include: 1. The Laboratory Director failed to sign and date six of 47 laboratory policies and procedures to indicate approval. Procedures include: -TEST REQUISITIONS -CYTOLOGY HANDLING, STORAGE AND RETRIEVAL OF SLIDES -PROCEDURE FOR REPROCESSING UNSATISFACTORY PAP TESTS FROM THINPREP VIAL -COLLECTION AND PREPARATION OF NON-GYNECOLOGIC SAMPLES -DOWNTIME PROCEDURE -AMENDING AND ADDING ADDENDUM TO FINALIZED REPORTS 2. During an interview on March 11, 2024 at 2:30 PM, these findings were confirmed with the Cytotechnologist. 3. During an interview on March 12, 2024 at 2:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

	This STANDARD is not met as evidenced by: Based on review of 47 laboratory policies and procedures and interviews the laboratory failed to maintain the date of discontinuance for one of one discontinued policy and procedure. Findings include: 1. The Survey Team reviewed one procedure that stated "Retired" in a binder titled CYTOLOGY PROCEDURE MANUAL. a. The laboratory failed to maintain the date of discontinuance for one of one discontinued procedures. Procedure includes: -DOCUMENTATION OF PREVIOUS CASE REVIEW ON CURRENT HSIL+ 2. During an interview on March 11, 2024 at 2:30 PM, these findings were confirmed with the Cytotechnologist. 3. During an interview on March 13, 2024 at 12:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Pathology Manager, Cytotechnologist and Director of Ancillary Services.
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: A. Based on review of manufacturer's instructions, laboratory policies and procedures and interviews the laboratory failed to establish and follow manufacturer's instructions for reprocessing Hologic ThinPrep Pap Tests following an unsatisfactory result. Findings include: 1. The HOLOGIC THINPREP GENESIS PROCESSOR OPERATOR'S MANUAL states: "Pour 30 ml of the CytoLyt Solution and 10% glacial acetic acid mixture into the centrifuge tube and cap securely." 2. The laboratory procedure PROCEDURE FOR REPROCESSING UNSATISFACTORY PAP TESTS FROM THINPREP VIALS stated: "Pour 20 ml of the CytoLyt Solution with glacial acetic acid mixture into the centrifuge tube and cap securely." a. The laboratory procedure failed to follow the manufacturer's instructions. 3. During an interview on March 13, 2024 at 8:50 AM, the Cytotechnologist was unsure how to reprocess a Hologic ThinPrep Pap Test and stated the Cytotechnologist would refer to the procedure manual to reprocess a Hologic ThinPrep Pap Test. 4. During an interview on March 13, 2024 at 12:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Pathology Manager, Cytotechnologist and Director of Ancillary Services. B. Based on review of the HOLOGIC THINPREP GENESIS PROCESSOR OPERATOR'S MANUAL, laboratory policies and procedures and interviews the laboratory failed to follow the manufacturer's instructions for processing nongynecologic cytology specimens using the Hologic ThinPrep Genesis Processor. Findings include: 1. The HOLOGIC THINPREP GENESIS PROCESSOR OPERATOR'S MANUAL states: "Specimens must be centrifuged and washed in CytoLyt Solution and transferred to PreservCyt Solution prior to being processed on the ThinPrep Genesis Processor." "Addition of CytoLyt Solution to cell pellets is required to wash the sample." "A CytoLyt Solution wash consists of the following process: Adding 30 ml of CytoLyt Solution to a cell pellet Mucoid Specimens Only: Mechanical agitation Concentration by centrifugation - 600 g x 10 minutes Pouring off the supernatant and vortexing to resuspend cell pellet" "When a sample is collected in CytoLyt Solution at a ratio less than 30 parts CytoLyt Solution to 1 part sample, this is considered a Collection Step and not a Wash Step.

