Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0974323	06/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Reference Laboratory Llc	9600 Datapoint Drive, San Antonio, TX	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to ensure the required maintenance for five of five Hologic ThinPrep 5000 Processors was performed (refer to D5429); failed to test staining materials for intended reactivity of the Papanicolaou and Diff-Quick stains used to stain nongynecologic cytology slide preparations for each day of use (refer to D5473); failed to establish and follow written policies and procedures for an annual statistical evaluation of the required laboratory statistics (refer to D5629); failed to establish and follow written policies and procedures for the establishment, reassessment and documentation of individual workload limits (refer to D5633, D5637 and D5647); failed to establish and follow written policies and procedures to ensure that workload limits would be prorated when examining slides in less than eight hours (refer to D5641); failed to establish and follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined and the total number of hours spent examining slides per 24-hour period (refer to D5645); and 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 (refer to D5791).
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 39 laboratory policies and procedures, interviews and laboratory records the laboratory failed to follow two written policies and procedures. Findings include: 1. The laboratory failed to follow the procedure TISSUE-TEK PRISMA SLIDE STAINER, which stated: "Stains are changed daily." "All reagents are replaced daily to prevent cross contamination." a. During an interview on June 4, 2024 at 9:30 AM, Staff A stated all stains and reagents were changed weekly and the alcohols were rotated. b. The Survey Team reviewed records titled CYTOLOGY PROCESSING STAIN LOG for January through May 2024. The records failed to detail which alcohols were rotated. 2. The laboratory failed to follow the procedure NON GYN STAINER TISSUE TEK DRS, which stated: "Stains are changed daily." "All reagents are replaced daily, replace and fill according to CP 02 Form A." a. During an interview on June 4, 2024 at 9:50 AM, Staff B stated all stains and reagents were changed weekly and the alcohols were rotated. b. The Survey Team reviewed records titled CYTOLOGY PROCESSING STAIN LOG for January through May 2024. The records failed to detail which alcohols were rotated. 3. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
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 the HOLOGIC THINPREP 5000 PROCESSOR OPERATOR'S MANUAL, 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 5000 PROCESSOR OPERATOR'S MANUAL states: "Prepare a wash solution of sufficient volume to add 30 mL to every ThinPrep Pap test specimen being reprocessed. The wash solution is made by mixing 9 parts CytoLyt Solution with 1 part glacial acetic acid." "Pellet the contents of the centrifuge tube by centrifugation at 12 x g for 5 minutes." "Pour 30 ml of the CytoLyt Solution and 10% glacial acetic acid mixture into the centrifuge tube and cap securely." "Pellet the cells again by centrifugation - 1200 x g for 5 minutes." 2. The laboratory procedure PROCESSING BLOODY SPECIMENS stated: "Add 5 ml of glacial acetic acid into the centrifuge tube." "Centrifuge the specimen at 400 rpm for 10 min." a. The laboratory procedure failed to follow the manufacturer's instructions for reprocessing Hologic ThinPrep Pap Tests. 3. During an interview on June 4, 2024 at 9: 30 AM, Staff A stated that 30 ml of StatLab Glacial Acetic Acid was added to the cell pellet and was centrifuged at 800 revolutions per minute (rpm) for 10 minutes. 4. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the

	CEO. B. Based on review of the HOLOGIC THINPREP STAIN USER'S MANUAL and interviews the laboratory failed to establish and follow manufacturer's instructions for staining Hologic ThinPrep Pap Tests for imaging on the Hologic ThinPrep Imaging System. Findings include: 1. The HOLOGIC THINPREP STAIN USER'S MANUAL states: "Change all solutions when the number of slides equals 1 slide for every 1ml of bath volume, or once a week, which ever comes first. (For example if your bath volume is 650 ml, then change the bath after 650 slides, or once a week, which ever comes first.)" 2. During an interview on June 4, 2024 at 9:30 AM, Staff A stated the laboratory failed to monitor the number of Hologic ThinPrep Pap Test slides that were stained to determine when the solutions needed to be changed. Staff A further stated that the solutions were changed once per week. 3. