Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0914812	03/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Primex Clinical Laboratories, Inc	16742 Stagg St, Ste 120, Van Nuys, CA	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the COLLEGE OF AMERICAN PATHOLOGISTS (CAP) gynecologic cytology proficiency test (PT) program instructions, gynecologic cytology PT participation records and interviews the laboratory failed to meet the specified requirements for the annual gynecologic cytology PT examination in 2024. The laboratory failed to administer the annual gynecologic cytology PT as required by the PT program's instructions in 2024 (refer to D2015).
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two

years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
Based on review of annual CAP gynecologic cytology PT program instructions, annual gynecologic cytology PT participation records and interviews the laboratory failed to administer and document the PT examination as required by the CAP PT laboratory proctor instructions in 2024. Findings include: 1. The laboratory failed to follow the COLLEGE OF AMERICAN PATHOLOGISTS PAP PT PROCTOR PACKET INSTRUCTIONS and PAP PT SLIDESET VERIFICATION AND ATTESTATION FORM instructions which stated: "Record each examinee's start time in the area located on the individual test form." "Record the examinee's end time and collect all test materials from them after 2 hours, whether or not he or she has completed the test." "I attest that the Gynecologic Cytology Proficiency Test was conducted in a confidential manner according to the instructions with no communication between individuals regarding challenge interpretation. The (above) slideset was kept in a secure location when not in use." a. During an interview on March 18, 2024 at 4:30 PM the Laboratory Manager/Proctor stated, "We don't have the PT test results yet because CAP said there was a problem with the times, but they have not contacted us again." b. The Survey Team reviewed records titled GYNECOLOGIC CYTOLOGY-PAP PT INDIVIDUAL RESULT FORM for 2024. Two of two Technical Supervisor's participated in the PT on the same SLIDESET #34403 at the same date and time in 2024. Examinees and record documentation includes: -Technical Supervisor A -Kit #38242513 Slideset #34403 Ten slides Test date: 02/05/2024 Start time: 03:00 PM Stop time: 04:30 PM -Technical Supervisor B -Kit #38242512 Slideset #34403 Ten slides Test date: 02/05/2024 Start time: 03:30 PM Stop time: 05:00 PM c. During an interview on March 18, 2024 at 4:30 PM the Survey Team asked the Laboratory Manager/Proctor if the COLLEGE OF AMERICAN PATHOLOGISTS GYNECOLOGIC CYTOLOGY PROFICIENCY TESTING PROGRAM KIT INSTRUCTIONS were followed. The Laboratory Manager/Proctor stated, "I am new and it was my first time proctoring so I didn't know they couldn't take the test at the same time." The Laboratory Manager/Proctor confirmed the two of two Technical Supervisors participated in the PT testing event during the same time, 3:30 PM-4:30 PM on 02/05/2024. 2. The laboratory failed to follow the COLLEGE OF AMERICAN PATHOLOGISTS PAP PT PROCTOR PACKET INSTRUCTIONS which stated: "Fax the result form immediately after the examinee is done. Do not wait until the end of the PAP PT event to fax the result form (s)." a. The Survey Team reviewed records titled GYNECOLOGIC CYTOLOGY-PAP PT INDIVIDUAL RESULTS FORM, PAP PT SLIDESET VERIFICATION AND ATTESTATION FORM and FAX TX REPORT for three examinees in 2024. Examinees and record documentation includes: -Technical Supervisor A Kit #38242513 Slideset #34403 Ten slides Test date: 02/05/2024 Start time: 03:00 PM Stop time: 04:30 PM Fax confirmation date and time: 02/06/2024 10:12 AM -Technical Supervisor B Kit #38242512 Slideset #34403 Ten slides Test date: 02/05/2024 Start time: 03:30 PM Stop time: 05:00 PM Fax confirmation date and time: 02/06/2024 10:12 AM -Cytotechnologist A Kit #38242514 Slideset #34403 Ten slides Test date: 02/05/2024 Start time: 10:30 AM Stop time: 12:00 PM Fax confirmation date and time: 02/06/2024 10:12 AM b. During an interview on March 19, 2024 at 3:45 PM the Laboratory Manager/Proctor confirmed the records titled GYNECOLOGIC CYTOLOGY PAP PT INDIVIDUAL RESULT FORM were not faxed immediately after the three of three examinee's completed the PT test.

