

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 35D2213935	<b>(X3) Date Survey Completed</b> 02/21/2024
<b>Name of Provider or Supplier</b> Skin Win Dermatology	<b>Street Address, City, State</b> 1213 15th Ave W Suite 102, Williston, ND	
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>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 observation, policy and procedure manual review, and staff interview, the laboratory failed to develop a written procedure for 1 of 1 provider performed microscopy testing procedure (potassium hydroxide [KOH]). The laboratory performed 26 patient KOH tests since beginning testing on 09/28/23. Findings include: 1. Observation of the microscope reading room on 02/21/24 at 8:15 a.m. showed two containers of 10% KOH and several prepared KOH slides. 2. During interview on 02/21/24 at 8:25 a.m., the laboratory director (#1) and an administrative staff member (#2) confirmed the presence of KOH reagent and prepared slides. Both staff members stated they were not aware providers performed KOH patient testing. 3. During interview on 02/21/24 at 9:30 a.m., an administrative staff member (#2) confirmed Provider #3 had started employment in August 2023 and had performed KOH patient testing. 4. Reviewed on 02/21/24, the laboratory's procedure manual failed to include a procedure for KOH testing. Upon request, the laboratory failed to provide a KOH testing procedure.</p>
<b>D6102</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated</p>

that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on observation, staff interview, and policy and procedure manual review, the laboratory director failed to ensure 1 of 1 potassium hydroxide (KOH) testing personnel (Provider #3) received the appropriate training and demonstrated reliable performance to provide and report accurate results. Provider #3 performed 26 patient KOH tests since 09/28/23. Findings include: 1. Observation of the microscope reading room on 02/21/24 at 8:15 a.m. showed two containers of 10% KOH and several prepared KOH slides. 2. During interview on 02/21/24 at 8:25 a.m., the laboratory director (#1) and an administrative staff member (#2) confirmed the presence of KOH reagent and prepared slides. Both staff members stated they were not aware providers /testing personnel performed KOH patient testing. 3. During interview on 02/21/24 at 9:30 a.m., an administrative staff member (#2) confirmed Provider #3 had performed KOH patient testing since beginning employment in August 2023. The laboratory director (#1) confirmed the laboratory failed to document KOH training and competency for Testing Personnel #3. 4. Reviewed on 02/21/24, the laboratory's policy and procedure manual failed to include a policy requiring training and demonstrated competency for testing personnel before starting patient testing.