

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 03D2092594	<b>(X3) Date Survey Completed</b> 04/06/2018
<b>Name of Provider or Supplier</b> Omni Dermatology, Inc	<b>Street Address, City, State</b> 9305 W Thomas Rd, Ste 305, Phoenix, 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>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of Quality Assessment policies and records and interview with the facility personnel, the laboratory failed to review and evaluate the results obtained from accuracy verification procedures conducted by the laboratory. Findings include: 1. The laboratory performs Mohs testing under the sub-specialty of Histopathology, with an approximate annual test volume of 200. The laboratory performs accuracy verification for non-regulated testing (Mohs testing) that is not included under subpart I. 2. The laboratory's established policy titled, "Proficiency Testing Policy" states, "Two cases will be evaluated by another Mohs physician per year to confirm and monitor accuracy of histopathology cases performed in house. A practicing Mohs physician shall confirm accuracy of the slides and the cases that were previously observed and diagnosed by the clinical director". 3. No documentation was presented for review to indicate the laboratory reviewed and evaluated the accuracy verification results from 2017 to determine whether or not the results of the review were acceptable or if corrective action was needed. 4. The facility personnel confirmed that the laboratory failed to document the evaluation of the accuracy verification results from 2017.</p>
<b>D5291</b>	<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</p>

through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's established Quality Assessment policies, review of QA records and interview with the facility personnel, the laboratory failed to identify errors found within the accuracy verification process. Findings include: 1. The laboratory performs Mohs testing under the sub-specialty of Histopathology, with an approximate annual test volume of 200. 2. It is the practice of the laboratory to randomly select two cases per year to be reviewed by another Mohs physician for accuracy verification. The laboratory uses a separate form titled "Mohs Case Review Form Estrella" to send with the cases and includes information that is completed by the laboratory prior to sending the form and slide(s). The information completed by laboratory personnel on the form includes: Patient Initials, Date of Procedure, Diagnosis, and # of Stages. The form also contains an area for the reviewing physician to circle yes or no with regard to "Agree with Reading". The form is signed by the reviewing physician once the review is complete. 3. During the survey conducted on April 6, 2018 the laboratory presented the Mohs Case Review Form Estrella 2017 for review. The form failed to include the date in which the review was conducted. 4. The test report, Mohs map and patient slides for one out of two patient cases listed on the review form for 2017 could not be located during the survey. The review form indicated the patient initials as H.T. who was tested on 09/05/17 but the laboratory could not identify which patient's records were reviewed from the Mohs log or any other laboratory records since the laboratory failed to maintain documentation on the review form of the specific case number or any other unique identifier specific to that patient's Mohs case. 5. The facility personnel confirmed that the date of review was missing from the review form and that the laboratory failed to have a mechanism in place to positively identify which cases are reviewed.