Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0699525	01/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Danner Laboratory	5230 Carroll Canyon Rd, Ste 114, San Diego, CA	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A focus survey was completed on December 16, 2022. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: Cytology- 42 CFR 493.1221 Laboratory Director- 42 CFR 493.1441 Technical Supervisor- 42 CFR 493.1447
D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to establish written policies and procedures for nine laboratory test processes (refer to D5403); failed to ensure that written procedures were approved, signed and dated by the Laboratory Director prior to use (refer to D5407); failed to follow manufacturer's instructions for the Becton Dickinson (BD) SurePath Pap Test and Hologic ThinPrep test system (refer to D5411); failed to establish performance specifications when the laboratory modified the Hologic ThinPrep test system manufacturer's instructions (refer to D5423); failed to ensure that the required maintenance for the Hologic ThinPrep 2000 Processors was performed, as specified by the manufacturer (refer to D5429); failed to test staining materials for intended reactivity of the Papanicolaou stain (refer to D5473); failed to follow written policies and procedures for an annual statistical evaluation of the required laboratory statistics (refer to D5629); failed to establish written policies and procedures for the establishment and reassessment of individual workload limits (refer to D5633 and D5637); 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); failed to establish written policies and procedures to document workload limits (refer to D5647); failed to establish written policies and procedures to ensure all nongynecologic preparations were reviewed by a Technical Supervisor and the report signed to reflect technical supervisory review (refer to D5653); failed to establish written policies and procedures to ensure unsatisfactory gynecologic patient specimens were identified and reported as unsatisfactory, and failed to identify and report four of four gynecologic tests as Unsatisfactory (refer to D5655); and failed to establish written policies and procedures to ensure corrected test reports indicated the basis for the correction on the test report (refer to D5659).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview the laboratory failed to establish written policies and procedures to assess the diagnostic competency of the Laboratory Director/Technical Supervisor. The laboratory failed to assess the diagnostic competency of one of one Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to assess the diagnostic competency of the Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide documentation that assessed the diagnostic competency of one of one Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on December 13, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Cytotechnologist A and Staff A.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the general laboratory phases of cytology testing to include assessing the diagnostic competency of the Laboratory Director/Technical Supervisor. Cross refer to D5209 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory phases of testing to include assessing the diagnostic competency of the Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide documentation of general

	laboratory quality assessment activities during 2020, 2021 and to the date of the survey in 2022. a. The laboratory failed to document a system for monitoring and evaluating the diagnostic competency of the Laboratory Director/Technical Supervisor. (See D5209)
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 68 laboratory policies and procedures, laboratory records and interview the laboratory failed to follow one written policy and procedure. Findings include: 1. The laboratory failed to follow the procedure BURLINGTON AUTOMATED GYN STAINING PROCEDURE, which stated: "Change the reagents and stains according to schedule. Wash the staining dishes after completing 650 slides." a. The Survey Team reviewed records titled THINPREP STAIN MAINTENANCE for January through the date of the survey in 2022. The records were used to document the number of slides stained and when the stains and solutions were changed. The laboratory exceeded the number of slides that were allowed to be stained prior to changing the stains and solutions on 16 dates. Dates include: -01/31 /22 (745 slides stained) -02/09/22 (675 slides stained) -02/24/22 (664 slides stained) -03/04/22 (692 slides stained) -03/11/22 (669 slides stained) -03/21/22 (711 slides stained) -03/29/22 (678 slides stained) -04/06/22 (678 slides stained) -04/15/22 (704 slides stained) -04/25/22 (689 slides stained) -05/03/22 (662 slides stained) -06/07/22 (685 slides stained) -07/12/22 (686 slides stained) -08/31/22 (667 slides stained) -09 /12/22 (699 slides stained) -10/07/22 (677 slides stained) 2. During an interview on December 13, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Cytotechnologist A and Staff 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 68 laboratory policies and procedures, laboratory records and interviews the laboratory failed to establish written policies and procedures for nine laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for documenting the nongynecologic stain quality assessment. a. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the Papanicolaou stain used to stain nongynecologic cytology slides was assessed each day of use in 2020, 2021 and to the date of the survey in 2022. b. During an interview on November 2, 2022 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for documenting the BD SurePath Pap Test stain quality assessment. a. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the Papanicolaou stain used to stain BD SurePath cytology slides was assessed each day of use in 2020, 2021 and to the date of the survey in 2022. b. During an interview on December 13, 2022 at 2: 00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Cytotechnologist A and Staff A. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for accessioning gynecologic specimens into the laboratory information system (LIS) system. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for receiving and accessioning nongynecologic specimens into the LIS system. 5. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for processing BD SurePath Pap Test specimens. 6. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for processing nongynecologic specimens. 7. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for reporting final nongynecologic test results. 8. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for coverslipping cytology specimen slides on the Leica CV5030 automatic coverslipper. 9. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for sending and receiving cytology specimens for external consultation. 10. During an interview on December 15, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Laboratory Manager and Staff A.
