Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0858234	10/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Calpath Medical Associates	2155 S Bascom Ave #120, Campbell, 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
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 the laboratory failed to establish policies and procedures for the random selection of ten percent of the gynecologic cases interpreted to be negative (refer to D5621); failed to establish policies and procedures for the evaluation and comparison of six annual statistics and failed to document three of six required annual statistics (refer to D5629); failed to establish policies and procedures for the establishment of individual workload limits and failed to reassess workload limits at least every six months (refer to D5633, D5635 and D5637); failed to establish policies and procedures to ensure the workload limit when examining slides in less than an 8-hour workday would be prorated to determine the number of slides that may be examined (refer to D5641); failed to maintain records of the total number of slides examined and the total number of hours spent examining slides (refer to D5645); failed to establish written policies and procedures to document the workload limit (refer to D5647); and failed to establish policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report gynecologic cytology test results (refer to D5657).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of 31 laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for one laboratory test process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for cytology PT enrollment and participation of personnel that perform gynecologic cytology testing. 2. During an interview on October 6, 2021 at 12:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Technical Supervisor C and Operations Manager.
D5621	CYTOLOGY CFR(s): 493.1274(c)(1) (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)(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under 493.1469 or 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section). (c)(1)(i) The review must be performed by an individual who meets one of the following qualifications: (c)(1)(i)(A) A technical supervisor qualified under 493.1449(b) or (k). (c)(1)(i)(B) A cytology general supervisor qualified under 493.1469. (c)(1)(i)(C) A cytotechnologist qualified under 493.1483 who has the experience specified in 493.1469(b)(2). (c)(1)(ii) Cases must be randomly selected from the total caseload and include negatives and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information. (c)(1)(iii) The review of those cases selected must be completed before reporting patient results. This STANDARD is not met as evidenced by: Based on the review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to detail how at least ten percent of the gynecologic cases interpreted to be negative would be randomly selected for review and how patients identified as having a higher than average probability of developing cervical cancer would be included with the

	random selection. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how at least ten percent of the gynecologic cases interpreted to be negative for intraepithelial lesion would be randomly selected for review. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how patients that are identified as having a higher than average probability of developing cervical cancer would be included with the random selection. 3. During an interview on October 6, 2021 at 12: 00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Technical Supervisor C and Operations Manager.
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, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of six of six laboratory statistics and failed to document three of six required annual statistics for 2019 and 2020. 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 laboratory statistics. 2. The Survey Team requested and the laboratory failed to provide three of six required annual statistics for 2019 and 2020. Statistics include: -Number of cytology cases examined -Number of specimens processed by specimen type -Number of patient cases reported by diagnosis, including the number reported as unsatisfactory 3. During an interview on October 5, 2021 at 9:15 AM the Laboratory Director /Technical Supervisor A confirmed that the statistics provided were for Facility A and Facility B combined. 4. During an interview on October 6, 2021 at 12:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Technical Supervisor C and Operations Manager.
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 laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that maximum workload limits were established for two of two Cytotechnologists in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that maximum workload limits were established for each Cytotechnologist who performed screening of cytology specimens. 2. The Survey Team requested and the laboratory failed to provide documentation that individual maximum workload limits were established for two of two Cytotechnologists in 2019, 2020, and to the date of the survey in 2021. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 3. During an interview on October 6, 2021 at 12:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Technical Supervisor C and Operations Manager.
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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure each Cytotechnologist's maximum workload limits would be based on the individual's performance. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the maximum workload limit for Cytotechnologists would be based on individual capabilities to include evaluations of the following: a. A review of ten percent of the Cytotechnologist's cases interpreted as negative and b. A comparison of the Cytotechnologist's interpretations with the Technical Supervisor's confirmations of patient slides. 2. During an interview on October 6, 2021 at 12:00 PM these findings were confirmed by Laboratory Director/Technical Supervisor A, Technical Supervisor B, Technical Supervisor C, and Operations Manager.
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 laboratory records and interview it was determined that the laboratory failed to establish written policies and

