

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D0916496	<b>(X3) Date Survey Completed</b>  06/08/2018
<b>Name of Provider or Supplier</b>  Clear Dermatology & Aesthetics Center	<b>Street Address, City, State</b>  8406 E Shea Blvd, Ste 100, Scottsdale, AZ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5607</b>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(d)(f)</p> <p>(d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, one out of one Mohs test report issued by the laboratory failed to include the signature of the individual making the diagnosis. Findings include: 1. The laboratory performs Mohs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 436. 2. One out of one Mohs test report reviewed during the survey (17-033 on 3/28/17) was not signed by the individual who made the diagnosis. 3. The facility personnel confirmed that Mohs test report indicated above was not signed by the individual who made the diagnosis.</p>
<b>D5805</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>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.</p>

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's test reports and interview with the facility personnel, the laboratory failed to list the correct facility name on the Mohs maps which are used for reporting patient test results. Findings include: 1. The laboratory performs Mohs testing on patient specimens in the sub-specialty of Histopathology, with an approximate annual test volume of 436. At the time of the survey conducted on June 8, 2018, the laboratory name listed is the CMS Database for CLIA# 03D09196496 was Valley of the Sun Surgical Dermatology. 2. One out of one Mohs maps reviewed during the survey (#YVM18-0013) was missing the name of the laboratory where the reading of the slides was performed. The Mohs map reviewed for case YVM18-0013 listed the name of the laboratory as Clear Dermatology. 3. The facility personnel confirmed that the correct laboratory name was missing on the Mohs map indicated above. The facility personnel also stated that one testing personnel who began patient testing on 4/13/2018 was using an incorrect version of the laboratory's Mohs maps.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:  
Based on lack of policy for review, review of patient test reports and interview with the facility personnel, the laboratory failed to establish a policy for reporting and maintaining test reports in an electronic record system. Findings include: 1. The laboratory performs Mohs testing on patient specimens under the sub-specialty of histopathology, with an approximate annual test volume of 436. The laboratory utilizes an electronic medical record (EMR) system to maintain patient records, including patient test reports which are electronically signed by the physician who made the diagnosis. 2. No documentation was presented for review to indicate the laboratory had established policies and procedures for maintaining test reports in an electronic system, including but not limited to, policies related to electronically signing patient test reports in a timely manner. 3. The facility personnel confirmed that the laboratory did not have an established policy related to signing test reports and test records that are maintained electronically.