

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2249215	(X3) Date Survey Completed 08/16/2022
Name of Provider or Supplier Advanced Dermatology And Cosmetic Surgery	Street Address, City, State 340 Heald Way Ste 238, The Villages, FL	
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
D0000	At the time of the announced onsite initial survey, Advanced Dermatology and Cosmetic Surgery, was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493.
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 record review and staff interview, the laboratory failed to have an effective quality assurance (QA) protocol in place to monitor when the Hematoxylin, Water, Acid Alcohol, Bluing, 95% Alcohol, Eosin, and Xylene Substitute stains/reagents used for Mohs testing were not changed per company policy for one of three weeks reviewed in June 2022. Findings include: Record review of the document titled "Advanced Dermatology V.Colony Location Mohs Log" shows 15 patients had Mohs surgery on June 15th, 2022. Record review of the document titled "H E Stain Log" dated June 22, shows a letter "N" (New) on June 8th and June 22nd. Record review of the laboratory policy titled "Quality Control Maintenance" revised on 2/2/2021 states "The stains and reagents must be filtered daily and changed weekly. The histotechnician on duty must initial the appropriate blank for the date of the performance." There was no documentation on the "H E Stain Log" on June 15th showing the Hematoxylin, Water, Acid Alcohol, Bluing, 95% Alcohol, Eosin, and Xylene Substitute had been changed. During the interview with the Office Manager on 8/16/22 at 2:00pm, it was confirmed that there was no documentation showing the stains/reagents were changed on June 15th, 2022.</p>