Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2115863	04/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Alexis Dougherty Inc	601 E Arrellaga St, Ste 101, Santa Barbara, 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 review of the laboratory's policies and procedures, lack of a laboratory safety procedure, and interview with office manager (OM); the laboratory failed to establish safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. Based on the survey on April 9, 2025, at approximately 1:30 p.m. the laboratory failed to provide a written policy and procedure for laboratory safety. 2. The OM confirmed by interviews April 9, 2025, at approximately 1:35p.m., that the laboratory lacked written safety policy and procedures based on the laboratory's risk assessment. 3. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 4/9/2025, the laboratory processed and reported approximately 544 patients' test samples.
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 patient testing records, patient final testing reports, and interviews with the laboratory director (LD) and the office manager (OM) on April 9, 2025, at approximately 12:30 p.m. it was determined that for four (4) out of five (5) randomly selected patient Mohs testing records reviewed, the laboratory failed to follow written policies and procedures for specimen analytical phase testing, through completion of testing and reporting results. The findings included: 1. Review of Mohs documentation and patient's final test report found the following discrepancies: Patient 1: Date of Mohs 03/08/2024, No QC slide prepared or found at the time of the survey Patient 2: Date of Mohs 06/14/2024, Mapping for Mohs missing Patient 3: Date of Mohs 08/23/2024, location; hand, reported as Stage I, two (2) slides prepared labelled as Stage III Patient 4: Date of Mohs 02/07/2025, Mapping for Mohs missing 2. The OM affirmed that records were discrepant and /or incomplete for four (4) out of five (5) Mohs patients records reviewed as stated in #1 above 3. Based on the laboratory's annual test volume declaration signed by the LD on 04/09/2025 the laboratory performed and reported 544 Mohs procedures for which its accuracy cannot be confirmed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the lack of a Quality Assurance plan (QA), review of the laboratory's policies and procedures, and interview with the laboratory director (LD) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. The findings include: 1. Based on the day survey on April 9, 2025, at approximately 12:30 p.m., no documentation could be retrieved by the laboratory to show that a QA plan was in place for the years 2024 and 2025. 2. The LD confirmed by interview on April 9, 2025, at approximately 1:00 p.m., that the laboratory did not establish a QA plan to follow written policies and procedures reflecting the current practice for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. 3. According to the testing declaration submitted on April 9, 2025, signed and dated by the laboratory director, the laboratory performed annually 544 dermatopathology, 5 KOH wet mounts, and 5 Sarcoptes scabiei slide preparations, analysis, and diagnosis without an established QA plan.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by:

	Based on review of the laboratory procedure manual and interview with the laboratory director (LD) and office manager (OM); the laboratory failed to perform quality assessment that included a review of the effectiveness of corrective actions taken to resolve problems, and/or revision of policies and procedures necessary to prevent recurrence of problems and failed to document all general laboratory systems quality assessment activities. The findings included: 1. The laboratory lacked a quality assurance policy manual to follow and document quality control for all phases of testing (preanalytic, analytic, and postanalytic), and incidents and actions taken that affected the quality of the patient testing. 2. The laboratory did not have any records of quality assessment or an incident log or other means of documentation of incidents. 3. The LD and OM confirmed this deficiency by interview on April 9, 2025, at approximately 1:15 p.m. 4. The laboratory records performing approximately 554 patient specimens annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the surveyor's examination of laboratory reagents and interview with the laboratory's office manager (OM) and laboratory director (LD); the laboratory failed in not using reagents when they have exceeded their expiration date. The findings include: 1. Based on the surveyor's examination, the laboratory stored two (2) bottles of KOH reagents: a. Lot # 3072, Expiration Date: 03/13/2025 b. Lot #K211D3 Expiration Date: 01/31/2024 No other KOH reagent was available. 2. The LD and OM affirmed on April 9, 2025, at approximately 11:00 a.m., that the laboratory only had at the time of the survey, expired KOH reagent used for visualization of yeast and fungal elements by microscopic KOH mounts as stated in #1 above. 3. Based on the laboratory's submitted testing declaration test volume, the laboratory tested and reported approximately five (5) KOH wet mount analysis annually where expired KOH reagent may have been used.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) (a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on the surveyor's review of policies and procedures, five (5) randomly selected Mohs patient records, and interviews with the laboratory director (LD) and office manager (OM); the laboratory failed to have an established and approved policy and procedure for corrective action. Findings include: 1. Based on review of policies and procedures, no corrective action policy or documentation was found, including any criteria necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate, reliable, and timely patient test results and reports. 2. Based on the review of five randomly selected Mohs patient records, four (4) out of

	five (5) were found to be discrepant for the years 2024 and 2025. 3. The LD and OM confirmed by interview on April 9, 2025 at approximately 12:30 p.m. that the laboratory did not have a policy and procedure for quality assessment that included the corrective action procedure as mentioned in statement #1. 4. Based on the testing declaration submitted at the time of the survey, the laboratory performed and reported 544 tests annually during the time that no corrective action policy and procedure was implemented; thus, the quality and accuracy of patient records cannot be assured.
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 surveyor's review of laboratory's policies and procedures, lack of a quality assurance plan, documentation of patients' quality assurance and management, lack of laboratory safety procedures, lack of corrective action documentation, five randomly selected patient records, storage of expired reagents, and interviews with the laboratory's director and office manager on April 9, 2025; the laboratory director failed to provide effective preanalytic, analytic, and postanalytic phases of testing direction of the laboratory. See D3011, D5203, D5291, D5293, D5417, and D5779.