

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0913736	(X3) Date Survey Completed 06/21/2018
Name of Provider or Supplier Strimling Institute Of Dermatology, The	Street Address, City, State 10105 Banburry Cross Dr Ste 350, Las Vegas, NV	
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	<p>This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on June 21, 2018. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.</p>
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a random audit of patient laboratory testing from 12/23/16 through 5/7/18 and an interview with the laboratory assistant, the laboratory failed to ensure positive identification of a patient's specimen from the time of collection through the completion of testing and the reporting of the laboratory results. Findings include: 1. A random audit of patient testing reports from 12/23/16 through 5/7/18 found that one of eight patients who had a Mohs procedure performed, failed to have the correct patient unique identification number from the test request through the completion of the test and the reporting of the patient test result. 2. A patient that had a Mohs procedure performed on 1/5/17 was found to have the identification of LH16M006 on the patient slides and the final report. The Mohs map had the patient unique identification as LH17M006. The patient request for Mohs did not have either of the patient unique identification numbers. 3. There was no patient unique identification used throughout the patient request, the patient log, the patient slides, the patient Mohs map and the patient final report. This was confirmed by the laboratory assistant</p>

on June 21, 2018 at approximately 4:00 PM. The laboratory performs approximately 17,321 histopathology tests annually.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on a review of the director approved policy and procedure manual, a review of the maintenance performed on the laboratory microscope and cryostat machine and an interview with the laboratory assistant, the laboratory failed to follow the policy and procedure manual for the maintenance of the laboratory equipment. Findings include: 1. The laboratory failed to follow the director approved policy for the maintenance of the laboratory microscope and cryostat. 2. The documentation of maintenance for the laboratory microscope was on 6/15/18 and previously on 6/4/16. 3. The documentation of maintenance for the laboratory cryostat machine was on 3/18 and previously on 4/3/15. This was confirmed by the laboratory assistant on June 21, 2018 at approximately 4:00 PM. The laboratory performs approximately 17,321 histopathology tests annually.

D5601

HISTOPATHOLOGY

CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a random audit of patient laboratory testing from 12/23/16 through 5/7/18 and an interview with the laboratory assistant, the laboratory failed to document the stain reaction of control slides to determine the adequacy of the quality of staining for patient histopathology slides. Findings include: The laboratory failed to document the adequacy of staining for patient histopathology slides. This was confirmed by the laboratory assistant on June 21, 2018 at approximately 4:00 PM. The laboratory performs approximately 17,321 histopathology tests annually.

D5805

TEST REPORT

CFR(s): 493.1291(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 a random audit of patient laboratory testing from 12/23/16 through 5/7/18 and an interview with the laboratory assistant, the laboratory failed to have on the patient final report, the name of the laboratory where the test was performed. Findings include: 1. A random audit of patient final test reports for Mohs procedures found that eight of eight patient final test reports failed to have the correct name of the laboratory indicated on the final laboratory report. 2. The patient final test reports indicated that the test was performed by "Robert B. Strimling, MD & Associates, LLC Dermatology, Cosmetic Laser & Vein Institute". The name of the laboratory performing the patient laboratory tests is "The Strimling Institute of Dermatology". This was confirmed by the laboratory assistant on June 21, 2018 at approximately 4:00 PM. The laboratory performs approximately 17,321 histopathology tests annually.