

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0956602	(X3) Date Survey Completed 12/23/2024
Name of Provider or Supplier Alamitos Dermatological Medical Clinic, Inc	Street Address, City, State 27725 Santa Margarita Pkwy Ste 110, Mission Viejo, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures manuals and interview with the Medical Biller on December 23, 2024, the laboratory failed to follow its own written policies and procedures for Quality Assurance (QA) in 2022, 2023 and 2024. The findings include: 1. According to the laboratory's written policies and procedures for QA, the office meetings are to be held every quarter to review QA finding and staff attendance is to be recorded. 2. On December 23, 2024, at approximately 11:30 am, the laboratory Medical Biller affirmed that the laboratory maintained no documentation for the office meetings for 3 of 3 years. 3. The laboratory's testing declaration form, signed by the laboratory director on December 18, 2024, stated that the laboratory performed approximately 3500 histopathology tests annually.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures manuals and interview with the Medical</p>

Billers on December 23, 2024, the laboratory director failed to meet the standard requirement to approve, sign, and date all policies and procedures. The findings include: 1. On December 23, 2024, at approximately 11:30 am, the laboratory Medical Biller affirmed that the laboratory maintained no documentation indicating that written policies and procedures had been approved, signed, and dated by the current laboratory director. 2. The laboratory's testing declaration form, signed by the laboratory director on December 18, 2024, stated that the laboratory performed approximately 3500 histopathology tests annually.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of policies and procedures manuals and Quality Control (QC) records and interview with the Medical Biller on December 23, 2024, the laboratory failed to provide QC procedures and QC record for monitoring the accuracy of the complete analytic process when performing histopathology examinations. 1. It was the practice of the laboratory to perform histopathology testing. the laboratory is responsible for having control procedures that monitor the accuracy of histopathology testing. 2. On December 23, 2024, at approximately 11:45 am, the laboratory Medical Biller affirmed that the laboratory maintained no documentation for control procedures and no records of monitoring the accuracy of histopathology testing in 2022, 2023 and 2024. 3. The laboratory's testing declaration form, signed by the laboratory director on December 18, 2024, stated that the laboratory performed approximately 3500 histopathology tests annually.

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's policies and procedures manuals, Quality Control (QC) and Quality Assurance (QA) records, review of 5 randomly selected patient test results and interview with Medical Biller on December 23, 2024, it was determined

that the Laboratory director of high complexity testing failed to ensure that testing systems developed and used for histopathology procedure provide quality laboratory services for all aspects of test performance. See D5291, D5407, D5441.