Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0916538	03/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Aw Cytohistology Laboratory	1700 C St, Bakersfield, 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 that the laboratory failed to establish policies and procedures to ensure positive patient identification (refer to D5203); failed to establish policies and procedures to assess the competency of two of two Technical Supervisors (refer to D5209); failed to establish written policies and procedures for specimen submission (refer to D5311); failed to follow manufacturer's instructions for preventive maintenance (refer to D5429); failed to establish policies and procedures for the evaluation and comparison of three annual statistics and failed to document three 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 and D5637); failed to establish 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 nongynecologic cytology test results (refer to D5657).
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of

	results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, observation and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure positive patient identification during fine needle aspiration specimen collection and labeling. The laboratory failed to label six of six fine needle aspiration slides from patient #1 and eight of eight fine needle aspiration slides from patient #2 with a unique identifier during fine needle aspiration specimen collection on March 29, 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure positive patient identification during fine needle aspiration specimen collection and labeling. 2. During observation of fine needle aspiration specimen accessioning and processing on March 29, 2022 at 2:00 PM the Survey Team identified six of six fine needle aspiration slides from patient #1 and eight of eight fine needle aspiration slides from patient #2 without a unique identifier. Specimens include: Specimen Identification: Written on Specimen Slide: -NG22-269 air-dried #1 WZ -NG22-269 air-dried #2 WZ -NG22-269 air-dried #3 WZ -NG22-269 alcohol-fixed #1 WZ -NG22-269 alcohol-fixed #2 WZ -NG22-269 alcohol-fixed #3 WZ -NG22-270 air-dried #1 SC -NG22-270 air-dried #2 SC -NG22-270 air-dried #3 SC -NG22-270 air-dried #4 SC -NG22-270 alcohol-fixed #1 SC -NG22-270 alcohol-fixed #2 SC -NG22-270 alcohol-fixed #3 SC -NG22-270 alcohol-fixed #4 SC 3. During an interview on March 29, 2022 at 2:00 PM these findings were confirmed by the Medical Assistant who stated: "Laboratory Director/Technical Supervisor A writes the patient initials and pass number on each slide. I write the case number on them when I get them." 4. During an interview on March 29, 2022 at 4:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A.
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 Technical Supervisors. The laboratory failed to assess the competency of two of two 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 Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for two of two 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 3. During an interview on March 28, 2022 at 4:00 PM these findings were confirmed by Laboratory Director/Technical Supervisor A.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

	The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. 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 fine needle aspiration specimen collection, labeling and transportation. Cross refer to D5203. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for fine needle aspiration specimen collection. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures for fine needle aspiration specimen labeling. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures for fine needle aspiration specimen transportation. 4. During an interview on March 29, 2022 at 4:00 PM these findings were confirmed by Laboratory Director/Technical Supervisor A.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. 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 follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the preanalytic systems. Findings include: 1. The procedure PREANALYTICAL POLICY/PROCEDURE stated: "2. Check the specimens if properly and accurately labeled. 3. Reject the specimen if ...b) the name on the specimen and requisition is not matched." 2. During observation of fine needle aspiration specimen accessioning and processing on March 29, 2022 at 2:00 PM the Survey Team identified fourteen of fourteen fine needle aspiration slides that were not labeled with a patient name or unique identifier. 3. During an interview on March 29, 2022 at 4:00 PM these findings were confirmed by Laboratory Director/Technical Supervisor A.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on the lack of laboratory records and interview it was determined that the

	laboratory failed to ensure that the required preventive maintenance for one of one Sakura DLS 601 cytology stainer, one of one Hologic ThinPrep 2000 Processor, one of one Clinaseal centrifuge and one of one Olympus BX40 microscope used for cytology testing was performed as specified by the manufacturers 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 preventive maintenance records for one of one Sakura DLS 601 cytology stainer for 2020, 2021 and to the date of the survey in 2022. Cytology stainer includes: -Serial #567 2. The Survey Team requested and the laboratory failed to provide preventive maintenance records for one of one Hologic ThinPrep 2000 Processor for 2020, 2021 and to the date of the survey in 2022. Processor includes: -Serial #04464J07DO 3. The Survey Team requested and the laboratory failed to provide preventive maintenance records for one of one Clinaseal centrifuge for 2020, 2021 and to the date of the survey in 2022. Centrifuge includes: -Serial #9876 4. The Survey Team requested and the laboratory failed to provide preventive maintenance records for one of one Olympus BX40 microscope for 2020, 2021 and to the date of the survey in 2022. Microscope includes: -Serial #8J12852 5. During an interview on March 28, 2022 at 4:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A. B. Based on review of manufacturer's instructions, lack of laboratory records and interviews it was determined that the laboratory failed to ensure that the required maintenance was performed, as specified by the manufacturer, for one of one Hologic ThinPrep 2000 Processor used for nongynecologic specimen processing for 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The HOLOGIC THINPREP 2000 OPERATOR'S MANUAL included the following MAINTENANCE SCHEDULE: Procedure: Frequency: -Waste Bottle Emptying As needed -Filter Cap Cleaning Daily -Pneumatic System Test Weekly -Cap Seal O-ring Lubrication Weekly (or as needed) -Filter Seal O-ring Lubrication As needed -Filter Seal O-ring Replacement As needed -Door Cleaning As needed -General Cleaning Monthly -Waste Tubing Replacement Six months -Waste Filter Replacement As needed -Cap Seal Cleaning Daily 2. The Survey Team requested and the laboratory failed to provide daily, weekly, monthly, six month and as needed maintenance records for one of one Hologic ThinPrep 2000 Processor used for nongynecologic specimen processing for 2020, 2021 and to the date of the survey in 2022. Hologic ThinPrep 2000 Processor includes: - Serial #04464J07DO a. During an interview on March 29, 2022 at 10:50 AM these findings were confirmed by the Laboratory Supervisor and Medical Assistant who stated: "We clean it but do not document it anywhere." 3. During an interview on March 29, 2022 at 4:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A.
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 interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of three of three laboratory statistics for nongynecologic specimens and failed to document three of three required annual statistics for 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of three of three laboratory statistics for nongynecologic specimens. 2. The Survey Team requested and the laboratory failed to provide three of three required annual statistics for 2020 and 2021. 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 March 28, 2022 at 4:00 PM these findings were confirmed by Laboratory Director/Technical Supervisor A.
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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure individual workload limits were established for Technical Supervisors who performed examinations of nongynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure Technical Supervisor A established individual workload limits for Technical Supervisors who performed examinations of nongynecologic cytology specimens. 2. During an interview on March 28, 2022 at 4:00 PM these findings were confirmed by Laboratory Director/Technical Supervisor A.
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 and interview it was determined that the laboratory failed to follow written policies and procedures to ensure the individual workload limits for Technical Supervisors were reassessed at least every six months and adjusted as necessary. Findings include: 1. The laboratory failed to follow the procedure WORKLOAD EVALUATION AND QA OF NON-GYN CYTOLOGY which stated: "2. Every six months, the workload maximum will be review and if needed adjusted." 2. During an interview on March 28, 2022 at 4:00