D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to follow written policies and procedures to review prior gynecologic cases and identify cases with a more significant lesion (refer to D5625); failed to establish and follow written policies and procedures to reassess a maximum workload limit at least every six months for two of two Cytotechnologists (refer to D5637); failed to establish and follow written policies and procedures to ensure workload limits for the Cytotechnologists would be prorated when examining slides in less than an eight-hour work day (refer to D5641); failed to establish and follow written policies and procedures to ensure the laboratory maintained records of the total number of hours Cytotechnologists spent examining slides during each 24-hour period (refer to D5645); failed to establish and follow written policies and procedures to ensure records were available to document the workload limit for three of three Cytotechnologists (refer to D5647); failed to establish and follow written policies and procedures to ensure that final gynecologic and nongynecologic test reports signed by Technical Supervisors reflected a secure electronic signature authorized by the Technical Supervisor (refer to D5651 and D5653).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of competency assessment records and interview with the Laboratory Manager the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisors. The laboratory failed to assess the competency of two of two Technical Supervisors in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process for assessing the competency of the Technical Supervisors who performed cytology testing on gynecologic and nongynecologic patient specimens. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for the cytology duties performed by two of two Technical Supervisors in 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During an interview on March 19, 2024 at 11:30 AM the Laboratory Manager confirmed these findings.
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, morphology certification records and interview the laboratory failed to follow manufacturer's instructions for Technical Supervisors to evaluate gynecologic cytology specimens using the Hologic ThinPrep Pap Test (TPPT) in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The HOLOGIC THINPREP 5000 SYSTEM OPERATOR'S MANUAL states: "Evaluation of microscope slides produced with the THINPREP 5000 SYSTEM 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 Survey Team requested and the laboratory failed to provide the required morphology certification records for one of two Technical Supervisors. Technical Supervisor includes: -Technical Supervisor B 3. During an interview on March 20, 2024 at 2:00 PM Technical Supervisor B and the Laboratory Manager confirmed these findings. B. Based on review of manufacturer's instructions, morphology certification records and interview the laboratory failed to follow manufacturer's instructions for Technical Supervisors to evaluate gynecologic cytology specimens using the Becton Dickinson (BD) SurePath Pap Test in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. 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 records for two of two Technical Supervisors who performed diagnostic interpretations of BD SurePath Pap Tests in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During an interview on March 20, 2024 at 2:00 PM Technical Supervisor B and the Laboratory Manager confirmed these findings.
D5625	CYTOLOGY CFR(s): 493.1274(c)(3) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, microscopic review of specimen slides and interviews the laboratory failed to follow written policies and procedures to ensure the review of prior gynecologic cases received within the previous five years for each patient with a current diagnosis of HSIL or malignancy. The laboratory failed to identify five of 15 patients with current

	HSIL's in 2023 as having prior negative gynecologic cases. The laboratory failed to identify one of six prior negative cases as having a more significant lesion than originally reported. Findings include: 1. The laboratory failed to follow the procedure RETROSPECTIVE REVIEW which stated: "All cases diagnosed as HSIL, adenocarcinoma or malignant neoplasm are researched in the LIS for a prior negative /normal pap to be reviewed with the current case." "If the patient is known to have a prior "Negative/Reactive" diagnosis within the data base system, the slide and report are pulled with the current slide and report, documented on the "Retrospective Pap Review" (RPR) and given to a Cytotech qualified as a Cytology Supervisor under CLIA-88 and if possible someone other than the original screener and Pathologist for rescreening." "If the Cytotech and Pathologist agree with the original "Negative" diagnosis, discrepancy code (1) "No discrepancy" is documented on the RPR sheet. If discrepancy is found, (2) "Minor discrepancy or (3) Major discrepancy" is documented." 2. The Survey Team reviewed records titled QUALITY CONTROL RETROSPECTIVE RESCREEN REPORT. a. The most recent completed record from 2022 was dated 05-18-2022. The laboratory failed to provide records for the search and review of prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of HSIL or malignancy from May 19, 2022 through December 2022. b. The laboratory failed to provide records for the search and review of prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of HSIL or malignancy from January through December 2023. c. The laboratory failed to provide records for the search and review of prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of HSIL or malignancy from January 1, 2024 to the date of the survey in 2024. d. During an interview on March 19, 2024 at 9:00 AM Cytotechnologist A confirmed these findings. 