Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0712326	12/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Associated Pathology Medical Group Inc	105 A Cooper Ct, Los Gatos, 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
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 and interview with the Cytology Supervisor, the laboratory failed to establish written policies and procedures to assess the competency of the Technical Supervisor, Cytotechnologists and Laboratory Assistants. 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 Supervisor, the Cytotechnologists and the Laboratory Assistants. 2. During an interview on December 10, 2024 at 10:45 AM, these findings were confirmed by the Cytology Supervisor.
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 BECTON-DICKINSON SUREPATH OPERATOR'S MANUAL, laboratory policies and procedures and interview with the Cytology Supervisor, the laboratory failed to validate results when the laboratory introduced a method of reprocessing unsatisfactory gynecologic cytology specimens utilizing the Becton-Dickinson SurePath system. Findings include: 1. The BECTON-DICKINSON SUREPATH OPERATOR'S MANUAL states: "Collect the cytology sample using either a broom-like device or combination brush/plastic spatula with detachable heads. Drop the detachable head device(s) into the BD SurePath vial. Place the cap on the vial and tighten. Send the BD SurePath vial to the lab for processing." 2. The laboratory procedure REPROCESSING SCANTY THINPREP SPECIMENS stated: "Label SurePath vial with the ThinPrep to be reprocessed. Pour from the ThinPrep vial 12 ml for scanty smear or 4 ml for bloody smear. Add the SurePath vial to the clamshell with the other SupePath to be processed. Process the SurePath vial according to the procedure for SurePath specimens." 3. The Survey Team requested and the laboratory failed to provide validation studies or a reference for the modification of the SurePath Pap Test. 4. During an interview on December 9, 2024 at 10:00 AM, these findings were confirmed by the Cytology Supervisor.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, statistical records and interview with the Cytology Supervisor, the laboratory failed to establish written policies and procedures for the evaluation and comparison of six of six required cytology statistics. The laboratory failed to document five of six required annual statistics for 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of six of six cytology statistics. 2. The Survey Team requested and the laboratory failed to provide records of five of six required annual statistics for 2023. Statistics include: - Number of cytology cases examined - Number of specimens processed by specimen type - Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison - Gynecologic cases where cytology and histology are discrepant - Gynecologic cases where a rescreen of a normal or negative specimen results in reclassification as LSIL, HSIL, adenocarcinoma or other malignant neoplasm 3. During an interview on

	December 9, 2024 at 3:00 PM, these findings were confirmed by the Cytology Supervisor.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload limit records and interview with the Cytology Supervisor, the laboratory failed to follow written policies and procedures to establish an individual maximum workload limit for one of three cytotechnologists in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the procedure JOB DESCRIPTION, which stated: "In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)" "Must establish the workload limit for each individual examining slides". 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor established an individual maximum workload limit for one of three Cytotechnologists in 2023 and January 1, 2024 to the date of the survey in 2024. Cytotechnologists include: - Cytotechnologist #3 3. During an interview on December 9, 2024 at 3:00 PM, these findings were confirmed by the Cytology 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, lack of workload limit reassessment records and interview with the Cytology Supervisor, the laboratory failed to follow written policies and procedures to reassess and adjust when necessary, a maximum workload limit at least every six months. The Technical Supervisor failed to reassess a maximum workload limit for one of three cytotechnologists in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the procedure JOB DESCRIPTION, which stated: "In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)" "Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary" 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor reassessed a maximum workload limit for one of three cytotechnologists in 2023 and January 1, 2024 to the date of the survey in 2024. Cytotechnologist includes: - Cytotechnologist #3 3. During an interview on December 9, 2024 at 3:00 PM, these findings were confirmed by the Cytology 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 and interview with the Cytology Supervisor, the laboratory failed to establish and follow written policies and procedures to ensure workload limits would be prorated for the Cytotechnologists when examining slides in less than an eight-hour work day. The laboratory failed to provide records of prorated workload limits for 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 records of prorated workload limits for 2023 and January 1, 2024 to the date of the survey in 2024 for two of three cytotechnologists. Cytotechnologists include: - Cytotechnologist #1 - Cytotechnologist #3. 3. During an interview on December 9, 2024 at 3:00 PM, these findings were confirmed by the Cytology Supervisor.
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 the microscopic review of 399/407 gynecologic cases/slides from November 2024 and December 2024 and confirmation by the Technical Supervisor on December 11, 2024, the Technical Supervisor failed to verify the accuracy of two gynecologic cytology tests. Findings include: 1. T24-18577 11/27/2024 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation. Scant Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for Interpretation. Scant Cellularity 2. T24-18811 12/3/2024 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation. Obscuring Inflammation TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for Interpretation. Scant Cellularity and Obscuring Inflammation
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and

	(c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on the lack of workload limit records and interview with the Cytology Supervisor, the Technical Supervisor failed to establish and reassess a maximum workload limit for one of three cytotechnologists in 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 established a maximum workload limit for one of three cytotechnologists in January through December 2023 and January 2024 to the date of the survey in 2024. Refer to D5633. Cytotechnologist includes - Cytotechnolgist #3 2. The Technical Supervisor failed to provide documentation that the Technical Supervisor reassessed a workload limit at least every six months for one of three cytotechnologist who performed primary examinations of cytology slides in January through December 2023 and January 2024 to the date of the survey in 2024. Cytotechnolgist includes: - Cytotechnologist #3 3. During an interview on December 9, 2024 at 3:00 PM, these findings were confirmed by the Cytology Supervisor.
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.