Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2033368	02/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Calpath Medical Associates	2425 Samaritan Dr, San Jose, 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 the lack of cytology proficiency testing (PT) enrollment records and interview it was determined that the laboratory failed to enroll in an approved PT program for gynecologic examination (refer to D2001).
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on the lack of cytology PT enrollment records and interview it was determined that the laboratory failed to enroll in an HHS-approved cytology PT program for

	gynecologic examination for 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide records of enrollment in an approved cytology PT program for 2020. 2. During an interview on January 31, 2022 at 9:50 AM, these findings were confirmed with Technical Supervisor B, the Manager of Regulatory and Accreditation and the Administrative Laboratory Director.
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 it was determined that the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the HOLOGIC THINPREP Pap Test (refer to D5411); failed to establish written policies and procedures to ensure that the search and review of prior negative gynecologic specimens received within the previous five years for each patient with a current high grade squamous intraepithelial lesion (HSIL) or malignancy was performed (refer to D5625); failed to establish written policies and procedures for an annual statistical evaluation of required laboratory statistics, and failed to document required statistics (refer to D5629); failed to establish written policies and procedures to ensure unsatisfactory cytology slide preparations were identified and reported as unsatisfactory (refer to D5655); failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results (refer to D5657); 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 it was determined that the laboratory failed to establish written policies and procedures to assess the competency of four of four Technical Supervisors. The laboratory failed to assess the competency of four of four 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 competency of the Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for four of four Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -

	Technical Supervisor B -Technical Supervisor C -Technical Supervisor D 3. During an interview on February 1, 2022 at 8:30 AM, these findings were confirmed with Technical Supervisor B and the Manager of Regulatory and Accreditation.
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: Based on review of manufacturer's instructions, laboratory records and interview it was determined that the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the HOLOGIC THINPREP Pap Test in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL states: "Evaluation of microscope slides produced with the THINPREP 2000 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 for three of four Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C 3. During an interview on February 1, 2022 at 8:30 AM, these findings were confirmed with Technical Supervisor B and the Manager of Regulatory and Accreditation.
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 and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that the search and review of prior negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy was performed. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for the search and review of all prior negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy reported by

	the laboratory. 2. During an interview on February 1, 2022 at 8:30 AM, Technical Supervisor B stated that Facility A (CLIA# 05D0858234) performed the search for prior negative specimens for each patient with a current HSIL or malignancy. Facility A reviewed any prior negative specimens and if there was a discrepancy the case was sent to this facility for review by the Technical Supervisors. 3. During an interview on February 2, 2022 at 8:20 AM, these findings were confirmed with Technical Supervisor B and the Manager of Regulatory and Accreditation.
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 interview it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation of one of six required gynecologic laboratory statistics. The laboratory failed to document three of six required gynecologic annual statistics for 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of one of six required gynecologic statistics. Statistic includes: -The number of gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results are available for comparison 2. The Survey Team requested and the laboratory failed to provide three of six required gynecologic annual statistics for 2020 and 2021. Statistics include: -The number of gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison -The number of gynecologic cases where cytology and histology are discrepant -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. During an interview on February 1, 2022 at 8:30 AM, these findings were confirmed with Technical Supervisor B and the Manager of Regulatory and Accreditation. B. Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation of three of three required nongynecologic cytology statistics. The laboratory failed to document three of three required nongynecologic annual statistics for 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of three of three required nongynecologic cytology statistics. Statistics include: -The number of cytology cases

	examined -The number of specimens processed by specimen type -The number of patient cases reported by diagnosis, including the number reported as unsatisfactory 2. The Survey Team requested and the laboratory failed to provide the three required nongynecologic annual statistics for 2020 and 2021. Statistics include: -The number of cases examined -The number of specimens processed by specimen type -The number of patient cases reported by diagnosis, including the number reported as unsatisfactory 3. During an interview on February 1, 2022 at 8:30 AM, these findings were confirmed with Technical Supervisor B and the Manager of Regulatory and Accreditation.
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 establish written policies and procedures to ensure unsatisfactory gynecologic and nongynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report two gynecologic cytology slide preparations from August through September 2020 as "Unsatisfactory for Evaluation". Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory for evaluation. a. The laboratory failed to identify and report two gynecologic cytology slide preparations from August through September 2020 as "Unsatisfactory for Evaluation". Cases include: -P20-766 -P20-805 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory for evaluation. 3. During an interview on February 1, 2022 at 8:30 AM, these findings were confirmed with Technical Supervisor B and the Manager of Regulatory and Accreditation.
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 it was determined that the laboratory failed to establish 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