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO. C. Based on review of the HOLOGIC THINPREP 5000 PROCESSOR OPERATOR'S MANUAL, laboratory policies and procedures and interviews the laboratory failed to follow manufacturer's instructions for processing nongynecologic cytology specimens using the Hologic ThinPrep 5000 Processor. Findings include: 1. The HOLOGIC THINPREP 5000 PROCESSOR OPERATOR'S MANUAL states: "Required Materials - Non-Gyn ThinPrep Filters (blue)" "Specimens must be centrifuged and washed in CytoLyt Solution and transferred to PreservCyt Solution prior to being processed on the ThinPrep 5000 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 NON GYN PROCESSING failed to include the required CytoLyt Solution Wash step and stated: "Run specimen on T5000 (use program "Urocyte" with yellow filter)." 3. During an interview on June 4, 2024 at 9:50 AM, Staff B described nongynecologic processing: Fluid specimens were centrifuged, supernatant decanted and 20 mL's of Becton Dickinson (BD) CytoRich Red was added to the cell pellet and resuspended. The specimen was centrifuged again, supernatant decanted and the cell pellet add to a Hologic PreservCyt Solution Vial. The vial was processed on the Hologic ThinPrep 5000 Processor using a yellow membrane filter (manufacturer - StatLab) using the Non-Gyn Sample Processing Sequence. a. The laboratory procedure failed to follow the manufacturer's instructions for processing nongynecologic cytology specimens using the Hologic ThinPrep 5000 Processor. 4. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
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: Based on review of the HOLOGIC THINPREP 5000 SYSTEM OPERATOR'S MANUAL, laboratory policies and procedures 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 gynecologic and nongynecologic 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. Refer to D5411
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 5000 OPERATOR'S MANUAL, laboratory records and interview the laboratory failed to ensure the required maintenance for five of five Hologic ThinPrep 5000 Processors was performed, as specified by the manufacturer, from March 2024 through May 2024. Findings include: 1. The HOLOGIC THINPREP 5000 OPERATOR'S MANUAL states the following maintenance is to be performed: -Change fixative reagent every 100 slides or daily, whichever comes first - Daily -Clean around the carousel, dispersion area and filter puncture/disposal area - Weekly -Clean slide holder pneumatic suction cups - Weekly 2. The Survey Team reviewed maintenance records titled CP 18 FORM A THINPREP 5000 PROCESSOR MAINTENANCE from March 2024 through May 2024 for the five Hologic ThinPrep 5000 Processors. a. The records failed to document the required daily and weekly maintenance was performed as required for the Hologic ThinPrep T5000 Processor - Serial #91109F16D0 on the following dates: Daily maintenance: -March 2024: 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 18, 19, 20, 21, 25 -April 2024: 1, 2, 3, 4, 5, 8, 10, 11, 12, 15, 16, 18, 19, 22, 23, 24, 25, 26, 29, 30 -May 2024: 1, 2, 3, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 20, 21, 22, 23, 24 Weekly maintenance: -Weeks of March 11, 18, 25 -Weeks of April 8, 15, 22 -Weeks of May 6, 13, 20, 28 b. The records failed to document the required daily and weekly maintenance was performed as required for the Hologic ThinPrep T5000 Processor - Serial #91107F16D0 on the following dates: Daily maintenance: -March 2024: 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 18, 19, 20, 21, 25 -April 2024: 1, 2, 3, 4, 5, 8, 10, 11, 12, 15, 16, 18, 19, 22, 23, 24, 25, 26, 29, 30 -May 2024: 1, 2, 3, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 20, 21, 22, 23, 24 Weekly maintenance: -Weeks of March 11, 18, 25 -Weeks of April 8, 15, 22 -Weeks of May 6, 13, 20, 28 c. The records failed to document the required daily and weekly maintenance was performed as required for the Hologic ThinPrep T5000 Processor - Serial #91104F16D0 on the following dates: Daily

