

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 03D2190532	<b>(X3) Date Survey Completed</b> 02/21/2023
<b>Name of Provider or Supplier</b> Avant Dermatology & Aesthetics	<b>Street Address, City, State</b> 8580 N Oracle Rd Ste 140, Oro Valley, 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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review for Mohs testing and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the sub-specialty of Histopathology at least twice annually during 2021 and 2022. Findings include: 1. No documentation was presented for review during the survey conducted on February 21, 2023 to indicate the laboratory verified the accuracy of the microscopic interpretation (reading/diagnosis) of histopathology specimens which are read during the Mohs procedure at least twice annually during 2021 and 2022. 2. The facility personnel interviewed on 2/21/23 at approximately 2:05pm confirmed that the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2021 and 2022. 3. The laboratory began testing under the sub-specialty of Histopathology on 10/29/2020 with an approximate annual test volume of 200.</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 through 493.1236.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to monitor, assess and correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. The laboratory began testing under the sub-specialty of Histopathology on 10/29/2020, with an approximate annual test volume of 200. The laboratory performs the microscopic interpretation (reading /diagnosis) of histopathology specimens which are read during the Mohs procedure 2. The laboratory's established QA policy presented for review during the survey conducted on February 21, 2023 states, "Twice a year, another dermatopathologist will review a case that has been done and completed in our laboratory. This will also include frozen sections (which must be sent out for review twice a year as well). Agreement or disagreement will be noted. If disagreement has been noted, the entire case will be reviewed". 3. During the survey, the laboratory provided documentation of completed Mohs cases from 2021 and 2022 which were sent out to another qualified dermatopathologist to verify the accuracy of the final diagnosis, however the cases were not sent out and reviewed until February 15, 2023. 4. The laboratory failed to follow the established QA policy indicated above as evidenced by the laboratory's failure to send out Mohs cases for review of accuracy during 2021 and 2022. 5. No QA documentation was presented for review during the survey to indicate the laboratory has 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. 6. The facility personnel interviewed on 2/21/23 at 2:20pm confirmed that the laboratory failed to follow their established QA policy and procedure related to the frequency of accuracy verification for Mohs cases and confirmed that the laboratory's QA processes at the time of the survey failed to monitor, assess and correct problems identified in the general laboratory systems.