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 68 laboratory policies and procedures and interview the laboratory failed to ensure that 68 of 68 written procedures were approved, signed and dated by

the Laboratory Director prior to use. Findings include: 1. The Laboratory Director failed to sign and date 43 of 43 laboratory procedures in a binder titled LABORATORY PROCEDURES prior to use. Procedures include: -STANDARD ACCEPTABLE ABBREVIATIONS -JOB DESCRIPTIONS -EQUIPMENT MAINTANCE -SPECIMEN COLLECTION AND SUBMISSION PROCEDURE REQUIREMENTS PAP TEST -PROFICIENCY AND COMPETENCY TESTING -RECORD AND SLIDE RETENTION -SPECIMEN RECEIPT AND REJECTION -PROCEDURES FOR SPECIMEN ACCESSIONING -COMPETENCY ASSESSMENT -PAP SMEAR PROCESSING PROCEDURE -SUREPATH SLIDE PREPARATION AND STAINING -MATURATION INDEX -PAPANICOLAOU STAINING METHOD -COVERSLIPPING -RESTAINING SLIDES -BROKEN SLIDES -PAP SMEAR REPORTING -SIGNING OF THE REPORTS -CYTOLOGY PERSONNEL REQUIREMENTS -CYTOPATHOLOGY QUALITY CONTROL POLICY -QUALITY ASSURANCE -GENERAL RULES AND REGULATIONS -PROCEDURES FOR SLIDE EXAMINATION/SCREENING -CYTOLOGY SCREENING QUALITY CONTROL -PROCEDURE FOR DAILY EVALUATION OF PAPANICOLAOU STAIN QUALITY -PREVIOUS NEGATIVE CASE REVIEW -PREVIOUS CASE REVIEW WITH HSIL OR HIGHER DIAGNOSIS -ANNUAL STATISTICAL EVALUATION POLICY -TURN AROUND TIME FOR THE REPORTING OF RESULTS -CORRELATION OF ABNORMAL CYTOLOGY WITH HISTOPATHOLOGY -PROBLEM IDENTIFICATION AND SOLUTION -CORRECTION OF REPORT FORM -CYTOTECHNOLOGIST PERFORMANCE REVIEW PROCEDURE -WORKLOAD SURVEILLANCE POLICY -SPECIMEN COLLECTION AND SUBMISSION PROCEDURE REQUIREMENTS ANAL PAP TEST -COMPLIANCE PROGRAM FOR FEDERAL HEALTH PROGRAMS -INSTRUCTIONS FOR ANCILLARY TESTING FROM LIQUID BASED PAP VIALS -LABORATORY QUALITY ASSURANCE POLICY -PATIENT TEST MANAGEMENT ASSESSMENT -QUALITY CONTROL ASSESSMENT -PERSONNEL EVALUATION -COMMUNICATION SYSTEMS REVIEW -DIFF QUICK STAIN 2. The Laboratory Director failed to sign and date 25 of 25 laboratory procedures in a binder titled CYTOLOGY NON-GYN prior to use. Procedures include: -CYTOLOGY SPECIMEN COLLECTION REQUIREMENTS -NONNGYN CYTOLOGY SPECIMENS AND HANDLING URINE CYTOLOGY -PARIS URINARY CODES -PREPARATION OF BODY FLUID SPECIMENS USING THE THINPREP PROCESSOR -FINE NEEDLE ASPIRATION (FNA) CYTOLOGY COLLECTION GUIDE -NONNGYN CYTOLOGY SPECIMENS AND HANDLING FINE NEEDLE ASPIRATIONS -THYROID FINE NEEDLE ASPIRATE DIAGNOSIS CATEGORIES -THYROID FNA ADEQUACY CRITERIA -SPECIMEN RECEIPT AND REJECTION -CYTOLOGY NON-GYN SPECIMEN PROCESSING -STAINING METHODS UTILIZED BY LABORATORY DIFF-QUICK STAINING PROCEDURE -STAINING NON-GYN BY HAND STAIN PROTOCOL -BURLINGTON AUTOMATED GYN STAINING PROCEDURE -BURLINGTON AUTOMATED GYN STAINING PROCEDURE (IMAGE GUIDED) -THINPREP STAIN PROTOCOL AUTOMATED STAINING USING THE SAKURA TISSUE-TEK DRS 2000 -SUREPATH STAIN PROTOCOL AUTOMATED STAINING USING THE SAKURA TISSUE-TEK DRS 2000 -PAP STAIN PROTOCOL AUTOMATED STAINING USING THE SAKURA TISSUE-TEK DRS 2000 -DECOLORIZING OF STAINED MICROSLIDES (GYNECOLOGIC AND NON-GYNECOLOGIC) -PROCEDURES USED TO PREVENT CROSS CONTAMINATION -NON-GYN CORRELATION -TURN-AROUND TIME -RESCREEN OF NEGATIVE GYN SMEARS INCREASED RISK CASES QC POLICY -FORMALIN AND XYLENE MONITORING -DISPOSAL OF WASTE

	PRODUCTS -THE HANDLING OF INFECTIOUS SPECIMENS 3. During an interview on December 13, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Cytotechnologist A and Staff A.
