

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0689176	(X3) Date Survey Completed 08/30/2018
Name of Provider or Supplier Dermatology Associates Lancaster Ltd	Street Address, City, State 1650 Crooked Oak Drive, Lancaster, PA	
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
D5409	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory competency policy, personnel competency assessment records and interview with the Laboratory Director (LD), Compliance Officer (CO) and Testing personnel (TP) #10, the laboratory failed to follow their written competency assessment policy to assess testing personnel and consultant yearly competency assessment for 2 of 10 TP in 2017. Findings Include: 1. Point #3 of the Laboratory's Competency Policy states, "Competency will be asses 6 months after initial competency then one year there after" and point # 4 states, "Supervisory performance will also assess for Technical consultant and general supervisory as part of competency. 2. On the day of survey, 08/30/2018, while reviewing personnel competency assessment records, it was discovered that the TP # 10 (Mohs grossing technologist) competency was not assessed and TP# 2 (on CLIA 209 hold positions of, Clinical Consultant, Technical consultant, and general supervisor) was not assessed for their regulatory responsibilities in 2017. 3. The LD and CO confirmed the findings above on 8/30/2018 around 9:45 am.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:

Based on tour of the MOHS laboratory, observation of Tissue Marking Dye bottles, interview with the Laboratory Director (LD), Compliance Officer (CO) and Testing Personnel #10, the laboratory failed to label 5 of 5 bottles and aliquots of Davidson Tissue Marking Dyes with open and expiration dates. Findings Include: 1. On the day of survey, 08/30/2018, while on tour of the MOHS laboratory, it was discovered that the laboratory does not write the open and expiration date of Davidson Tissue Marking Dyes in use. 5 of 5 bottles were found on site. 4. The LD and CO confirmed the findings above on 08/30/2018 around 10:00 am.