

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2028951	(X3) Date Survey Completed 11/04/2019
Name of Provider or Supplier Southeastern Dermatology Group, P A	Street Address, City, State 106 Westside Drive, 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, Proficiency Testing" reports and interviews with the Office Administrator and the MOHS Tech, the surveyor determined the Laboratory Director failed to document his reviews (as indicated by a signature and date) of the returned "Proficiency Testing" results and determine if corrective actions were required for any discrepancies in the MOHS surgical slide interpretations by the outside physician. This was noted on nine out of nine quarterly "Quality Assurance, Proficiency Testing" reports. 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 (QA) documentation and interviews with the Office Administrator and the MOHS Tech, the surveyor determined the laboratory failed to document a comparison of the assessments by the Testing Personnel (also the Laboratory Director) for the individual case slides sent out</p>

to the outside pathologist / reviewing surgeon. The Laboratory Director further failed to document his reviews (as indicated by a signature and date) of the returned "Proficiency Testing" results to determine if corrective actions were required for any discrepancies in the MOHS surgical slide interpretations by the outside physician. This was noted on nine out of nine quarterly "Quality Assurance, Proficiency Testing" reports. The findings include: 1. A review of laboratory procedures revealed the MOHS maps and Histopathology slides from frozen section specimens collected during four MOHS surgical cases were sent out quarterly each year for reviews by a "Pathologist or Reviewing Surgeon" in Panama City, Florida. The reviewing physician had documented his results, "+" (positive) or "-" (negative) for the individual slides on the "Quality Assurance, Proficiency Testing" (QA,PT) reports for the third quarter 2017 through the third quarter 2019. 2. In an interview with the Office Administrator (OA) and the MOHS Tech on 11/4/2019 at 12:40 PM, the OA confirmed the slide results (+ or -) on the "QA, PT" reports were the assessments of the reviewing physician in Panama City. The surveyor then asked where the Testing Personnel / Laboratory Director's results for the individual slides were documented. The OA stated the Director's results were on the MOHS maps, explaining there was a "mark" on the map if a tumor was present. 3. The surveyor then reviewed with the MOHS Tech and the OA, MOHS maps for the following accession numbers: A) J17M-0305: The map shows a "mark" in Stage I, Section B, however all the slides were "-" according to the referring physician in Panama City. B) J17M-0322: The map showed no mark indicating a tumor, however the referring physician in Panama City documented slides I-2A1 and I-2A2 were "+". C) J19M-065: The map showed no mark indicating a tumor, however the referring physician in Panama City documented slide I-2A was "+". 4. As interviews continued at approximately 12:50 PM, and again at 2:55 PM, the MOHS Tech and the OA were unsure whether the above examples were actual discrepancies; the Laboratory Director was not available for an interview due to his MOHS surgical schedule. The surveyor asked about the signature at the bottom of the report; the OA stated it was signed by the reviewing physician in Panama City. The surveyor then asked if the Laboratory Director signed and dated the reports to document his review and assessment of the returned "Proficiency Testing" results to determine if corrective actions were required for any discrepant diagnoses in the MOHS surgical slide interpretations by the outside physician. The OA stated the Lab Director "looked" at the reports, however he did not sign them. The surveyor explained the laboratory needed to implement a mechanism to compare the laboratory's results with those of the outside pathologist / reviewing surgeon with corrective actions documented for any discrepancies, and the Laboratory was required to document his review of the returned results. SURVEYOR ID#32558 Licensure and Certification Surveyor