	maintenance: -March 2024: 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 18, 19, 20, 21, 25 -April 2024: 1, 2, 3, 4, 5, 8, 10, 11, 12, 15, 16, 18, 19, 22, 23, 24, 25, 26, 29, 30 -May 2024: 1, 2, 3, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 20, 21, 22, 23, 24 Weekly maintenance: -Weeks of March 11, 18, 25 -Weeks of April 8, 15, 22 -Weeks of May 6, 13, 20, 28 d. The records failed to document the required daily and weekly maintenance was performed as required for the Hologic ThinPrep T5000 Processor - Serial #91110F16D0 on the following dates: Daily maintenance: -March 2024: 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 18, 19, 20, 21, 25 -April 2024: 1, 2, 3, 4, 5, 8, 10, 11, 12, 15, 16, 18, 19, 22, 23, 24, 25, 26, 29, 30 -May 2024: 1, 2, 3, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 20, 21, 22, 23, 24 Weekly maintenance: -Weeks of March 11, 18, 25 -Weeks of April 8, 15, 22 -Weeks of May 6, 13, 20, 28 e. The records failed to document the required daily and weekly maintenance was performed as required for the Hologic ThinPrep T5000 Processor - Serial #91105F16D0 on the following dates: Daily maintenance: -March 2024: 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 18, 19, 20, 21, 25 -April 2024: 1, 2, 3, 4, 5, 8, 10, 11, 12, 15, 16, 18, 19, 22, 23, 24, 25, 26, 29, 30 -May 2024: 1, 2, 3, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 20, 21, 22, 23, 24 Weekly maintenance: -Weeks of March 11, 18, 25 -Weeks of April 8, 15, 22 -Weeks of May 6, 13, 20, 28 3. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
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 Papanicolaou and Diff-Quick stains used to stain nongynecologic cytology slide preparations for each day of use from 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 Papanicolaou stain used to stain nongynecologic cytology slides for each day of use from January 1, 2024 to the date of the survey in 2024. 2. 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 from January 1, 2024 to the date of the survey in 2024. 3. The Survey Team reviewed records titled CYTOLOGY PROCESSING STAIN LOG. The records failed to specify which staining materials were being assessed for each day of use from January 1, 2024 to the date of the survey in 2024. 4. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
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 correlation records, gynecologic cytology slide preparations and interview the laboratory failed to follow written policies and procedures for a program to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. The laboratory failed to identify one of five cases from May 2023 through December 2023 as having a more significant lesion. Findings include: 1. The laboratory failed to follow the procedure GYNECOLOGIC SPECIMEN CORRELATION, which stated: "Negative Paps with a high grade or malignant tissue will be identified as part of the quality assurance program. The tissue report will be audited for inclusion of a review statement on any high grade or cancer biopsy with a negative Pap. If no review statement is evident, the Pap will be pulled for review. The negative Pap slides will be reviewed by the Cytotechnologist Manager or QC tech. If the CT manager disagrees with the negative Pap diagnosis, the Pap and corresponding tissue slides will be forwarded to the Cytopathology Technical Supervisor for review." 2. The Survey Team reviewed records titled GYN CYTOLOGY - HISTOLOGY CORRELATION LOG and the corresponding gynecologic cytology slide preparations from May 2023 through December 2023. a. The Survey Team reviewed five cases and identified one of five cases as having a more significant lesion than reported by the laboratory. Case includes: -C133885-23 b. On June 5, 2024, Technical Supervisor A reviewed the case and confirmed these findings. 3. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
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 interview 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. 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. The procedure HIERARCHICAL REVIEW OF GYNECOLOGIC SPECIMENS failed to describe the step-by-step process of how the search of current HSIL and malignant specimens was performed and documented. 2. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
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: A. Based on review of laboratory policies and procedures and interview the laboratory failed to establish and follow written policies and procedures for an annual statistical evaluation of three of six required gynecologic laboratory statistics. 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 a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasm. 2. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO. B. Based on review of laboratory policies and procedures, laboratory statistical records and interview the laboratory failed to follow written policies and procedures for an annual evaluation and comparison of one of three nongynecologic cytology statistics. The laboratory failed to document one of three required annual nongynecologic statistics for 2022 and 2023. Findings include: 1. The laboratory failed to follow the procedure STATISTICAL REPORTING POLICY, which stated: "Statistical records will be maintained monthly and evaluated annually. The statistical records will be maintained separately for gynecologic, non-gynecologic and fine needle aspiration cases." "Statistical records for non-gynecologic and fine needle aspiration cases will include the number of monthly cases and the number of reported cases by diagnostic category to include the number of unsatisfactory cases." 2. The Survey Team requested and the laboratory failed to provide records of an evaluation of one of three required annual nongynecologic statistics for 2022 and 2023. Statistic includes: -Number of patient cases reported by diagnosis (including the number

