

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2186296	(X3) Date Survey Completed 05/22/2024
Name of Provider or Supplier Natural Image Skin Center	Street Address, City, State 201 S Livingston Ave, Livingston, 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
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), observation of Staining Station (SS) and interview with the Office Manager (OM), the laboratory failed to follow the PM for Hematoxylin-Eosin (HE) staining from 7/26/22 to the date of the survey. The findings include: 1. The procedure in the PM "Hematoxylin and Eosin Staining Procedure" Does not match the order of the labeled coplin jars in the SS. 2. The OM confirmed on 5/22/24 at 1:00pm the laboratory did not follow the PM.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the microscope, maintenance records and interview with the Office Manager (OM), the laboratory failed to perform and document annual maintenance on the microscope used in Moh's testing from October 2022 to the date of the survey. The OM confirmed on 5/22/24 at 1:35 pm there was no documented evidence that annual maintenance was performed.</p>