3. The Survey Team randomly selected fifteen patients with a current diagnosis of HSIL or malignancy from June 2023 through December 2023. a. The laboratory failed to document the search for prior negative gynecologic cases received within the previous five years for each of the 15 HSIL patient cases. 2023 HSIL patient cases include: -10041009 -10052431 -10080884 -10090699 -10095862 -10094678 -10104213 -10112365 -10131266 -10159855 -10166891 -10182827 -10195204 -10198950 -10211083 b. Five of the 15 patients had a prior negative gynecologic case received within the previous five years. The laboratory failed to document the review of six of six prior negative gynecologic cases from the five patients. Prior negative cases include: -7479193 -8586217 -8883553 -8958099 -9647662 -9791040 c. The Survey Team identified and Technical Supervisor B confirmed on March 20, 2024 that the laboratory failed to identify one of the six prior negative gynecologic cases as having a more significant lesion than was originally reported. Prior negative case includes: -8958099 4. During an interview on March 20, 2024 at 2:00 PM Technical Supervisor B and the Laboratory Manager confirmed these findings.
D5635	CYTOLOGY CFR(s): 493.1274(d)(1)(i) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(i) The workload limit is based on the individual's performance using evaluations of the following: (d)(1)(i)(A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section. (d)(1)(i)(B) Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview with the Laboratory Manager the laboratory failed to establish and follow written policies and procedures to use evaluations of the individual Cytotechnologist's performance when assessing the workload limits for Cytotechnologists. The laboratory failed to establish workload limits for three of three Cytotechnologists in 2024 using the results of the 10 percent review of negative cases and the comparison of the individual's interpretation with the Technical Supervisor's confirmation of patient smears. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the individual workload limit for Cytotechnologists would include the results of the 10 percent review of negative cases and evaluations of a comparison of the Cytotechnologist's interpretations with the Technical Supervisor's confirmations of patient slides. 2. The Survey Team requested and the laboratory failed to provide documentation that the workload limit for three of three Cytotechnologists in 2024 was established using the results of the 10 percent review of negative cases and results of the comparison of the individual's interpretations with the Technical Supervisor's confirmation. a. The SEMI-ANNUAL WORKLOAD ASSESSMENT FORM FOR CYTOTECHNOLOGISTS was used to assess Cytotechnologist workload limits. The form did not include the results of the 10 percent review of negative cases and results of the comparison of the individual's interpretations with the Technical Supervisor's confirmation for three of three Cytotechnologists. Cytotechnologists include: -Cytotechnologist A Date of evaluation: 01-15-2024 Assessment period: July 2023-December 2023 - Cytotechnologist B Date of evaluation: 01-15-2024 Assessment period: July 2023-December 2023 -Cytotechnologist C Date of evaluation: No evaluation b. The SEMI-ANNUAL WORKLOAD ASSESSMENT FORM FOR CYTOTECHNOLOGISTS was used to assess Cytotechnologist workload limits. The form did not include an assessment or a signature by the Technical Supervisor. 3. During an interview on March 19, 2024 at 1:00 PM the Laboratory Manager confirmed these findings.
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, workload limit records and interviews the laboratory failed to establish and follow written policies and procedures to reassess a maximum workload limit at least every six months for two of two Cytotechnologists in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor would reassess each individual's workload limit at least every 6 months and adjust when necessary 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor reassessed a workload limit at least every six months in 2022, 2023 and January 1, 2024 to the date of the survey in 2024 for two of two Cytotechnologists who performed slide examinations in 2022. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B a. Records titled CYTOTECHNOLOGIST SLIDE PERFORMANCE EVALUATION from December

	2022 failed to include the date of the assessment period. b. Records titled CYTOTECHNOLOGIST SLIDE PERFORMANCE EVALUATION from December 2022 failed to include a re-assessed slide limit. c. Records titled SEMI-ANNUAL WORKLOAD ASSESSMENT FORM FOR CYTOTECHNOLOGISTS from January 15, 2024 failed to include a signature to reflect a Technical Supervisor review and assessment. 3. During an interview on March 18, 2024 at 1:30 PM, the Laboratory Manager stated that the Laboratory Manager performed the review and was new and "did not know that the review had to be done by the pathologist." 4. During an interview on March 18, 2024 at 4:30 PM the Laboratory Manager confirmed these findings.
