

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D2213935	(X3) Date Survey Completed 07/07/2025
Name of Provider or Supplier Skin Win Dermatology	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document all verification activities for 1 of 1 analyte (Mohs testing). The laboratory performed 149 Mohs procedures since July 2024. Findings include: 1. Reviewed at 3:30 p.m. on 07/07/25, the verification activities for Mohs procedures failed to include documentation the laboratory reviewed unsatisfactory findings and took corrective action. 2. During interview at approximately 4:00 p.m. on 07/07/25, the laboratory director (#1) confirmed the laboratory did not document the review of unsatisfactory verification activities and the corrective action taken. 3. The laboratory failed to provide a policy regarding verification activities.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria</p>

for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on observation, policy and procedure manual review, and staff interview, the laboratory failed to develop written policies and procedures to describe the frequency to change stains used for 1 of 1 analyte (Mohs testing). The laboratory performed 149 patient Mohs tests since July 2024. Findings include: 1. Observation of the Mohs specimen preparation room at 2:05 p.m. on 07/07/25 showed stain used for Mohs procedures on the counter by the sink. 2. The laboratory failed to provide written policies and procedures to describe the frequency staff are to change the stains. 3. During an interview at 2:10 p.m. on 07/07/25, a staff member (#3) stated staff would not change the H&E (Hematoxylin and Eosin) stains on 07/07/25 due to Mohs procedures scheduled for 07/08/25. 4. During an interview at 4:40 p.m. on 07/07/25, an administrative staff member (#2) stated "Most [histotechs] change [H&E stains] after every use, some histotechs won't change [H&E stains] if Mohs testing [is performed] the next day." 5. The laboratory failed to provide package inserts for H&E stains.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation, policy and procedure manual review, and staff interview, the laboratory failed to appropriately label 10 of 12 Mohs staining containers (containers 1-5, 7, 9-12). The laboratory performed 149 patient Mohs tests since July 2024. Findings include: 1. Observation in the Mohs specimen preparation room at 2:05 p.m. on 07/07/25 showed 12 filled containers by a sink with ten Mohs staining containers without legible identification. 2. During interview at approximately 2:05 p.m. on 07/07/25, a staff member (#3) confirmed staff did not label Mohs staining containers (container #1 - xylene, container #2 - xylene, container #3 - alcohol 100%, container #4 - alcohol 100%, container #5 - alcohol 100%, container #7 - alcohol 100%, container #9 - bluing, container #10 - H2O (water), container #11 - hematoxylin, and container #12 - H2O) in a legible manner. 3. Reviewed on 07/07/25, the laboratory's policy and procedure manual failed to include a policy related to proper labeling of the Mohs staining containers.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and staff interview, the laboratory director failed to establish and maintain a quality assurance program for 18 of 18 months reviewed (February 2024 - July 2025). (Refer to D6093.) The cumulative effect of this failure limited the laboratory director's ability to ensure the quality of laboratory services provided.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director failed to ensure the establishment and maintenance of a quality assessment program for 18 of 18 months reviewed (February 2024 - July 2025). Findings include: 1. Reviewed at 4:50 p.m. on 07/07/25, the laboratory's records lacked evidence of a quality assessment program. The laboratory did not establish and maintain quality assessments for the general laboratory system, pre-analytic system, analytic system, and post analytic system from February 2024 - July 2025. 2. During interview at 4:56 p.m. on 07/07/25, an administrative staff (#2) confirmed the laboratory had not completed quality assessment measures from February 2024 - July 2025. 3. Upon request, the laboratory did not provide a policy for a quality assessment program for the laboratory.