	For example, if one collects 15ml of a sample and adds 30ml of CytoLyt Solution to this sample, then the CytoLyt: sample ratio is only 2 to 1 and this is considered a sample collection step and still requires a CytoLyt Solution Wash." 2. The laboratory procedure COLLECTION AND PREPARATION OF NON-GYNECOLOGIC SAMPLES stated: "Pour specimen into a properly labeled (patient name/case number) centrifuge tube and concentrate by centrifugation - 600g for 10 minutes or 1200g for 5 minutes." "Pour off supernatant and vortex to resuspend cell pellet." "Add specimen to PreservCyt Solution Vial." 3. During an interview on March 13, 2024 at 8:50 AM, the Cytotechnologist stated the laboratory did not use CytoLyt Solution to wash nongynecologic cytology specimens. After the fresh specimen was centrifuged the cell pellet was added directly to the PreservCyt Solution Vial without the required CytoLyt Wash. 4. During an interview on March 13, 2024 at 10:30 AM, the Cytotechnologist stated fine needle aspirate (FNA) specimens received in PreservCyt Solution Vials were not washed with CytoLyt Solution prior to processing on the Hologic ThinPrep Genesis Processor. a. The Cytotechnologist confirmed the laboratory failed to follow manufacturer's instructions for processing nongynecologic cytology specimens using the Hologic ThinPrep Genesis Processor. 5. During an interview on March 13, 2024 at 12:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Pathology Manager, Cytotechnologist and Director of Ancillary Services.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: A. Based on review of the HOLOGIC THINPREP GENESIS PROCESSOR OPERATOR'S MANUAL and interview the laboratory failed to establish performance specifications when the laboratory modified the Hologic ThinPrep test system manufacturer's instructions with an alternate method of reprocessing Hologic ThinPrep Pap Tests following an unsatisfactory result. Findings include: 1. The laboratory failed to establish performance specifications or evidence that the accuracy, precision, analytical sensitivity and specificity of the modified procedure, reportable range of test results or any other performance characteristic was adequate to provide accurate diagnostic interpretations 2. The HOLOGIC THINPREP GENESIS PROCESSOR OPERATOR'S MANUAL states: "Pour 30 ml of the CytoLyt Solution and 10% glacial acetic acid mixture into the centrifuge tube and cap securely." 3. The laboratory procedure PROCEDURE FOR REPROCESSING UNSATISFACTORY PAP TESTS FROM THINPREP VIALS stated: "Pour 20 ml of the CytoLyt Solution with glacial acetic acid mixture into the centrifuge tube and cap securely." 4. During an interview on March 13, 2024 at 12:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Pathology Manager, Cytotechnologist

	and Director of Ancillary Services. B. Based on review of the HOLOGIC THINPREP GENESIS PROCESSOR OPERATOR'S MANUAL and interviews the laboratory failed to establish performance specifications when the laboratory modified the Hologic ThinPrep test system manufacturer's instructions with an alternate method of processing nongynecologic cytology specimens. Findings include: 1. The laboratory failed to establish performance specifications or evidence that the accuracy, precision, analytical sensitivity and specificity of the modified procedure, reportable range of test results or any other performance characteristic was adequate to provide accurate diagnostic interpretations. 2. The HOLOGIC THINPREP GENESIS PROCESSOR OPERATOR'S MANUAL states: "Specimens must be centrifuged and washed in CytoLyt Solution and transferred to PreservCyt Solution prior to being processed on the ThinPrep Genesis Processor." "Addition of CytoLyt Solution to cell pellets is required to wash the sample." "A CytoLyt Solution wash consists of the following process: Adding 30 ml of CytoLyt Solution to a cell pellet Mucoid Specimens Only: Mechanical agitation Concentration by centrifugation - 600 g x 10 minutes Pouring off the supernatant and vortexing to resuspend cell pellet" "When a sample is collected in CytoLyt Solution at a ratio less than 30 parts CytoLyt Solution to 1 part sample, this is considered a Collection Step and not a Wash Step. For example, if one collects 15ml of a sample and adds 30ml of CytoLyt Solution to this sample, then the CytoLyt: sample ratio is only 2 to 1 and this is considered a sample collection step and still requires a CytoLyt Solution Wash." 3. The laboratory procedure COLLECTION AND PREPARATION OF NON-GYNECOLOGIC SAMPLES stated: "Pour specimen into a properly labeled (patient name/case number) centrifuge tube and concentrate by centrifugation - 600g for 10 minutes or 1200g for 5 minutes." "Pour off supernatant and vortex to resuspend cell pellet." "Add specimen to PreservCyt Solution Vial." 4. During an interview on March 13, 2024 at 8:50 AM, the Cytotechnologist stated the laboratory did not use CytoLyt Solution to wash nongynecologic cytology specimens. After the fresh specimen was centrifuged the cell pellet was added directly to the PreservCyt Solution Vial without the CytoLyt Wash. 5. During an interview on March 13, 2024 at 10:30 AM, the Cytotechnologist stated that fine needle aspirate specimens received in PreservCyt Solution Vials were not washed with CytoLyt Solution prior to processing on the Hologic ThinPrep Genesis Processor. 6. During an interview on March 13, 2024 at 12:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A, Pathology Manager, Cytotechnologist and Director of Ancillary Services.
