Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2141683	01/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Associated Pathologists, Llc	200 Stonecrest Blvd, Pathology Dept, Smyrna, TN	

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
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 ensure the laboratory identified cases with a more significant lesion during the review of all negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy. The laboratory failed to identify four of ten prior negative gynecologic cases from 45 current HSIL cases from March 2022 through October 2023, as having a more significant lesion than originally reported. Findings include: 1. The laboratory failed to follow policy and procedure titled RETROSPECTIVE REVIEW FOR HIGH-GRADE PAP SMEARS which stated: -"The cytology manager or a cytotechnologist designated by the manager reviews the previous negative slides. If atypia is found on any previously reported negative slide, the cytology manager will forward to a pathologist for review." 2. The Survey Team was provided records titled PS-GYN CYTOLOGY PROCESSED AT STONECREST MEDICAL CENTER 2022 and 2023. The Survey Team reviewed ten previous negative gynecologic cases from seven current cases of HSIL from March 2022 through October 2023. a. The Survey Team identified and the Laboratory Director/Technical Supervisor A confirmed on January 31, 2024 that the

	laboratory failed to identify four of ten prior negative gynecologic cases as having a more significant lesion than was originally reported. Prior negative cases include: -20-PS-006775 -22-PS-058151 -22-PS-066717 -22-PS-077144
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: A. Based on the microscopic review of 297 non-negative gynecologic cytology cases from November 30, 2023 through December 27, 2023, the Technical Supervisor failed to verify the accuracy of one gynecologic cytology test. Cases include: 1. 23-PS-665311 12/01/2023 ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Atypical Squamous Cells, Cannot Exclude a High Grade Squamous Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Suspicious For Endometrial Adenocarcinoma LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS: Rare Atypical Clusters Of Glands Suspicious For Adenocarcinoma, Endometrial Origin Favored B. Based on the microscopic review of 36 negative nongynecologic cytology cases from October 26, 2022 through July 28, 2023, the Technical Supervisor failed to verify the accuracy of three nongynecologic cytology tests. Cases include: 1. 23-GN-003645 07/28/23 Urine, voided LABORATORY DIAGNOSIS Negative For High-Grade Urothelial Carcinoma SURVEY TEAM DIAGNOSIS Suspicious For High Grade Urothelial Carcinoma LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS Rare Atypical Cells, Cannot Exclude High Urothelial Carcinoma 2. 22-GN-005823 11/09/22 Urine, clean catch LABORATORY DIAGNOSIS Negative For High-Grade Urothelial Carcinoma SURVEY TEAM DIAGNOSIS Suspicious For High Grade Urothelial Carcinoma LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS Rare Hyperchromatic Atypical Cell Clusters, Cannot Exclude High Urothelial Carcinoma 3. 22-GN-005578 10/27/22 Endocervical with stent LABORATORY DIAGNOSIS Negative For Intraepithelial Lesion Or Malignancy SURVEY TEAM DIAGNOSIS Suspicious for Endocervical Adenocarcinoma In-Situ LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS Atypical Endocervical Cells Suspicious For Either Endocervical Adenocarcinoma In-Situ Or Partial Involvement Of Endocervical Glands By Squamous Intraepithelial Lesion (High Grade)
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