	reported as unsatisfactory for diagnostic interpretation) 3. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload limit records and interviews the laboratory failed to establish and follow written policies and procedures to establish an individual maximum workload limit for each Technical Supervisor who performed primary screening of nongynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor would establish maximum workload limits for each Technical Supervisor who performed primary screening of nongynecologic cytology specimens. Refer to D6130
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures to reassess and adjust when necessary, a maximum workload limit at least every six months for the Technical Supervisors when performing primary screening of nongynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor would reassess a maximum workload limit for the Technical Supervisors at least every six months and adjust when necessary. 2. During an interview on June 4, 2024 at 2:15 PM, the Quality Manager stated the Technical Supervisors began performing primary screening of nongynecologic cytology specimens "about two months ago." 3. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be

examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

This STANDARD is not met as evidenced by:
A. Based on review of laboratory policies and procedures, laboratory records and interview the laboratory failed to follow written policies and procedures to ensure the prorated workload limits for one of five Cytotechnologists would not be exceeded when examining slides in less than eight hours. Findings include: 1. The laboratory failed to follow the procedure WORKLOAD SURVEILLANCE POLICY, which stated: "Workload limits will be set for individuals examining slides on other than an 8-hour workday basis. This includes full-time employees with duties other than slides examination and part-time employees. The number of slides that may be examined will be prorated by allowing no more than an average of 12.5 slides per available slide examination hour." 2. The Survey Team reviewed laboratory records titled CYTOTECHNOLOGIST DAILY TALLY from February 2024 through March 2024 for Cytotechnologist A. a. Cytotechnologist A (maximum workload limit - 7.5 slides per hour) exceeded the prorated workload limit on 32 of 47 days that slides were examined. Dates include: Date: 2/1/24 TIME SCREENING: 7.5 hours SLIDES EXAMINED: 68 PRORATED SLIDES ALLOWED: 60 Date: 2/2/24 TIME SCREENING: 8.0 hours SLIDES EXAMINED: 100 PRORATED SLIDES ALLOWED: 64 Date: 2/5/24 TIME SCREENING: 6.0 hours SLIDES EXAMINED: 60 PRORATED SLIDES ALLOWED: 48 Date: 2/6/24 TIME SCREENING: 6.5 hours SLIDES EXAMINED: 70 PRORATED SLIDES ALLOWED: 52 Date: 2/12/24 TIME SCREENING: 5.0 hours SLIDES EXAMINED: 60 PRORATED SLIDES ALLOWED: 40 Date: 2/13/24 TIME SCREENING: 1.98 hours SLIDES EXAMINED: 26 PRORATED SLIDES ALLOWED: 15 Date: 2/14/24 TIME SCREENING: 3.57 hours SLIDES EXAMINED: 46 PRORATED SLIDES ALLOWED: 28 Date: 2/15/24 TIME SCREENING: 8.0 hours SLIDES EXAMINED: 71 PRORATED SLIDES ALLOWED: 64 Date: 2/16/24 TIME SCREENING: 7.77 hours SLIDES EXAMINED: 89 PRORATED SLIDES ALLOWED: 62 Date: 2/20/24 TIME SCREENING: 8.0 hours SLIDES EXAMINED: 76.5 PRORATED SLIDES ALLOWED: 64 Date: 2/21/24 TIME SCREENING: 8.0 hours SLIDES EXAMINED: 100 PRORATED SLIDES ALLOWED: 64 Date: 2/22/24 TIME SCREENING: 6.14 hours SLIDES EXAMINED: 66 PRORATED SLIDES ALLOWED: 49 Date: 2/23/24 TIME SCREENING: 5.0 hours SLIDES EXAMINED: 55 PRORATED SLIDES ALLOWED: 40 Date: 2/26/24 TIME SCREENING: 1.58 hours SLIDES EXAMINED: 19 PRORATED SLIDES ALLOWED: 12 Date: 2/28/24 TIME SCREENING: 4.12 hours SLIDES EXAMINED: 42 PRORATED SLIDES ALLOWED: 32 Date: 2/29/24 TIME SCREENING: 8.0 hours SLIDES EXAMINED: 100 PRORATED SLIDES ALLOWED: 64 Date: 3/1/24 TIME SCREENING: 7.5 hours SLIDES EXAMINED: 70.5 PRORATED SLIDES ALLOWED: 60 Date: 3/5 /24 TIME SCREENING: 7.5 hours SLIDES EXAMINED: 84 PRORATED SLIDES ALLOWED: 60 Date: 3/6/24 TIME SCREENING: 6.0 hours SLIDES EXAMINED: 63 PRORATED SLIDES ALLOWED: 48 Date: 3/7/24 TIME SCREENING: 3.9 hours SLIDES EXAMINED: 43 PRORATED SLIDES ALLOWED: 31 Date: 3/8/24 TIME SCREENING: 3.09 hours SLIDES EXAMINED: 31 PRORATED SLIDES ALLOWED: 24 Date: 3/13/24 TIME SCREENING: 5.0 hours SLIDES EXAMINED: 45 PRORATED SLIDES ALLOWED: 40 Date: 3/14/24 TIME SCREENING: 6.5 hours SLIDES EXAMINED: 70 PRORATED SLIDES ALLOWED: 52 Date: 3/15/24 TIME SCREENING: 2.68 hours SLIDES EXAMINED: 28 PRORATED SLIDES ALLOWED: 21 Date: 3/18/24 TIME SCREENING: 2.75 hours SLIDES EXAMINED: 32 PRORATED SLIDES ALLOWED: 22 Date: 3/20/24 TIME

