

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2101230	(X3) Date Survey Completed 11/13/2019
Name of Provider or Supplier Southeastern Dermatology Group Pa	Street Address, City, State 201 A Longwood Drive Se, Huntsville, 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
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 MOHS Tech, the surveyor determined the Laboratory Director (also the Testing Personnel) failed to document reviews (as indicated by his signature and date) of the returned "Proficiency Testing" results, and further failed to determine if corrective actions were required for any discrepancies in the MOHS surgical slide interpretations by the outside physician, as per laboratory policy. This was noted on six out of six 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" form and signed the reports for the first, second and third quarters of 2018 and 2019. There was no evidence (signature and date) the returned results had been reviewed by the Laboratory Director or a qualified designee. 2. A review of the Quality Assurance policy revealed, "... Once the outside Laboratory Director has reviewed the cases given, he/she will notate any discrepancies and comment on the case quality. The slides will be returned and the Laboratory Director will sign off on receipt of the Peer Review and notate any discrepancies at that time. ...". 3. In an interview on 11/13/2019 at 10:25 AM, the surveyor reviewed the above noted findings with the MOHS Tech who confirmed the</p>

laboratory had not been following their policy which required documentation of review and evaluation of the returned slide results. SURVEYOR ID #32558 Licensure and Certification Surveyor