Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0916538	03/13/2025
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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour, review of the laboratory's policy and procedure, and interviews with the laboratory director (LD); the laboratory failed to establish safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. Based on the surveyor's observations during the laboratory tour on 3/13/2025 at approximately 12:30 p.m. the laboratory processing and staining of samples took place, it was found that: a. The laboratory lacked an eye wash. b. No chemical spill kit was available. c. No monitoring records of exposure of Xylene and Formaldehyde to processing personnel was available. 2. During the laboratory survey on March 13, 2025, at approximately 1:00 p.m. the laboratory failed to provide a written policy and procedure for laboratory safety. 3. The LD confirmed by interviews March 13, 2025 at approximately 1:15 p.m. that the laboratory lacked safety procedures, eyewash, a chemical spill kit, and monitoring records on exposure to known carcinogens (Xylene and Formaldehyde) in the laboratory sample processing area. 4. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 3 /13/2025, the laboratory processed approximately 9,708 Histopathology and Cytology patients' test samples for which safety procedures and measures were lacking.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or

	procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor's review of proficiency testing performance (peer review), ten (10) randomly selected patients, and interviews with the laboratory director (LD) on March 13, 2025; the laboratory failed to verify the accuracy of nongynecologic cytology testing at least twice annually. The findings include: 1. The laboratory performed histopathology and nongynecologic cytology for samples. The laboratory failed to perform evaluation of proficiency testing performance for cytopathology for testing personnel for the years 2023 and 2024. Therefore, the accuracy of the laboratory's test results cannot be assured. 2. On the day of the sruvey 3/13/2025 at approximately 11: 00 a.m; the LD confirmed the lack of proficiency testing for cytology. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/13/2025 stated that the laboratory performed 1,056 tests in nongynecologic cytology annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 the interviews with the laboratory director (LD), review of policies and procedures, proficiency test records, and ten (10) randomly chosen patient records for Histopathology and Cytology, the laboratory failed to establish required written procedures for various cytology and histopathology processes. Findings included: 1. Review of the procedure manual revealed lack of the following required written procedures: criteria for determining unsatisfactory cytology specimens, cytology annual statistics, cytology/histology correlation, laboratory retrieval of final results and slides, process and documentation of individual vs. laboratory statistics for cytology, labelling of reagents, preventive maintenance, implementation of corrective action, and histopathology special stains (Immuno-Histo-Chemistry IHC). 2. During an interview with the LD at approximately 12:00 p.m. on March 3, 2025, at approximately 12:30 p.m., the LD confirmed the lack of required written procedures for cytology and histopathology listed in 1 above. 3. According to the submitted

	laboratory declaration of test volume, the laboratory performed 9,708 histopathology and cytology samples testing for which there is a lack of various required written procedures.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory's tour and interview with the laboratory director (LD); the laboratory failed to label various reagents and solutions used in the laboratory to indicate, as appropriate, the identity, opening, preparation, and expiration dates when such reagents and solutions are used in the laboratory. The findings include: 1. Based on the surveyor's observation during the laboratory tour on March 13, 2025, at approximately 12:30 p.m. the laboratory lacked labeling for various reagents and solutions to identity received, opening, preparation, and/or expiration dates, as appropriate, that were used throughout the laboratory (alcohols, stains, and dyes). 2. The LD confirmed by interview on 3/13/ 2025 at approximately 10:50 a.m., that the reagent and solution materials mentioned in statement #1 above were not labeled with the received, opening, preparation, and/or expiration dates, as applicable. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 9,708 Histopathology and Cytology tests for which various reagents and solutions were not labelled.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (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: 1. The surveyor requested, and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of three (3) of three (3) required Non-GYN 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 LD confirmed by interview on the day of the survey 3/13/2025 at approximately 11: 00 a.m. that findings stated in 1 above were correct. 3. According to the laboratory

	testing declaration, the laboratory tested and reported 1,056 Non-GYN cytology samples for which annual statistics were not evaluated. cytology samples for which annual statistics were not evaluated.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) 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 the surveyor's review of the laboratory's policies and procedures, randomly selected patient test records, observations during the tour of the facility, and interviews with the laboratory director (LD) on March 13, 2025, the LD is cited herein due to failure to ensure that several aspects of the preanalytic, analytical, and postanalytic phases of the laboratory testing were monitored. The findings include: 1. Safety procedures and processes were not established. See D 3011 2. Proficiency testing for Cytology was not performed for the years 2023 and 2024 for testing personnel. See D5217. 3. Lack of required written procedures for Histopathology and Cytology. See 5403. 4. Labelling of testing reagents was incomplete. See D5415. 5. Non-Gyn Cytology Statistics was not performed for the years 2023 and 2024. See D5429.