	SCREENING: 4.75 hours SLIDES EXAMINED: 83 PRORATED SLIDES ALLOWED: 38 Date: 3/21/24 TIME SCREENING: 4.75 hours SLIDES EXAMINED: 47 PRORATED SLIDES ALLOWED: 38 Date: 3/22/24 TIME SCREENING: 2.97 hours SLIDES EXAMINED: 35.5 PRORATED SLIDES ALLOWED: 23 Date: 3/25/24 TIME SCREENING: 4.25 hours SLIDES EXAMINED: 54.5 PRORATED SLIDES ALLOWED: 34 Date: 3/26/24 TIME SCREENING: 3.5 hours SLIDES EXAMINED: 43 PRORATED SLIDES ALLOWED: 28 Date: 3/27/24 TIME SCREENING: 4.0 hours SLIDES EXAMINED: 45 PRORATED SLIDES ALLOWED: 32 Date: 3/28/24 TIME SCREENING: 5.0 hours SLIDES EXAMINED: 48 PRORATED SLIDES ALLOWED: 40 3. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO. B. Based on review of laboratory policies and procedures, lack of workload records and interview the laboratory failed to establish and follow written policies and procedures to ensure workload limits for the Technical Supervisors would be prorated when examining slides in less than an eight-hour work day. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate workload limits for the Technical Supervisors when examining slides in less than an eight-hour day, or with duties other than examining cytology specimen slides. 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor established an individual maximum workload limit for two of two Technical Supervisors. Refer to D6130 3 The Survey Team requested and the laboratory failed to provide documentation of the total number of slides examined in each 24-hour period and the number of hours examining slides per 24-hour period for two of two Technical Supervisors from April 1, 2024 to the date of the survey in 2024. Refer to D6133 4 During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload records and interviews the laboratory failed to establish and follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined by each Technical Supervisor per 24-hour period and the number of hours Technical Supervisors spent examining slides per 24-hour period. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the laboratory maintained records of the total number of slides examined by each Technical Supervisor per 24-hour period and the number of hours Technical Supervisors spent examining slides per 24-hour period. 2. The Survey Team requested and the laboratory failed to provide records of the total number of slides examined in each 24-hour period and the number of hours examining slides per 24-hour period for two of two Technical Supervisors from April 1, 2024 to the date of the survey in 2024. Refer to D6133

D5647	CYTOLOGY CFR(s): 493.1274(d)(4) (d) Workload limits.The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload limit records and interviews the laboratory failed to establish and follow written policies and procedures to ensure records were available to document the workload limit for two of two Technical Supervisors who performed primary screening of nongynecologic cytology specimens from April 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 ensure records were available to document the workload limit for the Technical Supervisors who performed primary screening of nongynecologic cytology specimens. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for two of two Technical Supervisors who performed primary screening of nongynecologic cytology specimens from April 1, 2024 to the date of the survey in 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor E 3. During an interview on June 4, 2024 at 2:15 PM, the Quality Manager stated the Technical Supervisors began performing primary screening of nongynecologic cytology specimens "about two months ago." 4. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
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 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 five of five Hologic ThinPrep 5000 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 Papanicolaou and Diff-Quick stains 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 annual statistical evaluation of the required laboratory statistics. Refer to D5629 d. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate workload records to ensure prorated workload limits would not be exceeded when examining slides in less than eight hours. Refer to D5641 3. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