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, workload records and interview the laboratory failed to establish and follow written policies and procedures to ensure workload limits for the Cytotechnologists would be prorated when examining slides in less than an eight-hour work day. The laboratory failed to prorate workload limit records for the Cytotechnologists in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate workload limits for the Cytotechnologists 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 of prorated workload limits for three of three Cytotechnologists when examining slides in less than eight hours in 2023 and January 1, 2024 to the date of the survey in 2024. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B - Cytotechnologist C a. The Technical Supervisor failed to reassess a workload limit and the Cytotechnologists failed to document the time spent evaluating slides during each 24-hour day, which resulted in the laboratory not having the required data to prorate the number of slides that could be evaluated. Refer to D5637, D6130 and D6167 3. During an interview on March 19, 2024 at 9:00 AM the Laboratory Manager and Cytotechnologist A confirmed these findings.
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, laboratory 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 hours individuals spent examining slides during each 24-hour period. The laboratory failed to maintain records of the number of hours three of three Cytotechnologists spent examining slides in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the written procedure CYTOTECHNOLOGIST JOB DESCRIPTION, DUTIES AND RESPONSIBILITIES which stated: "Document the number of hours spent examining slides in each 24-hour period." 2. During an interview on March 19, 2024 at 9:00 AM Cytotechnologist A stated that the Cytotechnologists "do not record the number of hours they screen slides." Refer to D6167 3. During an interview on March 19, 2024 at 1:00 PM the Laboratory Manager confirmed these findings.
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, workload limit records and interview with the Laboratory Manager the laboratory failed to establish and follow written policies and procedures to ensure records were available to document the workload limit for three of three Cytotechnologists who performed screening of cytology specimens in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to establish and follow written policies and procedures to document the workload limit for the Cytotechnologists. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for two of two Cytotechnologists in 2022, two of two Cytotechnologists in 2023 and three of three Cytotechnologists January 1, 2024 to the date of the survey in 2024. 2022 Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 2023 Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 2024 Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B -Cytotechnologist C 3. During an interview on March 19, 2024 at 1::00 PM the Laboratory Manager confirmed these findings.
D5651	CYTOLOGY CFR(s): 493.1274(e)(2) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(2) The report of gynecologic slide preparations with conditions specified in paragraph (e)(1) of this section must be signed to reflect the 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, interviews and review of laboratory records the laboratory failed to establish and follow written policies and procedures to ensure that final gynecologic test reports signed by Technical Supervisors reflected a secure electronic signature authorized by the Technical Supervisor. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that an authorized electronic signature for Technical Supervisors was protected from use by unauthorized individuals. 2. During an interview on March 18, 2024 at 1:30 PM the Laboratory Manager and Staff A explained the release of final gynecologic test reports as follows: a. The Technical Supervisor writes the slide evaluation results on a PAP SMEAR WORKSHEET. b. Staff A then enters the written results into the laboratory information system (LIS) from the PAP SMEAR WORKSHEET. c. The LIS generated draft gynecologic test report is brought to the Technical Supervisor who hand signs the draft gynecologic test report and returns it to Staff A. Changes and edits may occur at this time and are hand-written by the Technical Supervisor on the draft gynecologic test report. d. The final gynecologic test report is pulled up in the LIS, authorized and then released by Staff A using the Technical Supervisor's electronic signature. 3. During an interview on March 18, 2024 at 4:30 PM the Survey Team asked the Laboratory Manager to explain why the Technical Supervisor's signature and review date was recorded on the PAP SMEAR WORKSHEET as being evaluated a day earlier than the final gynecologic test report date. The Laboratory Manager explained that Staff A released the test reports from the LIS on the following day and confirmed that the Technical Supervisor's did not enter or release the gynecologic test results in the LIS. 4. During an interview on March 20, 2024 at 2:00 PM Technical Supervisor B confirmed that the electronic signature that appeared on the final gynecologic test reports was not released by the 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, interviews and review of laboratory records the laboratory failed to establish and follow written policies and procedures to ensure that final nongynecologic reports signed by Technical Supervisors reflected a secure electronic signature authorized by the Technical Supervisor. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that an authorized electronic signature for Technical Supervisors was protected from use by unauthorized individuals. 2. During an interview on March 18, 2024 at 4:30 PM the Laboratory Manager explained the release of final nongynecologic test reports as follows: a. The Technical Supervisor dictates the slide evaluation results. b. Staff A then enters the dictated results into the LIS. c. The LIS generated draft nongynecologic test report is brought to the Technical Supervisor who hand signs the draft nongynecologic test report and returns it to Staff A. d. The final nongynecologic test report is authorized and then released by Staff A using the Technical Supervisor's electronic signature. 3.