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 records, interview with the Laboratory Director/Technical Supervisor and review of specimen slides the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the BD SurePath Pap Test in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The BD SUREPATH IMPLEMENTATION GUIDE states: "Training on the preparation and evaluation of BD SurePath test slides is a product labeling requirement." 2. The Survey Team requested and the laboratory failed to provide the required morphology certification for one of three Cytotechnologists who performed diagnostic interpretations of BD SurePath Pap Tests in 2020, 2021 and to the date of the survey in 2022. Cytotechnologist includes: - Cytotechnologist C a. During an interview on November 2, 2022 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor. 3. The Survey Team reviewed 29 BD SurePath Tests that Cytotechnologist C performed diagnostic interpretations on in October 2022. D22-26694 D22-26695 D22-26696 D22-26697 D22-26698 D22-26699 D22-26700 D22-26701 D22-26702 D22-26703 D22-26704 D22-26705 D22-26706 D22-26707 D22-26708 D22-26709 D22-26710 D22-26711 D22-26712 D22-26713 D22-26714 D22-26807 D22-26808 D22-26809 D22-26810 D22-26811 D22-26812 D22-26813 D22-26814 B. Based on review of the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL and interviews the laboratory failed to follow the manufacturer's instructions for processing nongynecologic cytology specimens using the Hologic ThinPrep 2000 Processor. Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM 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 2000 Processor." "Addition of CytoLyt Solution to cell pellets is required to wash the sample." "Concentrate by centrifugation - 600g for 10 minutes The purpose of this procedure is to concentrate the cellular material in order to separate the cellular component(s) from the supernatant. This step is performed with fresh samples and after the addition of CytoLyt Solution." "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. During an interview on December 13, 2022 at 2:45 PM, Staff A stated that fresh nongynecologic specimens were centrifuged, decanted and the cell pellet added to a Hologic ThinPrep PreservCyt vial. The Hologic ThinPrep 2000 Processor was then used to prepare a specimen slide. Staff A stated that the laboratory did not perform CytoLyt washes on specimens. a. The laboratory failed to follow the manufacturer's instructions when processing

	nongynecologic specimens. The laboratory failed to perform a CytoLyt wash on nongynecologic specimens during processing. 3. During an interview on December 15, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director /Technical Supervisor, Laboratory Manager and Staff A.
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 2000 SYSTEM OPERATOR'S MANUAL and interviews it was determined that 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 2000 SYSTEM 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 2000 Processor." "Addition of CytoLyt Solution to cell pellets is required to wash the sample." "Concentrate by centrifugation - 600g for 10 minutes The purpose of this procedure is to concentrate the cellular material in order to separate the cellular component(s) from the supernatant. This step is performed with fresh samples and after the addition of CytoLyt Solution." "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. During an interview on December 13, 2022 at 2:45 PM, Staff A stated that fresh nongynecologic specimens were centrifuged, decanted and the cell pellet added to a Hologic ThinPrep PreservCyt vial. The Hologic ThinPrep 2000 Processor was then used to prepare a specimen slide. Staff A stated that the laboratory did not perform CytoLyt washes on specimens. a. The laboratory failed to follow the manufacturer's instructions when processing nongynecologic specimens. The laboratory failed to perform a CytoLyt wash on nongynecologic specimens during processing. 4. During an interview on December 15, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director /Technical Supervisor, Laboratory Manager and Staff A.
