

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D1045440	(X3) Date Survey Completed 08/16/2021
Name of Provider or Supplier Shoreline Skin Corporation	Street Address, City, State 3427 Superior Ave, Sheboygan, WI	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with staff, the laboratory has not documented and retained records of reagents and stains used in testing including lot numbers and expiration dates. Findings include: 1. Review of laboratory records showed reagent inventory logs that were not completed. No reagent inventory records were available for the last two years. 2. Interview with staff A on August 16, 2021 at 10:15 AM confirmed the laboratory did not document lot numbers and expiration dates of reagents and stains used for testing in the laboratory. Further interview confirmed the laboratory had no records to show when the eosin or hematoxylin stains or 95 % alcohol had expired.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of laboratory supplies and interview with staff, the laboratory used several expired supplies for slide staining and preparation. Findings include: 1. Observation of stains and supplies in the laboratory on August 16, 2021 at</p>

10:20 AM revealed one bottle of Cover Safe, lot 16012934 with an expiration date of March 29, 2018 was available for use with the stain line. No supply of hematoxylin or eosin stain and no 95% alcohol was available in the laboratory. 2. Interview with laboratory personnel, staff A, on August 16, 2021 at 10:20 AM confirmed the Cover Safe was expired and in use. Further interview confirmed the hematoxylin and eosin stain and 95% alcohol had expired and were discarded.