

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1103654	(X3) Date Survey Completed 11/20/2019
Name of Provider or Supplier Skin And Cancer Associates Llp	Street Address, City, State 2925 Ne 199 Street, Ste 205, Aventura, 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	An announced CLIA recertification survey was conducted at Skin and Cancer Associates LLP on 11/20/19. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observations and interview with the Risk Manager the laboratory failed to dispose of alcohol, xylene substitute, and eosin reagents per the manufacturers' instructions for at least 2 (2017-2019) out of 2 years reviewed. Findings Included: During a tour of the laboratory on 11/20/19 at 10:30 AM it was observed alcohol, xylene substitute, and eosin in the flammable cabinet. No chemical waste container was observed. Interview with the Risk Manager on 11/20/19 at 10:30 AM revealed that the chemicals were dumped down the drain in the sink for disposal. Review of the label on the bottle of all 3 chemicals revealed that the manufacturers' instructions state "Dispose of contents/container to an approved waste disposal plant."</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview with the Risk Manager the laboratory failed to verify the accuracy of testing of Histopathology for 1 (2018) out of 2 years (2018-2019) reviewed. Findings Included: Review of the policy for "MOHS Proficiency Testing" revealed that "Semi-annually, 2 cases will be randomly selected by the histotechnologist and will be submitted to a Board-Certified Dermatopathologist /Dermatologist for review." Review of the peer review revealed that in 2018 it was only done on 12/24/18. Interview on 11/20/19 at 11:00 AM the Risk Manager confirmed that the peer review was only done once in 2018.