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 laboratory records and interview the laboratory failed to ensure that the required maintenance for three of three Hologic ThinPrep 2000 Processors was performed, as specified by the manufacturer, in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide maintenance records for three of three Hologic ThinPrep 2000 Processors in 2020, 2021 and to the date of the survey in 2022. Hologic ThinPrep 2000 Processors include: -Serial #04074K06C0 -Serial #04594 -Serial #07565 2. During an interview on December 13, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Cytotechnologist A and Staff 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: A. Based on review of laboratory records and interview the laboratory failed to test staining materials for intended reactivity of the Papanicolaou stain used to stain nongynecologic cytology slides for each day of use in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the Papanicolaou stain used to stain nongynecologic cytology slides was assessed each day of use in 2020, 2021 and to the date of the survey in 2022. 2. During an interview on November 2, 2022 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor. B. Based on review of laboratory records and interview the laboratory failed to test staining materials for intended reactivity of the Papanicolaou stain used to stain BD SurePath cytology slides for each day of use in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the Papanicolaou stain used to stain BD SurePath cytology slides was assessed each day of use in 2020, 2021 and to the date of the survey in 2022. 2. During an interview on December 13, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Cytotechnologist A and Staff 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 and microscopic review of specimen slides the laboratory failed to follow written policies and procedures to review prior gynecologic cases and identify cases with a more significant lesion. The laboratory failed to identify two of 35 prior negative gynecologic cases from current HSIL's from January through August 2022, as having a more significant lesion than originally reported. Findings include: 1. The laboratory failed to follow the procedure PREVIOUS NEGATIVE CASE REVIEW which stated: "Each patient diagnosed with a current high grade intraepithelial lesion or a malignancy is listed on the work sheet entitled REVIEW OF PREVIOUS PAPS ON CURRENT HIGH GRADE PAPS. If previous Paps are available, the slides are pulled and reviewed". 2. The Survey Team reviewed records titled REVIEW OF PREVIOUS PAPS ON CURRENT HIGH GRADE PAPS. The Survey Team reviewed 35 previous negative gynecologic cases from 22 current cases of HSIL from January through August 2022. 3. The Survey Team identified and the Survey Team Pathologist confirmed on December 16, 2022 that the laboratory failed to identify two of 35 prior negative gynecologic cases as having a more significant lesion than was originally reported. Prior negative case includes: -D18-27866 -D19-0506
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, laboratory records and interviews the laboratory failed to follow written policies and procedures for an annual statistical evaluation of two of six required gynecologic laboratory statistics for 2020 and 2021. Findings include: 1. 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:" "The number of cases reported by diagnosis; i.e., NEG, ASCUS, ASC-H, AGUS, LSIL,

	HSIL, SIL, Malignant and Unsatisfactory." "The number of GYN cases where any rescreening of a negative specimen results in reclassification as ASCUS, LSIL, HSIL, or malignancy." 2. The Survey Team requested and the laboratory failed to provide two of six required annual gynecologic laboratory statistics. Statistics include: -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation; -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 neoplasms. 3. The Survey Team reviewed records titled CYTOLOGY SUMMARY REPORT LABORATORY SPECIMEN AND FOLLOW-UP STATISTICS for 2020 and 2021. a. During an interview on December 12, 2022 at 1:45 PM, Cytotechnologist A stated that Cytotechnologist A combined the gynecologic and nongynecologic diagnostic statistics together. 4. During an interview on December 13, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Cytotechnologist A and Staff A. B. Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to follow written policies and procedures for an annual statistical evaluation of two of three required nongynecologic laboratory statistics for 2020 and 2021. Findings include: 1. 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:" "The breakdown of Non-Gyn cases into specimen type; i.e. Breast, Urine, etc." "The number of cases reported by diagnosis" 2. The Survey Team requested and the laboratory failed to provide two of six required annual nongynecologic laboratory statistics. Statistics include: -The number of specimens processed by specimen type; -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation. 3. The Survey Team reviewed records titled CYTOLOGY SUMMARY REPORT LABORATORY SPECIMEN AND FOLLOW-UP STATISTICS for 2020 and 2021. a. During an interview on December 12, 2022 at 1:45 PM, Cytotechnologist A stated that Cytotechnologist A combined the gynecologic and nongynecologic diagnostic statistics together. 4. During an interview on December 13, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Cytotechnologist A and Staff A.
