

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D2317394	(X3) Date Survey Completed 02/24/2026
Name of Provider or Supplier Skin Win Dermatology	Street Address, City, State 3712 Lockport St Suite B, Bismarck, 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	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to evaluate all verification activities for 1 of 1 analyte (Mohs testing). The laboratory performed 80 Mohs procedures over the last year. Findings include: 1. Reviewed at 12:34 p.m. on 02/24/26, the Laboratory Director failed to provide evaluation of verification activities for Mohs procedures. 2. During interview at 1:29 p.m. on 02/24/26, a staff member (#1) stated the Laboratory Director's peer review was sent to another dermatology lab on 08/07/26 but the peer review was never returned to the Laboratory Director. 3. Upon request, the laboratory failed to provide a policy related to peer review evaluations.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by:

	Based on record review and staff interviews, the laboratory failed to document the laboratory temperature and relative humidity for 7 of 8 patient testing days (09/09/25, 10/20/25, 10/21/25, 11/17/25, 11/18/25, 01/29/26, and 01/30/26) reviewed since August 2025. Findings included: 1. Reviewed at 12:45 p.m. on 02/24/26, the laboratory failed to document humidity readings on the Laboratory Temperature (Range: 68°F to 80°F) & Humidity (Less than 60%) Log (Laboratory Temperature and Humidity Log) on 09/09/25, 10/20/25, 10/21/25, 11/17/25, and 11/18/25. 2. During interview at 1:29 p.m. on 02/24/26, a staff member (#1) confirmed the laboratory performed Mohs testing on 01/29/26 and 01/30/26. 3. Reviewed at 1:29 p.m. on 02/24/26, the laboratory failed to document temperature and humidity readings on the Laboratory Temperature and Humidity Log on 01/29/26 and 01/30/26. 4. During interview at 2:15 p.m., the Laboratory Director (#2) confirmed the laboratory failed to document temperature and humidity readings on 09/09/25, 10/20/25, 10/21/25, 11/17/25, 11/18/25, 01/29/26, and 01/30/26. 5. Reviewed at 2:15 p.m., the undated Laboratory Temperature and Humidity Log, stated, "Room temperature & humidity will be documented after QC slide is completed. . . ."
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, policy review, and staff interview, the Laboratory Director failed to maintain a quality assurance program for 5 of 5 months reviewed (September 2025 through January 2026). (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, policy review, and staff interview, the Laboratory Director failed to ensure the maintenance of a quality assessment program for 5 of 5 months reviewed (September 2025 - January 2026). Findings include: 1. Review of Quality Assurance (QA) documents at 12:37 p.m. on 02/24/26, showed the laboratory failed to complete Quality Assurance in December 2025. 2. Reviewed at 12:39 p.m. on 02/24/26, the "Policy for QA", dated 08/19/25, stated, ". . . The COO (Chief Operating Officer) or lab director will confirm the QA has been completed in both June and December of each year. . . ." 3. During interview at 1:29 p.m. on 02/24/26, a staff member (#1) confirmed the laboratory had not completed quality assessment measures in December 2025.