

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2167996	(X3) Date Survey Completed 03/02/2021
Name of Provider or Supplier Hightower Dermatology	Street Address, City, State 957 E Del Webb Blvd Ste 101, Sun City Center, 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 Hightower Dermatology on 03/02/2021. 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, record review, and interview with the General Supervisor the laboratory failed to dispose of Eosin, 95% Reagent Alcohol, and Xylene Substitute per the manufacturer instructions since 10/02/2019. Findings Included: During a tour of the laboratory on 03/02/2021 at 12:30 PM it was observed that there was no chemical waste container in the flammable cabinet. Review of the manufacturer instructions on the bottle of Eosin, 95% Reagent Alcohol, and Xylene Substitute stated to "Dispose of contents/container to an approved waste disposal plant." On 03/02/2021 at 12:30 PM, the General Supervisor confirmed that the Eosin, 95% Reagent Alcohol, and Xylene Substitute were disposed of down the sink.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview with the General Supervisor, the laboratory failed to have competency evaluations on the General Supervisor and Testing Person #B since 10/02/2019. Findings Included: Review of the CMS 209 (signed by the Laboratory Director on 03/02/2021) revealed that the General Supervisor was also Testing Person #B. Review of personnel records revealed no competency evaluations for the General Supervisor and Testing Person #B since 10/02/2019. On 03/02/2021 at 1:30 PM, the General Supervisor confirmed that there was no competency evaluations done for him as General Supervisor or Testing Person.