

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2223140	(X3) Date Survey Completed 10/27/2025
Name of Provider or Supplier Mi Skin Center	Street Address, City, State 133 W Main Street Suite 251, Northville, MI	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) 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 observation and interview with the Practice Administrator (PA), the laboratory failed to ensure that three bottles of reagents used for histopathology tissue examination were not available for use beyond their expiration dates. Findings include: 1. On 10/27/2025 at 9:45 am, during a tour of the laboratory, the surveyor observed the following expired reagents: a. 1 of 1 bottle of Delasco Liquified Phenol with an expiration date of 8/1/2025. b. 1 of 1 bottle of CoverSeal -T with an expiration date 8/3/2025. c. 1 of 1 bottle of 70% Isopropyl Alcohol with an expiration date of 04 /2016. 2. An interview with the PA on 10/27/2025 at 9:50 am confirmed the reagents were expired.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Practice Administrator (PA), the laboratory failed to establish verification of performance for histopathology microscopic tissue examinations prior to reporting patient results for 4 (July 2025 to October 2025) of 4 months reviewed. Findings include: 1. A record review of 7 patient test reports revealed that verification of performance had not been conducted prior to reporting patient test results since testing began in July 2025 for the following patients: a. Patient 1 with a testing date of 07/23/2025. b. Patient 2 with a testing date of 07/23/2025. c. Patient 3 with a testing date of 08/28/2025. d. Patient 4 with a testing date of 09/25/2025. e. Patient 5 with a testing date of 09/25/2025. f. Patient 6 with a testing date of 10/23/2025. g. Patient 7 with a testing date of 10/23/2025. 2. The surveyor requested documentation for verification of performance for histopathology microscopic tissue examinations; however, it was not provided. 3. An interview with the PA on 10/27/2025 at 2:00 pm confirmed that verification of performance testing had not been conducted prior to reporting patient results.