

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>05D0945248</p>	<p>(X3) Date Survey Completed</p> <p>07/30/2024</p>
<p>Name of Provider or Supplier</p> <p>Ocean Skin And Vein Institute</p>	<p>Street Address, City, State</p> <p>1101 N Sepulveda Blvd, Ste 100, Manhattan Beach, CA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D5787</p>	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory testing records for Mohs surgeries, missing information, and interview with the laboratory administrative person, it was determined the laboratory failed to maintain complete records. Findings included: a. The Mohs Map form/template failed to identify the name of the Surgeon performing the Mohs procedure. b. Four out of 11 Mohs maps failed to specify the Mohs Case #, as follows: Date Patient ID ----- 4/25/23 Q, A " S, D 5/16/23 W, E 3/18/24 S, S c. Three out of 8 records documenting the quality of staining for Mohs slides failed to have Mohs surgeons approval, as follows: Date Patient ID ----- 3/18/24 S, S 4/30/24 G, S 5/20/24 G, L d. Review of the Mohs Peer Review Log revealed 6 records of peer review were missing out of 37 records, as follows: Date Patient ID ----- 10/31/23 Y, P 1/30/24 M, J 2/27/24 W, R 2/27/24 W, B 4/30/24 G, M 5/14/24 F, W e. Review of the Mohs Peer Review Log on 5/20/24 and the corresponding peer review record revealed the last name for patient B, T was misspelled. f. The laboratory administrative person affirmed the aforementioned findings (7/30/24 at 2:00 PM) f. And thus, the quality and reliability of laboratory records could not assured. The laboratory performed 128 Mohs procedures annually (form CMS116, CLIA Application, 7/24/24). .</p>

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on the deficiency cited at D5787, it was determined that the laboratory failed to establish and follow written policy and procedure for an ongoing process to regularly monitor laboratory records for completeness and accuracy; and correct problems as they are identified. Findings included: a. The laboratory failed to have a written policy and activities to regularly perform and document reviews of randomly selected patients test records and slides for quality assessment. .

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on the serious nature of the deficiencies cited (D5787, D5791), the Laboratory Director is herein cited for deficient administration in ensuring that quality assessment processes are established and regularly performed to assure the accuracy, completeness, and reliability of all test records. Findings included: a. The Laboratory Director had not established a written policy or process for monitoring/reviewing test records for accuracy and completeness.