

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1096817	(X3) Date Survey Completed 08/23/2023
Name of Provider or Supplier Clark Dermatology	Street Address, City, State 1075 Central Avenue, Clark, NJ	
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
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 surveyor observation of the laboratory reagents and interview with the Office Manager (OM), the laboratory failed to ensure protection from chemical and physical hazards from 9/13/21 to the date of survey. The findings include: 1. All flammable and inhalation risk reagents were not kept in a flammable cabinet. 2. Five containers of 100% alcohol reagent, one container of Histoclear reagent and two containers of Xylene reagent were observed under the sink in the laboratory. 3. The OM confirmed on 8/23/23 at 2:00 pm that the laboratory did not ensure protection from chemical and physical hazards.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), the lack of a Reagent Tracking Log and interview with the Office Manager (OM), the laboratory failed to provide documented evidence for the procedure "Statement of Policy" Letter C from 9</p>

/13/21 to the date of survey. The findings include: 1. The procedure states "Reagents and other supplies must be inspected at time of delivery." 2. There was no documented evidence the above mentioned procedure was followed. 3. The OM confirmed on 8/23/23 at 1:45 pm that the laboratory failed to have documented evidence that reagents were inspected at time of delivery.