	February 1, 2022 at 8:30 AM, these findings were confirmed with Technical Supervisor B and the Manager of Regulatory and Accreditation.
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 and interview it was determined that 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 February 1, 2022 at 8:30 AM, these findings were confirmed with Technical Supervisor B and the Manager of Regulatory and Accreditation.
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 interview it was determined that 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. 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. 2. The Survey Team requested and the laboratory failed to provide documentation of any postanalytic quality assessment activities or problems. 3. The Survey team identified one random final test report that failed to report a diagnosis. Report includes: -C21-000415 4. The Survey Team identified seven random final test reports with a significant delay from specimen receipt to final test result reporting. Cases include: - C21-000135 Received date: 03/25/2021 Report date: 11/23/2021 -C21-000145 Received date: 03/30/2021 Report date: 11/23/2021 - C21-000176 Received date: 04/29/2021 Report date: 11/23/2021 -C21-000191 Received date: 05/13/2021 Report date: 11/23/2021 -C21-000233 Received date: 06 /21/2021 Report date: 11/23/2021 -C21-000245 Received date: 06/23/2021 Report date: 11/23/2021 -C21-000257 Received date: 06/30/2021 Report date: 11/23/2021 5. During an interview on February 2, 2022 at 8:20 AM, these findings were confirmed with Technical Supervisor B and the Manager of Regulatory and Accreditation.
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 it was determined that 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 the laboratory enrolled in an annual gynecologic cytology PT program for 2020 (refer to D6088); 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 the Technical Supervisors had received the appropriate morphology training prior to reporting patient specimens (refer to D6102); and failed to ensure that written policies and procedures were established to assess, monitor and maintain the competency of the Technical Supervisors (refer to D6103).
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the lack of PT enrollment records and interview it was determined that the Laboratory Director failed to ensure that the laboratory enrolled in an annual gynecologic cytology PT program for 2020. Cross refer to D2001 Findings include: 1. The Laboratory Director failed to ensure that the laboratory enrolled in an HHS-approved PT program for 2020.
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 interview it was determined that the Laboratory Director failed to ensure quality assessment programs were established to assure the quality of cytology services and identify failures in quality as they occur in 2020 and 2021. Cross refer to D5891 Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide records of an established quality assessment program and failed to identify failures in quality as they occured in 2020 and 2021.
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: Based on review of manufacturer's instructions, laboratory records and interview it was determined that the Laboratory Director failed to ensure that three of four Technical Supervisors who performed Hologic ThinPrep 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. Cross refer to D5411 Findings include: 1. The Survey Team requested and the laboratory failed to provide documentation of appropriate training to accurately report cytology test results prior to performing Hologic ThinPrep Pap test evaluations.
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, lack of laboratory records and interview it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of four of four Technical Supervisors performing cytology test procedures. Cross refer to D5209 Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess the competency of the Technical Supervisors, and when necessary identify methods to improve the skills of the Technical Supervisors. 2. The Survey Team requested and the Laboratory Director failed to provide documentation of competency assessments for four of four Technical Supervisors in 2020, 2021 and to the date of the survey in 2022.
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 239 random negative gynecologic cases/250 slides and the corresponding final test reports from May 2020 through December 2021 and confirmation by Technical Supervisor B on February 2, 2022 it was determined that the Technical Supervisor failed to verify the accuracy of two gynecologic cytology

	tests. 1. C20-000766 08/03/2020 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion and Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory. Insufficient Cellularity TECHNICAL SUPERVISOR B DIAGNOSIS: Unsatisfactory. Insufficient Cellularity 2. C20-000805 09/04/2020 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory. Insufficient Cellularity TECHNICAL SUPERVISOR B DIAGNOSIS: Unsatisfactory. Insufficient Cellularity
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.