	During an interview on March 18, 2024 at 4:30 PM the Laboratory Manager confirmed that the Technical Supervisors did not enter or release the nongynecologic test results in the LIS. 4. During an interview on March 20, 2024 at 2:00 PM Technical Supervisor B confirmed these findings.
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 and interview the laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. During an interview on March 20, 2024 at 2:00 PM Technical Supervisor B and the Laboratory Manager confirmed these findings.
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview the laboratory failed to establish and follow written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. 2. During an interview on March 20, 2024 at 2: 00 PM Technical Supervisor B and the Laboratory Manager confirmed these findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, specimen slides and interviews the laboratory failed to establish and follow written policies and

	procedures for an ongoing mechanism to monitor, assess and correct problems identified in the analytic cytology systems. The laboratory failed to document analytic quality assessment activities during 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow written policies and procedures to document and audit a program to review prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of HSIL or malignancy and identify cases with a more significant lesion. Refer to D5625 a. The Survey Team reviewed records titled RETROSPECTIVE REVIEW AUDIT. The most recent completed record was dated 10-25-2022. The laboratory failed to provide records for 2023 and January 1, 2024 to the date of the survey in 2024. b. During an interview on March 19, 2024 at 9:00 AM, Laboratory Manager confirmed these findings. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess and maintain the quality of the DIFF-QUIK staining solutions that were used to stain nongynecologic specimen slides. a. During an observation of the Diff-Quik staining solutions on March 19, 2024 at 8:30 AM when asked if there were records to document how or when the staining solutions used in the DIFF-QUIK staining were filtered, changed or monitored for intended quality the Laboratory Manager and Staff B replied, "no."
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations (refer to D6079); failed to ensure testing of samples for the annual gynecologic cytology CAP PT program was performed in accordance with 493.801, which requires the laboratory to administer the PT events as required by the PT program's instructions (refer to D6089); and failed to ensure two of two Technical Supervisors had the required morphology training to evaluate and report Hologic ThinPrep Pap Tests and BD SurePath Pap Tests slide preparations (refer to D6102).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are

	properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, specimen slides and interviews the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory, for assuring compliance with applicable regulations and ensuring all duties are properly performed. Findings include: 1. The Laboratory Director failed to provide direction and oversight to ensure policies and procedures were followed to review prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of HSIL or malignancy and identify cases with a more significant lesion. Refer to D5625 2. The Laboratory Director failed to provide direction and oversight to ensure policies and procedures were established and followed to ensure workload limits were not exceeded. a. The Laboratory Director failed to ensure the Cytotechnologists documented the time spent evaluating slides to ensure prorated workload limits were not exceeded. Refer to D5641 and D6167 b. The Laboratory Director failed to ensure the Technical Supervisor reassessed workload limits for the Cytotechnologists to ensure the Cytotechnologists workload would be based on abilities and would not be exceeded. Refer to D5637, D5641 and D6130 3. During an interview on March 20, 2024 at 2:00 PM Technical Supervisor B and the Laboratory Manager confirmed these findings
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of annual gynecologic CAP PT program instructions, annual gynecologic cytology PT participation records and interviews the Laboratory Director failed to ensure testing of samples for the annual gynecologic cytology PT program was performed in accordance with 493.801, which requires the laboratory to administer the PT events as required by the PT program's instructions. The laboratory failed to administer the CAP PT examination as required by the PT provider's laboratory proctor instructions in 2024. Findings include: 1. The Laboratory Director failed to ensure the laboratory administered the CAP PT events as required by the PT program's instructions in 2024. Refer to D2015 2. During an interview on March 20, 2024 at 2:00 PM Technical Supervisor B and the Laboratory Manager confirmed these findings.
