

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1045035	(X3) Date Survey Completed 08/08/2024
Name of Provider or Supplier Skin Clinic Md	Street Address, City, State 3737 4th Ave, San Diego, 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 a review of the laboratory's policies and procedures and interview with the office manager (OM), it was determined that the laboratory failed to 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 survey on August 8, 2024, at approximately 2:30 p.m., no documentation could be retrieved by the laboratory to show that quality assessment and assurance was performed for the years 2022, 2023, and 2024. 2. The OM affirmed by interview on August 8, 2024, at approximately 2:30 p.m., that the laboratory did not have any documentation that followed the 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 August 8, 2024, signed and dated by the laboratory director, the laboratory performed 405 tests for KOH, scabies, and Dermatopathology annually.</p>
D5309	<p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p>

This STANDARD is not met as evidenced by:
 Based on the review of five (5) randomly chosen Mohs patient records and an interview with the office manager (OM), it was determined that the laboratory failed to transcribe or enter accurate information into a record system or a laboratory information system. The findings include: 1. Based on the review of randomly chosen Mohs patient test records results, four (4) out of five (5) records covering the period from 7/6/2022 to 7/17/2024 were found to have inconsistent information between the patient log sheets, slide labels, and final reports retrieved from the Electronic Health Records (EHR). a. For M22-164 patient records reviewed, site or source of specimen from patient log sheet and final report did not match the the site or source labeled on the slide. b. For M23-134 patient records reviewed, it was found that the site or source of the specimen between the patient log sheet and final report were inconsistent; c. In reviewing patient records for M23-269, one out of five slides that were created had a missing identifier used by the facility (date of birth (DOB)); and, d. For M24-086 patient records reviewed, between record systems, it contained a misspelled patient's name and the site or source of the specimen were inconsistent. Also, the number of stages and slides documented were different from the patient log and final report. 2. The OM affirmed by interview on August 8, 2024, at approximately 3:00 p.m. that the laboratory failed to ensure that the information transcribed was accurate on the Mohs patient log, slides, and final report from EHR. 3. Based on the testing declaration form submitted on the day of the survey, the laboratory performed approximately 400 Mohs tests annually.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(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 surveyors' observations during the laboratory tour, patient records review, examination of laboratory reagents, and interview with the office manager (OM), it was determined that the laboratory is herein cited for using reagents when they have exceeded their expiration date. The findings include: 1. Based on the observations during the laboratory tour on August 8, 2024, at approximately 3:30 p. m., the surveyor found an expired reagent: 10% KOH (Lot# 3234-00, exp: 3/31/2024), which was used for microscopic examination for the presence of yeast and fungal elements. 2. Based on the patient records review, one patient was found on April 26, 2024, who was tested for KOH during the time that the reagent was expired. Therefore, the accuracy of the results reported cannot be assured. 3. The OM affirmed on August 8, 2024, at approximately 3:30 p.m. that the bottle found during the laboratory tour was the only bottle in-use for the KOH test in the laboratory. 4. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory tested and reported approximately four tests annually for KOH.

D5435

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check

protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the written policy and procedure manual for equipment quality control and maintenance, an interview with the office manager (OM), and a review of eight (8) randomly selected patient test results for KOH, scabies, and Dermatopathology, it was determined that the laboratory had missed recording the preventive maintenance (PM) and temperature for cryostat and staining PM for 2023. The findings include: 1. Based on the survey on August 8, 2024, at approximately 3:30 p.m. and the review of the laboratory's equipment quality control policy and procedure manual and PM log, the surveyor observed that on May 17, 2023, the PM record for stain was missing an entry, while on October 25, 2023, there were missing entries for cryostat temperature and no PM was found. 2. The OM affirmed by interview on August 8, 2024, that although the PM is performed every time there is a patient sample to be processed, the technician had missed recording the PM performed as mentioned in statement #1. 3. Based on the laboratory's testing declaration submitted on August 8, 2024, and review of 8 randomly selected patient test records for KOH, scabies, and Dermatopathology, the laboratory performed 405 tests annually during the time that PM was missed to be recorded.

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 the interview with the office manager, lack the quality assessment records, observations during the laboratory tour, and review of eight randomly selected patient records on August 8, 2024, the laboratory director is herein cited for failure to ensure that several aspects of the analytic, and postanalytic phases of the laboratory testing were monitored. 1. Lack of quality assessment records. See D5291 2. Test report discrepancies. See D5309 3. Missing preventive maintenance records. See D5417 and D5435