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 review of the HOLOGIC THINPREP GENESIS PROCESSOR OPERATOR'S MANUAL, laboratory maintenance records and interviews the laboratory failed to ensure the required maintenance for two of two Hologic ThinPrep Genesis Processors was performed, as specified by the manufacturer, from April 2022 through December 2022, January through December 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The HOLOGIC THINPREP GENESIS PROCESSOR OPERATOR'S MANUAL states the following maintenance is to be performed: -Change fixative every 100 slides or daily, whichever comes first -

	Daily -Clean the slide nest and slide gripper - Daily -Clean the pipette tip disposal cup - Daily -Clean the processing area - Weekly -Clean the pipettor - Weekly -Clean the touch screen - Weekly -Clean the door and handle - Weekly -Clean the print head on the slide printer - Weekly -Clean the transportation rollers on the slide printer - Weekly -Clean the input roller on the slide printer - Weekly -Clean the exterior of the slide printer - Weekly 2. The Survey Team requested maintenance records for two of two HOLOGIC THINPREP GENESIS PROCESSORS. HOLOGIC THINPREP GENESIS PROCESSORS include: -S/N P0086F21D0 -S/N P0061I20D0 a. The laboratory provided one maintenance record titled THINPREP GENESIS PROCESSOR MAINTENANCE from April 2022 through December 2022, January through December 2023 and January 1, 2024 to the date of the survey in 2024. b. The record failed to specify which of the two THINPREP GENESIS PROCESSORS had received the required daily and weekly maintenance. 3. During an interview on March 11, 2024 at 2:30 PM, these findings were confirmed with the Cytotechnologist. 4. During an interview on March 12, 2024 at 2:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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 review of laboratory records and interviews the laboratory failed to test staining materials for intended reactivity of the Diff-Quick stain used to stain nongynecologic cytology 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 records documenting an assessment of the characteristics of the Diff-Quick stain used to stain nongynecologic cytology slides for each day of use in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. 2. During an interview on March 11, 2024 at 2:30 PM, these findings were confirmed with the Cytotechnologist. 3. During an interview on March 12, 2024 at 2: 30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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, laboratory records and interviews the laboratory failed to establish and follow written policies and procedures for a program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL, adenocarcinoma, or malignant neoplasms with available histopathology. The laboratory failed to determine the cause of discrepancy between gynecologic cytology cases with a diagnosis of HSIL or malignancy and the histopathology diagnosis for 13 of 13 cases for 2022 and 2023. 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. The Survey Team reviewed records titled ABNORMAL PAP REPORT for 2022 and 2023. The laboratory failed to document the cause of discrepancy between the gynecologic cytology report with a diagnosis of HSIL and the histopathology diagnosis of Negative for 13 of 13 cases for 2022 and 2023. Cases include: -G22-00913 -G22-00967 -G22-02552 -G22-03850 -G22-04248 -G22-04907 -G22-07788 -G22-21013 -G23-01201 -G23-01249 -G23-04728 -G23-07136 -G23-18076 3. During an interview on March 11, 2024 at 2:30 PM, the Cytotechnologist stated the report titled ABNORMAL PAP REPORT listed all HSIL and malignant Pap results. The Cytotechnologist looked up the Pap reports in the laboratory information system (LIS) for any histopathology follow-up. The Cytotechnologist documented the histopathology results on the report titled ABNORMAL PAP REPORT. a. The Cytotechnologist stated the discrepancies between the gynecologic cytology report and histopathology were not reviewed to determine the cause of the discrepancy. 4. During an interview on March 12, 2024 at 2:30 PM, these findings were confirmed with 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, laboratory records microscopic review of specimen slides and interview the laboratory failed to follow written policies and procedures to ensure the review of prior 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. The laboratory failed to identify four of 16 prior negative gynecologic cases from current HSIL's from 2022 and 2023, as having a more significant lesion than originally reported. Findings include: 1. The laboratory failed to follow the procedure DOCUMENTATION OF PREVIOUS CASE REVIEW ON CURRENT HSIL+, which stated: "When a current HSIL+ case is detected, the CT will use Orchard LIS

	and/or EMR to search the database for previous gyn cytology cases going back five years. All available previous negative slides are pulled and rescreened by the current CT. Any abnormal cells found are called to the attention of the CT who screened the case. The rescreened slides are sent to the Pathologist with the current HSIL+ case." 2. The Survey Team reviewed records titled PREVIOUS CASE REVIEW ON CURRENT HSIL. The Survey Team reviewed 16 previous negative gynecologic cases from 14 current cases of HSIL from 2022 and 2023. 3. The Survey Team identified and the Laboratory Director/Technical Supervisor A confirmed on March 12, 2024 the laboratory failed to identify four of 16 prior negative gynecologic cases as having a more significant lesion than was originally reported. Prior negative cases include: -G20-11313 -G21-05182 -G21-08551 -G21-11954
