Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1016329	05/19/2026
Name of Provider or Supplier	**Street Address, City, State**	
Aw Dermatopathology Service	3715 Prytania St, Suite 306, New Orleans, LA	

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
D0000	A Recertification survey was performed at AW Dermatopathology Service, CLIA ID 19D1016329, on May 19, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 the laboratory's policies and interview with personnel, the laboratory failed to establish a complete written competency assessment policy for personnel serving as Clinical Consultant, Technical Supervisor, and General Supervisor. Findings: 1. Review of the laboratory's competency assessment policy revealed the laboratory did not include frequency of performance of competency assessments for the Clinical Consultant, Technical Supervisor, and General Supervisor. 2. In interview on May 19, 2026 at 10:52 am, Testing Personnel 1 confirmed the laboratory's policy did not include the frequency of performance of competency assessments for personnel serving as Clinical Consultant, Technical Supervisor, and General Supervisor.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if

	applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, review of manufacturers' storage requirements, and interview with personnel, the laboratory failed to monitor the room temperature of one (1) of one (1) storage rooms where laboratory supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on May 19, 2026 at 9:28 am revealed the following items were stored in a storage room without temperature monitoring: a) Epredia 10% Neutral Buffered Formalin Prefilled Container b) Stat Lab 10% Neutral Buffered Formalin 2. Review of the manufacturers' storage requirements revealed the following: a) Epredia 10% Neutral Buffered Formalin Prefilled Container storage 15-30 degrees Celsius b) Stat Lab 10% Neutral Buffered Formalin store at room temperature 3. In interview on May 19, 2026 at 9:43 am, Testing Personnel 1 stated the room temperature of the storage room was not monitored.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of random selection of patient final rest reports and interview with personnel, the laboratory failed to include the name and address of the laboratory performing the technical and interpretation portion of the Histopathology testing for eight (8) of eight (8) randomly selected patients. Findings: 1. In interview on May 19, 2026 at 12:20 pm, Testing Personnel 1 and Testing Personnel 2 stated the laboratory only grosses the patient samples. Testing Personnel 1 further stated the technical portion and interpretation of results by the laboratory's pathologists are performed at a different location/laboratory. 2. Review of the following random selection of patient final reports revealed only the name and address of the laboratory performing the grossing was listed: Patient WD25-352 Patient WD25-4403 Patient WD25-7800 Patient WD25-13312 Patient WD26-1019 Patient WD26-1522 Patient WD26-4090 Patient WD26-4062 3. In further interview on May 19, 2026 at 12:20 pm, Testing Personnel 1 confirmed the laboratory's patient final reports did not include the name and address of the laboratory performing the technical and interpretation portion.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

	This STANDARD is not met as evidenced by: Based on observation, review of manufacturers' storage requirements, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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 record review and interview with personnel, the Laboratory Director failed to ensure complete policies and procedures for assessing personnel competency were established. Refer to D5209.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide written job descriptions for all laboratory personnel. Findings: 1. Review of the laboratory's personnel records and laboratory policies revealed the laboratory did not have written job descriptions for Laboratory Director, Clinical Consultant,

	Technical Supervisor, and General Supervisor duties. 2. In interview on May 19, 2026 at 10:52 am, Testing Personnel 1 confirmed the laboratory did not have job descriptions for the identified personnel.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Supervisors failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to monitor the room temperature of one (1) of one (1) storage rooms where laboratory supplies were stored. Refer to D5413. 2. The laboratory failed to include the name and address of the laboratory performing the technical and interpretation portion of the Histopathology testing for eight (8) of eight (8) randomly selected patients. Refer to D5805.