Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2003037	03/31/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ameripath/Colorado Pathology Consultants	1375 E 19th Ave, Denver, CO	

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
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, cytology slide preparations and corresponding final test reports and interview it was determined that the laboratory failed to follow written policies and procedures to ensure that one of one anal cytology slide preparations from December 2020 was identified and reported as unsatisfactory. Findings include: 1. The written procedure ANAL-RECTAL CYTOLOGY stated "The Bethesda System for Reporting Cervical Cytology atlas contains guidelines for specimen adequacy for Anal-Rectal Cytology (ARC). Minimal Cellularity for an adequate ARC sample is approximately 2,000 to 3,000 nucleated squamous cells. Scant cellularity or those that consist primarily of anucleated squames are unsatisfactory for evaluation." 2. The Survey Team reviewed one negative anal cytology case from December 2020. The laboratory failed to identify and report the one of one case as unsatisfactory for evaluation due to inadequate cellularity. 3. During an interview on March 31, 2021 at 12:45 PM Technical Supervisor B confirmed that the laboratory failed to identify and report the one of one anal cytology case as "Unsatisfactory for Evaluation."
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 57 random negative nongynecologic cases/132 slides and the corresponding final test reports from January through December 2020 and confirmation by Technical Supervisor B on March 31, 2021 it was determined that the Technical Supervisor failed to verify the accuracy of one nongynecologic cytology test. 1. C20-75 12/29/2020 LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Unsatisfactory due to insufficient number of squamous cells TECHNICAL SUPERVISOR B DIAGNOSIS: Unsatisfactory
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.