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 and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure maximum workload limits were established for the Laboratory Director/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 ensure the Technical Supervisor established maximum workload limits for the Laboratory Director/Technical Supervisor. 2. During an interview on November 2, 2022 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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 interview with the Laboratory Director/Technical Supervisor 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 Laboratory Director/Technical Supervisor. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how the Laboratory Director/Technical Supervisor's workload limit would be reassessed at least every six months and adjusted when necessary. 2. During an interview on November 2, 2022 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.
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: Based on review of laboratory policies and procedures, lack of laboratory records and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure that the workload limit for the Laboratory Director/Technical Supervisor would be prorated when examining slides in less than eight hours. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limits for the Laboratory Director/Technical Supervisor when examining slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for the Laboratory Director /Technical Supervisor when examining slides in less than eight hours. 3. During an interview on November 2, 2022 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.
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: A. Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure that the laboratory maintained records of the total number of nongynecologic slides examined and the total number of hours the Laboratory Director/Technical Supervisor spent examining nongynecologic slides per 24-hour period. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained records of the total number of slides examined and total number of hours the Laboratory Directory/Technical Supervisor spent examining slides. 2. During an interview on November 2, 2022 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor. B. Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to follow written policies and procedures to ensure that the laboratory maintained records of the total number of hours one of three Cytotechnologists spent examining slides per 24-hour period. Findings include: 1. The laboratory failed to follow the procedure WORKLOAD SURVEILLANCE POLICY, which stated: "Each cytotechnologist is required to keep a record of slides screened and the time spent screening in each 24 hour period. The time spent screening is to be recorded on the daily screening Q.C. sheet "Cytopathology Quality Control Worksheet."" 2. The Survey Team reviewed records titled CYTOPATHOLOGY QUALITY CONTROL WORKSHEET from January through September 2022 for Cytotechnologist B. The records failed to document the number of hours Cytotechnologist B spent examining slides. 3. During an interview on December 13, 2022 at 8:50 AM, Cytotechnologist B stated that Cytotechnologist B documented the work hours on the records but failed to document the time spent screening. 4. During an interview on December 13, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Cytotechnologist A and Staff A.
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 laboratory records and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for one of one Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. 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 Supervisor. 2. The Survey Team requested and the laboratory failed to provide records of an established maximum workload limit for the one of one Technical Supervisors. Technical Supervisors include: -Laboratory Director/Technical Supervisor 3. During an interview on November 2, 2022 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

D5653	CYTOLOGY CFR(s): 493.1274(e)(3) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(3) All nongynecologic preparations are reviewed by a technical supervisor. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review. 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 written policies and procedures to ensure all nongynecologic reports were signed to reflect technical supervisory review. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for reporting nongynecologic test results, to ensure reports are signed to reflect technical supervisory review. 2. During an interview on December 15, 2022 at 8:55 AM, Staff B described the process for reporting nongynecologic test results: -Staff C transcribed the Laboratory Director/Technical Supervisor's results into the LIS. -Staff B printed the report from LIS for the Laboratory Director/Technical Supervisor to review. -The Laboratory Director/Technical Supervisor used a rubber stamp to stamp the reports with the Laboratory Director/Technical Supervisor's signature. -The stamped reports were filed at an off-site storage facility. 3. The Survey Team reviewed 18 nongynecologic final test reports from September through October 2022. Eighteen of 18 final test reports were stamped with the Laboratory Director/Technical Supervisor's name. Reports include: -NG22-601 -NG22-602 -NG22-603 -NG22-605 -NG22-612 -NG22-613 -NG22-617 -NG22-624 -NG22-625 -NG22-626 -NG22-633 -NG22-636 -NG22-637 -NG22-642 -NG22-643 -NG22-645 -NG22-647 -NG22-648 4. During an interview on December 15, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Laboratory Manager and Staff A.