	procedures to ensure the maximum workload limits for two of two Cytotechnologists were reassessed at least every six months and adjusted as necessary in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how the laboratory would reassess the workload limit of the Cytotechnologists at least every six months and adjust when necessary. 2. The Survey Team requested and the laboratory failed to provide records of workload limit reassessments for two of two Cytotechnologists at least every six months in 2019, 2020 and to the date of the survey in 2021. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 3. During an interview on October 6, 2021 at 12:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Technical Supervisor C and Operations Manager.
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 it was determined that the laboratory failed to establish written policies and procedures to ensure the workload limit for two of two Cytotechnologists when examining slides in less than an 8-hour workday and with duties other than slide examination, would be prorated to determine the number of slides that may be examined. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to determine how to prorate the workload limit for two of two Cytotechnologists when time was spent on duties other than slide examination or when examining slides in less than an 8-hour day. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 2. During an interview on October 6, 2021 at 12:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Technical Supervisor C and Operations Manager.
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 and interview it was determined that the laboratory failed to establish written policies and procedures to

	ensure the laboratory would maintain records of the total number of slides examined and the total number of hours spent examining slides during each 24-hour period for two of two Cytotechnologists. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how records would be maintained of the total number of slides examined and the total number of hours spent examining slides during each 24-hour period for two of two Cytotechnologists. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 2. During an interview on October 6, 2021 at 12:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Technical Supervisor C and Operations Manager.
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, lack of records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for two of two Cytotechnologists who performed screening of cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limit for two of two Cytotechnologists who performed screening of cytology specimens. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 2. During an interview on October 6, 2021 at 12:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Technical Supervisor C and Operations Manager.
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 the 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 gynecologic 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 gynecologic cytology test results. 2. During an interview on October 5, 2021 at 4:00 PM these findings were confirmed by Technical Supervisor C and Operations Manager.
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, lack of 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 analytic phases of cytology testing. Cross refer to D5621, D5633, D5637, D5645 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 with the random selection of at least ten percent of the negative gynecologic cases for review to include patients identified as having a higher than average probability of developing cervical cancer. 2. 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 with the establishment of individual workload limits. 3. 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 with the reassessment of individual workload limits at least every six months. 4. 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 with workload records to include the total number of slides examined and time spent examining slides. 5. During an interview on October 6, 2021 at 12:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Technical Supervisor C, and Operations Manager.
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 laboratory records and interview it was determined that Technical Supervisor A failed to establish individual workload limits and to reassess the workload limits at least every six months for two of two Cytotechnologists in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and Technical Supervisor A failed to provide documentation that Technical Supervisor A established a maximum workload limit for two of two Cytotechnologists in 2019, 2020 and to the date of the survey in 2021. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 2. The Survey Team requested and Technical Supervisor A failed to provide records of a workload reassessment at least every six months for two of two Cytotechnologists in 2019, 2020 and to the date of the survey in 2021. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 3. During an interview on October 6, 2021 at 12:00 PM these findings were confirmed by Technical Supervisor A.

D6166	CYTOTECHNOLOGIST RESPONSIBILITIES CFR(s): 493.1485(b) The cytotechnologist is responsible for documenting, for each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer. This STANDARD is not met as evidenced by: Based on review of laboratory records it was determined that one of two Cytotechnologists failed to document the total number of slides examined for 15 of 19 days spent examining slides in 2021. Findings include: 1. The Survey Team reviewed cytotechnologist workload logs for 2021. Cytotechnologist B failed to document the total number of slides examined for 15 of 19 days spent examining slides in 2021. Dates include: -January 21 -February 18 -March 9 -March 11 -March 12 -April 11 -April 15 -April 24 -May 5 -May 8 -May 9 -May 30 -June 12 -August 12 -August 14
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: A. Based on review of laboratory records and interview it was determined that one of two Cytotechnologists failed to document the number of hours spent examining slides for each 24-hour period in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team reviewed cytotechnologist workload logs from 2019, 2020 and 2021. The document used by Cytotechnologist A did not include a column for time spent examining slides for any day in 2019, 2020 and to the date of the survey in 2021. 2. During an interview on October 6, 2021 at 12:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Technical Supervisor C and the Operations Manager. B. Based on review of laboratory records and interview it was determined that one of two Cytotechnologists failed to document the number of hours spent examining slides in each 24-hour period for 15 of 19 days in 2021. Findings include: 1. The Survey Team reviewed cytotechnologist workload logs from 2021. Cytotechnologist B failed to document the number of hours spent examining slides in each 24-hour period for 15 of 19 days in 2021. Dates include: -January 21 -February 18 -March 9 -March 11 -March 12 -April 11 -April 15 -April 24 -May 5 -May 8 -May 9 -May 30 -June 12 -August 12 -August 14 2. During an interview on October 6, 2021 at 12:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B, Technical Supervisor C and the Operations Manager.
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.