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 statistical records and interviews the laboratory failed to establish and follow written policies and procedures for an annual statistical evaluation of three of six required gynecologic laboratory statistics. The laboratory failed to document one of six required gynecologic laboratory 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 three of six required gynecologic statistics. Statistics include: -The number of gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison -The number of gynecologic cases where cytology and histology are discrepant -The number of gynecologic cases where any rescreen of normal or negative specimen results in reclassification as LSIL, HSIL, adenocarcinoma, or other malignant neoplasms. 2. The Survey Team requested and the laboratory failed to provide one of six required annual gynecologic laboratory statistics for 2022 and 2023. Statistic includes: -The number of 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 March 11, 2024 at 2:30 PM, these findings were confirmed with the Cytotechnologist. 4. During an interview on March 12, 2024 at 2:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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, corrected cytology test reports and interviews the laboratory failed to follow written policies and procedures to ensure corrected cytology test reports indicated the basis for correction on the corrected test report. One of two corrected cytology test reports from February 2023 and January 2024 failed to indicate the basis for correction on the corrected cytology test report. Findings include: 1. The laboratory failed to follow the procedure AMENDING AND ADDING ADDENDUM TO FINALIZED REPORTS, which stated, "Document in the report the reason for the addendum or amendment." 2. The Survey Team reviewed two corrected cytology test reports from February 2023 and January 2024. a. One of two corrected cytology test reports failed to indicate the basis for correction on the corrected cytology test report. Report includes: -N23-0194 3. During an interview on March 12, 2024 at 11:00 AM, these findings were confirmed with the Cytotechnologist. 4. During an interview on March 12, 2024 at 2:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews the laboratory failed to maintain records of the date the search and retrospective review (microscopic evaluation and reporting of interpretive results) of prior negative gynecologic cases was performed for current HSIL or malignant cases. Findings include: 1. The Survey Team reviewed laboratory records titled 2023 PREVIOUS CASE REVIEW ON CURRENT HSIL for 2023. a. The records failed to document the date the search of 29 of 29 current HSIL or malignant cases for prior negative cases was performed. Cases include: -G23-30131 -G23-29881 -G23-28494 -G23-28101 -G23-22271 -G23-21211 -G23-20925 -G23-18851 -G23-18076 -G23-16082 -G23-13248 -G23-12673 -G23-12303 -G23-12004 -G23-11870 -G23-11697 -G23-10050 -G23-08172 -G23-07136 -G23-05363 -G23-04977 -G23-04728 -G23-03501 -G23-02858 -G23-01984 -G23-01972 -G23-01249 -G23-01201 -G23-01108 b. The records failed to document the date the retrospective review of ten of ten prior negative cases was performed. Cases include: -G22-20692 -G21-08551 -G21-05182 -G20-11313 -G20-09114 -G20-09108 -G19-10554 -G19-08139 -G18-13580 -G18-03655 2. During an interview on March 11, 2024 at 2:30 PM, these findings were confirmed with the Cytotechnologist. 3. During an interview on March 12, 2024 at 2:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

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, specimen slides and interviews the laboratory failed to establish and 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 Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing program to monitor, assess and correct problems identified in the analytic cytology systems. 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 monitor and evaluate the performance of the required maintenance of two of two Hologic ThinPrep Genesis Processors. Refer to D5429 b. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the testing of staining materials for intended reactivity of the Diff-Quick stain used to stain nongynecologic cytology 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 the program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL, adenocarcinoma, or malignant neoplasms with available histopathology. Refer to D5623 d. The Survey Team requested and the laboratory failed to provide written policies 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 the annual statistical evaluation of the required laboratory statistics. Refer to D5629 f. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate corrected cytology test reports to ensure corrected cytology test reports indicated the basis for correction on the corrected cytology test report. Refer to D5659 g. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate records to ensure the date the search and retrospective review (microscopic evaluation and reporting of interpretive results) of gynecologic cases was performed was documented. Refer to D5787
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue

	corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of final cytology test reports and interviews the laboratory failed to maintain duplicates of two of two original final cytology test reports from February 2023 and January 2024 when a correction was made to the original final cytology test report. Findings include: 1. The Survey Team requested and the laboratory failed to provide a duplicate of the original final cytology test report for two of two corrected cytology test reports. Reports include: -N23-0194 -N24-0023 2. During an interview on March 12, 2024 at 11:00 AM, the Cytotechnologist stated the laboratory did not keep duplicates of original cytology test reports when corrections were made to the original final cytology test report. The Cytotechnologist stated "the original report goes away" in the LIS. 3. During an interview on March 12, 2024 at 2:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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 and interview 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 be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations (refer to D6079); failed to ensure testing of samples for the annual gynecologic cytology PT program was performed in accordance with 493.801, which requires the laboratory to administer the PT events as required by the PT program's instructions (refer to D6089); and failed to ensure quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur (refer to D6094).