	PM these findings were confirmed by the Laboratory Director/Technical Supervisor A.
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, lack of records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure the individual workload limit 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 by Technical Supervisors. The laboratory failed to provide records to document prorated individual workload limits for two of two Technical Supervisors for 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 determine how to prorate the individual workload limits for Technical Supervisors when time was spent on duties other than slide examination or when examining slides in less than an 8-hour workday. 2. The Survey Team requested and the laboratory failed to provide records to document prorated individual workload limits for two of two Technical Supervisors for 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. During an interview on March 29, 2022 at 4:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A.
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 individual workload limits for Technical Supervisors who performed screening of nongynecologic cytology specimens. The laboratory failed to document the individual workload limits for two of two Technical Supervisors who performed screening of nongynecologic cytology specimens 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 ensure records were available to document the individual workload limits for Technical Supervisors who performed screening of

	nongynecologic cytology specimens. 2. The Survey Team requested and the laboratory failed to provide records to document the individual workload limits for two of two Technical Supervisors who performed screening of nongynecologic cytology specimens in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. During an interview on March 28, 2022 at 4:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A.
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 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 March 28, 2022 at 4:00 PM these findings were confirmed by Laboratory Director /Technical Supervisor A.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of records and interviews it was determined that the Laboratory Director failed to ensure that testing systems developed and used for cytology provided quality laboratory services for all aspects of nongynecologic cytology test performance. Cross refer to D5429. Findings include: 1. The Laboratory Director failed to ensure that preventive maintenance was performed for equipment used during the preanalytic phase of nongynecologic cytology testing for 2020, 2021 and to the date of the survey in 2022. 2. The Laboratory Director failed to ensure that manufacturer's instructions were followed for the specimen processor used during the preanalytic phase of nongynecologic cytology testing for 2020, 2021, and to the date of the survey in 2022. 3. The Laboratory Director failed to ensure that preventive maintenance was performed for the microscope used during the analytic phase of nongynecologic cytology testing for 2020, 2021, and to the date of the survey in 2022. 4. During an interview on March 29, 2022 at 4:00 PM these findings were confirmed by the Laboratory Director.
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 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 Technical Supervisors, Laboratory Supervisors and Medical Assistants 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, monitor and maintain the competency of Laboratory Supervisors. 2. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess, monitor, and maintain the competency of Medical Assistants. 3. During an interview on March 28, 2022 at 4:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of records and interviews it was determined that Technical Supervisor A failed to establish written policies and procedures to ensure that evaluation of the competency of Laboratory Supervisors and Medical Assistants included review of preventive maintenance records for laboratory equipment used in the preanalytic phase of cytology testing. Cross refer to D5429. Findings include: 1. The Survey Team requested and Technical Supervisor A failed to provide written policies and procedures to assess, monitor and maintain the competency of Laboratory Supervisors and Medical Assistants to include the review of preventive maintenance records. 2. The Survey Team requested and Technical Supervisor A failed to provide daily, weekly, monthly, six month and as needed maintenance records for the specimen processor for 2020, 2021 and to the date of the survey in 2022. 3. The Survey Team requested and Technical Supervisor A failed to provide preventive maintenance records for the cytology stainer, specimen processor and centrifuge for 2020, 2021 and to the date of the survey in 2022. 4. During an interview on March 29, 2022 at 4:00 PM these findings were confirmed by Technical Supervisor A.
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 Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5633 and D5637. Findings include: 1. The Survey Team requested and Technical Supervisor A failed to provide documentation that Technical Supervisor A established individual workload limits for two of two 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 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 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 3. During an interview on March 28, 2022 at 4:00 PM these findings were confirmed by Technical Supervisor A.
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.