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, interview, review of final test reports and specimen slides the laboratory failed to establish written policies and procedures to ensure unsatisfactory gynecologic patient specimens were identified and reported as unsatisfactory. The laboratory failed to identify and report four of four gynecologic tests from October 2022 as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory gynecologic slide preparations were identified and reported as unsatisfactory for evaluation. a. The procedure PAP SMEAR REPORTING failed to describe the required cellularity for a satisfactory gynecologic slide preparation. b. During an interview on December 13, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor,

	Cytotechnologist A and Staff A. 2. The laboratory failed to identify and report four of four gynecologic tests from October 2022 as unsatisfactory. Tests include: -NG22-26189 -NG22-27548 -NG22-27549 -NG22-27795
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, laboratory records and interview the laboratory failed to establish written policies and procedures to ensure corrected test reports indicated the basis for the correction on the test report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected test reports indicated the basis for the correction on the test report. 2. During an interview on December 12, 2022 at 10:15 AM, Staff B provided a corrected report to the Survey Team. The corrected report failed to indicate that it was a corrected report and failed to state the basis for the correction. Report includes: -D22-27074 3. During an interview on December 13, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director /Technical Supervisor, Cytotechnologist A and Staff 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 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 2020, 2021 and to the date of the survey in 2022. Cross refer to D5411, D5423, D5429, D5473, D5629, D5655 and D5659 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 2020, 2021 and to the date of the survey in 2022. a. The laboratory failed to document a system for monitoring and evaluating the laboratory's adherence to manufacturer's instructions. (See D5411) b. The laboratory failed to document a system for monitoring and evaluating performance specifications when modifying the Hologic ThinPrep test system manufacturer's instructions with an alternate method of processing. (See D5423) c. The laboratory failed to document a system for monitoring and evaluating the required maintenance for three of three Hologic ThinPrep 2000 Processors was performed, as specified by the manufacturer. (See D5429) d. The

	laboratory failed to document a system for monitoring and evaluating the stain assessment for each day cytology slides were stained. (See D5473) e. The laboratory failed to document a system for monitoring and evaluating annual statistics. (See D5629) f. The laboratory failed to document a system for monitoring and evaluating unsatisfactory specimens to ensure unsatisfactory specimens were reported accurately. (See D5655) g. The laboratory failed to document a system for monitoring and evaluating the basis for correction on final test reports. (See D5659) 3. During an interview on December 15, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Laboratory Manager and Staff A.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of final test reports and interviews it was determined that one of 1729 final test reports from October 2022 failed to indicate the test result. Findings include: 1. The Survey Team reviewed 1729 final test reports from October 2022. One of 1729 final test reports failed to indicate the test result. Report includes: -D22-27074 2. During an interview on December 12, 2022 at 12:15 AM, Staff B stated that the final test report was reported without a test result in error. 3. During an interview on December 15, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Laboratory Manager and Staff A.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. 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 written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the postanalytic phases of cytology testing by monitoring the accuracy of final test reports. Cross refer to D5805 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic phases of testing by monitoring the accuracy of final test reports. 2. The Survey Team identified one final test report requiring technical supervisory review from October 2022 that failed to document that a Technical Supervisor reported the results of the case. The results were reported by a Cytotechnologist. Report includes: -D22-26350 a. During an interview on December

	14, 2022 at 10:05 AM, Staff C stated that the results were incorrectly transcribed into the LIS as ASCUS and the Technical Supervisor did not report the results. b. The Survey Team reviewed the record used by the laboratory to document the diagnosis for the case prior to transcription into the LIS. Cytotechnologist A and Cytotechnologist B reported the results of the case as Negative for Intraepithelial Lesion or Malignancy. c. The laboratory failed to identify the transcription error and failed to identify that a report requiring technical supervisory review did not indicate a review by a Technical Supervisor. 3. The Survey Team identified one final test report from October 2022 that failed to report a test result. (See D5805) 4. During an interview on December 15, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Laboratory Manager and Staff 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, specimen slides and interviews the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to ensure that quality control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur (refer to D6093); failed to ensure quality assessment programs were established to assure the quality of cytology services and identify failures in quality as they occur (refer to D6094); failed to ensure that one of three Cytotechnologists had received the appropriate morphology training prior to reporting BD SurePath Pap Test specimens (refer to D6102); and failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of the Laboratory Director /Technical Supervisor (refer to D6103).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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, specimen slides and interviews it was determined that the Laboratory Director failed to ensure that quality control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5473, D5625, D5629 and D5655 Findings include: 1. The Laboratory Director failed to provide records of an established quality control program and failed to identify failures in quality as they occur. 2. The Laboratory Director failed to provide records of an established quality control program and failed to identify failures in quality as they occurred in 2020, 2021 and to the date of the survey in 2022. a. The Laboratory Director failed to ensure quality