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 5000 PROCESSOR OPERATOR'S MANUAL, laboratory certification records and interview the Laboratory Director failed to ensure five of nine Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests had received the required morphology certification prior to reporting patient specimens in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The HOLOGIC THINPREP 5000 PROCESSOR OPERATOR'S MANUAL states: "Evaluation of microscope slides produced with the ThinPrep 5000 processor should be performed only by cytotechnologists and pathologists who have been trained to evaluate ThinPrep-prepared slides by Hologic or by organizations or individuals designated by Hologic." 2. The Laboratory Director failed to ensure five of nine Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests received the required morphology certification prior to reporting test results. Technical Supervisors include: -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F 3. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 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 Technical Supervisor who meets the qualification requirements of 493.1451 of this subpart. The Technical Supervisor

	failed to establish performance characteristics, including the precision and accuracy of each test and test system, when the laboratory modified manufacturer's instructions with an alternate method of processing specimens (refer to D6115); failed to establish a workload limit for two of two Technical Supervisors (refer to D6130); and failed to ensure two of two Technical Supervisors documented the number of slides screened and the hours devoted to screening slides during each 24-hour period (refer to D6133).
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 laboratory procedures, laboratory records and interviews the Technical Supervisor failed to establish performance characteristics, including the precision and accuracy of each test and test system, when the laboratory modified Hologic's manufacturer's instructions with an alternate method of processing gynecologic and nongynecologic specimens. Findings include: 1. The Technical Supervisor failed to establish performance characteristics, including the precision and accuracy of each test and test system, when the laboratory modified Hologic's manufacturer's instructions with an alternate method of processing gynecologic and nongynecologic specimens. Refer to D5411 and D5423
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on the lack of workload limit records and interviews the Technical Supervisor failed to establish a maximum workload limit for two of two Technical Supervisors from April 1, 2024 to the date of the survey in 2024. Findings include: 1. The Technical Supervisor failed to provide documentation the Technical Supervisor established an individual maximum workload limit for two of two Technical Supervisors who performed primary screening of nongynecologic cytology specimens from April 1, 2024 to the date of the survey in 2024. Technical Supervisors include: - Technical Supervisor A -Technical Supervisor E 2. During an interview on June 4, 2024 at 2:15 PM, the Quality Manager stated the Technical Supervisors began performing primary screening of nongynecologic cytology specimens "about two months ago." 3. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
D6133	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6)

	In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides. This STANDARD is not met as evidenced by: Based on the lack of laboratory workload records and interviews two of two Technical Supervisors failed to document the number of slides evaluated and the number of hours devoted to screening during each 24-hour period from April 1, 2024 to the date of the survey in 2024. Findings include: 1. Two of two Technical Supervisors failed to document the total number of slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides from April 1, 2024 to the date of the survey in 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor E 2. During an interview on June 4, 2024 at 2:15 PM, the Quality Manager stated the Technical Supervisors began performing primary screening of nongynecologic cytology specimens "about two months ago." 3. During an interview on June 5, 2024 at 10:20 AM, these findings were confirmed with Technical Supervisor A, the Cytology Manager, Quality Manager, Staff A and the CEO.
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.