

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D2033975	<b>(X3) Date Survey Completed</b> 09/22/2022
<b>Name of Provider or Supplier</b> Springville Dermatology And Diagnostics	<b>Street Address, City, State</b> 732 N Main Street, Springville, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, and interview with staff the laboratory failed to have competency performance documentation for 3 out of 3 testing personnel performing KOH testing. The laboratory performs approximately 30 KOH test per year. Findings include: 1. The laboratory failed to have competency performance documentation for 3 out of 3 testing personnel performing KOH testing during 2020, 2021 and 2022. 2. General Supervisor and Laboratory Director confirmed during an interview on 09/22 /2022 at approximately 11:45 a.m., that the laboratory failed to have competency documentation for the 3 testing personnel performing KOH testing.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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 lack of documentation and interview with staff, the laboratory failed to have written procedures for Potassium Hydroxide (KOH) testing. The laboratory performs approximately 30 KOH tests annually. Findings include: 1. The laboratory failed to</p>

have written procedures for KOH testing. 2. General Supervisor and Laboratory Director confirmed during an interview on 09/22/2022 at approximately 11:45 a.m., that the laboratory did not have written procedures for KOH testing.

**D5473**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of stain quality control documentation, and interview with staff, the laboratory failed to document Hematoxylin and Eosin (H&E) staining materials controls. The laboratory performed H&E staining totaling approximately 25 cases per month. Findings include: 1. The laboratory quality control records failed to include histopathology H&E stain quality control for 2020, 2021 and 2022. 2. General Supervisor and Laboratory Director confirmed during an interview on 09/22/2022 at approximately 11:45 a.m., that the laboratory failed to record H&E stain quality controls each day of testing.