	control programs were established to test staining materials for intended reactivity of the Papanicolaou stain for each day of use. (See D5473) b. The Laboratory Director failed to ensure quality control programs were established to review prior gynecologic cases and identify cases with a more significant lesion. (See D5625) c. The Laboratory Director failed to ensure quality control programs were established for an annual statistical evaluation of the required laboratory statistics. (See D5629) d. The Laboratory Director failed to ensure quality control programs were established to ensure unsatisfactory gynecologic patient specimens were identified and reported as unsatisfactory. (See D5655)
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 occurred in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5291, D5791 and D5891 Findings include: 1. The Laboratory Director failed to ensure the establishment of written policies and procedures for a quality assessment program. 2. The Laboratory Director failed to provide records of an established quality assessment program and failed to identify failures in quality as they occurred in 2020, 2021 and to the date of the survey in 2022. a. The Laboratory Director failed to ensure quality assessment programs were established to monitor, assess and correct problems in the general laboratory phases of cytology testing. (See D5291). b. The Laboratory Director failed to ensure quality assessment programs were established to monitor, assess and correct problems identified in the analytic cytology systems. (See D5791) c. The Laboratory Director failed to ensure quality assessment programs were established to monitor, assess and correct problems in the postanalytic phases of cytology testing. (See D5891)
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: A. Based on review of manufacturer's instructions, laboratory records, specimen slides and interview the Laboratory Director failed to ensure that one of three Cytotechnologists who performed BD SurePath Pap Test evaluations had received the appropriate morphology training prior to reporting patient specimens in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Laboratory Director failed to ensure appropriate training for one of three Cytotechnologists to accurately

	report cytology test results prior to performing BD SurePath Pap Test evaluations. 2. The BD SUREPATH IMPLEMENTATION GUIDE states: "Training on the preparation and evaluation of BD SurePath test slides is a product labeling requirement." 3. The Laboratory Director failed to ensure one of three Cytotechnologists who provided diagnostic interpretations of BD SurePath Pap Tests had the required morphology certification. Cytotechnologist includes: - Cytotechnologist C a. During an interview on November 2, 2022 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor. 4. The Survey Team reviewed 29 BD SurePath Tests that Cytotechnologist C performed diagnostic interpretations on in October 2022. D22-26694 D22-26695 D22-26696 D22-26697 D22-26698 D22-26699 D22-26700 D22-26701 D22-26702 D22-26703 D22-26704 D22-26705 D22-26706 D22-26707 D22-26708 D22-26709 D22-26710 D22-26711 D22-26712 D22-26713 D22-26714 D22-26807 D22-26808 D22-26809 D22-26810 D22-26811 D22-26812 D22-26813 D22-26814 B. Based on review of the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL and interviews the Laboratory Director failed to ensure staff received appropriate training to follow manufacturer's instructions for processing nongynecologic cytology specimens using the Hologic ThinPrep 2000 Processor. Findings include: 1. The Laboratory Director failed to ensure staff received appropriate training to follow manufacturer's instructions for processing nongynecologic cytology specimens using the Hologic ThinPrep 2000 Processor. 2. The HOLOGIC THINPREP 2000 SYSTEM 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 2000 Processor." "Addition of CytoLyt Solution to cell pellets is required to wash the sample." "Concentrate by centrifugation - 600g for 10 minutes The purpose of this procedure is to concentrate the cellular material in order to separate the cellular component(s) from the supernatant. This step is performed with fresh samples and after the addition of CytoLyt Solution." "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. During an interview on December 13, 2022 at 2:45 PM, Staff A stated that fresh nongynecologic specimens were centrifuged, decanted and the cell pellet added to a Hologic ThinPrep PreservCyt vial. The Hologic ThinPrep 2000 Processor was then used to prepare a specimen slide. Staff A stated that the laboratory did not perform CytoLyt washes on specimens. a. The Laboratory Director failed to ensure manufacturer's instructions were followed when processing nongynecologic specimens. The laboratory failed to perform a CytoLyt wash on nongynecologic specimens during processing. 4. During an interview on December 15, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Laboratory Manager and Staff A.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, specimen slides and interview the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of personnel interpreting gynecologic cytology specimens. Cross refer to D5209 and D6115 Findings include: 1. The Laboratory Director failed to provide written policies and procedures to assess the competency of the Laboratory Director/Technical Supervisor, and when necessary identify methods to improve the skills of the Laboratory Director/Technical Supervisor. (See D5209) a. The Laboratory Director failed to ensure competency was assessed for the Laboratory Director/Technical Supervisor in 2020, 2021 and to the date of the survey in 2022. b. The Laboratory Director failed to ensure the need for remedial training or continuing education was identified to improve upon the diagnostic skills of one of one Technical Supervisors when evaluating gynecologic specimens. Technical Supervisors include: -Laboratory Director/Technical Supervisor 2. The Laboratory Director failed to ensure the need for remedial training or continuing education was identified to improve upon the diagnostic skills of three of three Cytotechnologists when evaluating gynecologic specimens. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B -Cytotechnologist C 3. The Survey Team reviewed 1558 negative gynecologic cytology cases from October 2022. a. The Survey Team Pathologist confirmed on December 16, 2022 diagnostic interpretation errors on 20 of 1558 cases. (See D6115) b. The laboratory failed to identify the need for remedial training or continuing education to improve upon the diagnostic skills to recognize and report the following entities: -High Grade Squamous Intraepithelial Lesion -Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion -Atypical Glandular Cells -Low Grade Squamous Intraepithelial Lesion -Unsatisfactory for Interpretation 5. During an interview on December 15, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Laboratory Manager and Staff A.
