

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0304727	(X3) Date Survey Completed 11/05/2019
Name of Provider or Supplier Affiliated Dermatology	Street Address, City, State 4300 West Main St, Suite 102, Dothan, AL	
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
D5211	<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 a review of the MOHS Quality Assurance documentation and an interview with MOHS Tech #1, the surveyor determined the Laboratory Director failed to document his reviews (as indicated by a signature and date) of the returned "Proficiency Testing" results. This was noted on four out of four Quality Assurance / "Proficiency Testing" reports and one of one case (#19014) from the American Society of MOHS Surgery. The findings include: 1. Refer to D5791. .</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the MOHS Quality Assurance documentation and interviews with MOHS Tech #1 and the Laboratory Director, the surveyor determined the laboratory failed to implement and follow the quality assurance procedure to send two cases, twice a year to an outside MOHS surgeon or pathologist for review in 2017-2019. The Laboratory Director further failed to document his reviews (as indicated by a signature and date) of the returned "Proficiency Testing" results. This was noted on</p>

four out of four Quality Assurance / "Proficiency Testing" reports and one of one case (#19014) from the American Society of MOHS Surgery. The findings include: 1. A review of Quality Assurance procedures revealed "Twice a year, two cases will be sent to outside MOHS surgeon, dermatopathologist or pathologist for review". This procedure was included in the laboratory Policy and Procedure Manual, reviewed periodically by the Laboratory Director, and signed most recently on 12/3/2018. 2. A review of the Quality Assurance / "Proficiency Testing" reports revealed two cases from 2017 (17-111 and 17-559) were sent to a reviewing physician in Charleston, SC. One case from 2018 (18-258) and one case from 2019 (19-040) were sent to a reviewing physician in Venice, FL. Results from Case #19014 with a letter dated 4/21 /2019 from the American Society for MOHS Surgery (ASMS) was also counted as part of the "Proficiency Testing". 3. During an interview with the Laboratory Director and MOHS Tech #1 on 11/5/2019 at 11:30 AM, the surveyor asked if there was any additional "Proficiency Testing" reports since their procedure stated the laboratory would perform "two cases, twice a year". The Laboratory Director stated the procedure was "poorly worded". The laboratory sent out one case twice a year for a total of two cases a year. The surveyor observed the laboratory procedures had been provided by a Lab Consulting firm, and the procedure reflected the CLIA requirement of performing "accuracy verification" twice a year. The procedure had been approved and signed by the Laboratory Director, however the laboratory had failed to implement the procedure as written. 4. As the interview continued with MOHS Tech #1 at approximately 11:45 AM, the surveyor asked if the Laboratory Director documented his reviews (as indicated by a signature and date) of the returned "Proficiency Testing" results. MOHS Tech #1 stated he looked at the results, however she had not realized he needed to sign the reports. Thus, the above noted findings were confirmed. SURVEYOR ID# 32558 Licensure and Certification Surveyor