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 the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations. Findings include: 1. The Laboratory Director failed to provide direction and oversight to ensure the laboratory followed two written policies and procedures. Refer to D5401 2. The Laboratory Director failed to provide direction and oversight to ensure written policies and procedures were established for all laboratory test processes. Refer to D5403 3. The Laboratory Director failed to provide direction and oversight to ensure all laboratory policies and procedure were approved by the current Laboratory Director. Refer to D5407 4. The Laboratory Director failed to provide direction and oversight to ensure manufacturer's instructions were followed. Refer to D5411, D5423 5. The Laboratory Director failed to provide direction and oversight to ensure the required maintenance for two of two Hologic ThinPrep Genesis Processors was performed, as specified by the manufacturer. Refer to D5429 6. The Laboratory Director failed to provide direction and oversight to ensure the laboratory tested staining materials for intended reactivity of the Diff-Quick stain used to stain nongynecologic cytology slides for each day of use. Refer to D5473 7. The Laboratory Director failed to provide direction and oversight to ensure a program was established to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL, adenocarcinoma, or malignant neoplasms with available histopathology. Refer to D5623 8. The Laboratory Director failed to provide direction and oversight to ensure policies and procedures were followed 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 9. The Laboratory Director failed to provide direction and oversight to ensure the compilation, documentation and evaluation of the required annual laboratory statistics. Refer to D5629 10. The Laboratory Director failed to provide direction and oversight to ensure corrected cytology test reports indicated the basis for correction on the corrected cytology test report. Refer to D5659 11. The Laboratory Director failed to provide direction and oversight to ensure records were maintained of the date the search and retrospective review (microscopic evaluation and reporting of interpretive results) of gynecologic cases was performed for current HSIL or malignant cases. Refer to D5787 12. The Laboratory Director failed to provide direction and oversight to ensure duplicates of original final cytology test reports were maintained when a correction was made to the original final cytology test report. Refer to D5821
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 annual gynecologic PT program instructions, annual gynecologic cytology PT participation records and interviews the Laboratory Director failed to ensure testing of samples for the annual gynecologic cytology PT program was performed in accordance with 493.801, which requires the laboratory to administer the PT events as required by the PT program's instructions. The laboratory failed to administer the PT examination as required by the PT provider's laboratory proctor

	instructions in 2022, 2023 and 2024. Findings include: 1. The Laboratory Director failed to ensure the laboratory administered the PT events as required by the PT program's instructions in 2022, 2023 and 2024. Refer to D2015
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews the Laboratory Director failed to ensure quality assessment programs were established to assure the quality of cytology services. The Laboratory Director failed to identify failures in quality as they occur. Findings include: 1. The Laboratory Director failed to ensure quality assessment programs were established to monitor, assess and correct problems identified in the analytic cytology systems. Refer to D5791 a. The Laboratory Director failed to ensure the establishment of written policies and procedures for an analytic quality assessment program. b. The Laboratory Director failed to provide records of an established quality assessment program and failed to identify failures in quality as they occurred in 2022, 2023 and January 1, 2024 to the date of the survey in 2024.
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.