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 certification records and interviews the Laboratory Director failed to ensure that one of two Technical Supervisors had received the required Hologic ThinPrep Pap Test (TPPT) morphology certification prior to evaluating and reporting Hologic TPPT patient specimens in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Laboratory Director failed to ensure one of two Technical Supervisors received the required morphology certification prior to performing diagnostic evaluations of Hologic TPPT in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Refer to D5411 2. During an interview on March 20, 2024 at 2:00 PM Technical Supervisor B and the Laboratory Manager confirmed these findings. B. Based on review of manufacturer's instructions, laboratory certification records and interviews the Laboratory Director failed to ensure that two of two Technical Supervisors who performed diagnostic interpretations of BD SurePath 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 Laboratory Director failed to ensure two of two Technical Supervisors received the required morphology certification prior to performing diagnostic evaluations of BD SurePath Pap Tests from January through December 2022, January through December 2023 and January 1, 2024 to the date of the survey in 2024. Refer to D5411 2. During an interview on March 20, 2024 at 2:00 PM Technical Supervisor B and the Laboratory Manager confirmed these findings.
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 and interviews the Laboratory Director failed to ensure written policies and procedures were established and followed to assess, monitor and maintain the competency of the Technical Supervisors performing cytology test procedures and reporting of cytology test results. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess the competency of the two of two Technical Supervisors to perform cytology test procedures and reporting of cytology test results, and when necessary identify methods to improve the skills of the Technical Supervisors. Refer to D5209 2. The Survey Team requested and the Laboratory Director failed to provide documentation of competency assessments for two of two Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024 Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During an interview on March 20, 2024 at 2:00 PM Technical Supervisor B and the Laboratory Manager confirmed these findings.
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 review of workload records and interviews the Technical Supervisor failed to reassess a maximum workload limit at least every six months for two of two Cytotechnologists in 2022 and 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Technical Supervisor failed to provide documentation that the Technical Supervisor reassessed a maximum workload limit at least every six months for two of two Cytotechnologists in 2022 and 2023 and January 1, 2024 to the date of the survey in 2024. Refer to D5637 and D5647. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 2. During an interview on March 20, 2024 at 2:00 PM Technical Supervisor B and the Laboratory Manager confirmed these findings.
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 workload records and interviews three of three Cytotechnologists failed to document the number of hours spent examining slides in each 24-hour period, in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Laboratory Manager provided laboratory records from January through December 2023 and January 1, 2024 to the date of the survey in 2024 for three of three Cytotechnologists. The records failed to include the time spent evaluating slides during each 24-hour period spent examining slides. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B -Cytotechnologist C a. Records titled CYTOTECHNOLOGIST SCREENING HOURS /CASE RECORDS included the number of slides evaluated but failed to include the the time spent evaluating the slides during each 24-hour period at the laboratory being surveyed. b. Records titled CYTOTECHNOLOGIST SCREENING HOURS/CASE RECORDS included the number of slides evaluated "elsewhere" but failed to include the the time spent evaluating the slides during each 24-hour period elsewhere. c. During an interview on March 19, 2024 at 9:00 AM Cytotechnologist A stated that the three of three Cytotechnologists also examined cytology slides at other facilities and were not documenting the time spent examining those slides. 2. During an interview on March 19, 2024 at 9:00 AM Cytotechnologist A stated: -"I didn't think we had to do that in California since we have to clock in and out." a. When asked if the time was documented anywhere to reflect the actual time spent evaluating the slides at the microscope Cytotechnologist A replied "no." b. Cytotechnologist A located a previously utilized and retired workload record which included an area to document the time spent evaluating slides. The workload record was no longer being used by the Cytotechnologists. The current workload record being used by the Cytotechnologists did not include an area to document or record the time spent evaluating slides. c. Cytotechnologist A confirmed that the number of hours spent examining slides in each 24-hour period in 2023 and January 1, 2024 to the date of the survey 2024 was

	not documented. 3. During an interview on March 20, 2024 at 2:00 PM Technical Supervisor B and the Laboratory Manager confirmed these findings
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.