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 1558 negative gynecologic cytology cases/slides and corresponding final test reports, laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to have a Technical Supervisor who meets the qualification requirements of 493.1451 of this subpart. The Technical Supervisor failed to verify the accuracy of 20 gynecologic cytology tests (refer to D6115); failed to establish and reassess a workload limit for the Laboratory Director/Technical Supervisor (refer to D6130); and failed to document the number of 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 microscopic review of 1558 negative gynecologic cases/slides and the corresponding final test reports from October 2022 and confirmation by the Survey Team Pathologist on December 16, 2022 the Technical Supervisor failed to verify the accuracy of 20 gynecologic cytology tests. Findings include: 1. NG22-26532 10/14 /2022 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 2. NG22-27635 10/27 /2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 3. NG22-27829 10/28/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Squamous Intraepithelial Lesion 4. NG22-26717 10/18/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 5. NG22-26760 10/18/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 6. NG22-27579 10/26/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 7. NG22-27642 10/26/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Squamous Cells, cannot exclude High Grade Squamous Intraepithelial Lesion 8. NG22-27031 10 /21/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Glandular Cells 9. NG22-26240 10/11/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 10. NG22-26578 10/14 /2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 11. NG22-26733 10/18/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 12. NG22-27224 10/24/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 13. NG22-27343 10/25 /2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 14. NG22-27449 10/25/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 15. NG22-27453 10/25/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 16. NG22-27670 10/27 /2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous

	Intraepithelial Lesion 17. NG22-26189 10/12/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation. Insufficient Cellularity. 18. NG22-27548 10/26/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation. Insufficient Cellularity. 19. NG22-27549 10/26/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation. Insufficient Cellularity. 20. NG22-27795 10/28/2022 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation. Insufficient Cellularity.
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 laboratory records and interview with the Laboratory Director /Technical Supervisor the Technical Supervisor failed to establish a workload limit and failed to reassess workload limits at least every six months for the Laboratory Director/Technical Supervisor in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5633 and D5637. Findings include: 1. The Technical Supervisor failed to establish a maximum workload limit for the Laboratory Director/Technical Supervisor. (See D5633) 2. The Technical Supervisor failed to reassess workload limits at least every six months for the Laboratory Director/Technical Supervisor. (See D5637)
D6133	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6) In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides. This STANDARD is not met as evidenced by: Based on review of workload records and interview with the Laboratory Director /Technical Supervisor the Technical Supervisor failed to document the number of hours devoted to screening slides during each 24-hour period from June through October 2022. Findings include: 1. The Survey Team requested and the Technical Supervisor failed to provide records of the total number of hours the Laboratory Director/Technical Supervisor devoted to screening slides during each 24-hour period from June through October 2022. 2. During an interview on October 31, 2022 at 10:30 AM, the Laboratory Director/Technical Supervisor provided a record titled DAILY WORKLOAD which documented the number of slides screened by the Laboratory Director/Technical Supervisor from June through October 2022. When asked if there

	were records to document the number hours devoted to screening slides from June through October 2022, the Laboratory Director/Technical Supervisor replied "no". 3. During an interview on November 2, 2022 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.
D6167	CYTOTECHNOLOGIST RESPONSIBILITIES CFR(s): 493.1485(c) The cytotechnologist is responsible for documenting the number of hours spent examining slides in each 24-hour period. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews one of three Cytotechnologists failed to maintain records of the total number of hours spent examining slides per 24-hour period from January through September 2022. Findings include: 1. The Survey Team reviewed records titled CYTOPATHOLOGY QUALITY CONTROL WORKSHEET from January through September 2022 for Cytotechnologist B. The records failed to document the number of hours Cytotechnologist B spent examining slides. 2. During an interview on December 13, 2022 at 8:50 AM, Cytotechnologist B stated that Cytotechnologist B documented the work hours on the records but failed to document the time spent screening. 3. During an interview on December 13, 2022 at 2:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor, Cytotechnologist A and Staff A.
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.