

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1015730	(X3) Date Survey Completed 08/06/2025
Name of Provider or Supplier Livonia Dermatology	Street Address, City, State 14801 Farmington Road, Livonia, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Mohs Tech (MT), the laboratory failed to ensure staff protection from chemically hazardous materials by not storing hazardous chemical reagents in accordance with the laboratory's policy for 6 of 6 bottles of chemical reagents observed. Findings include: 1. During a tour of the laboratory on 08/06/2025 at 9:30 AM, the surveyor observed the following six (6) bottles of hazardous chemical reagents stored on an open shelf: a. One (1) bottle of Medical Chemical Corporation (MCC) Xylene b. One (1) bottle of Epredia Clarifier c. One (1) bottle of Medline 95% Reagent Grade Alcohol d. One (1) bottle of Epredia 100% Dehydrant e. One (1) bottle of Astral Diagnostics Eosin Y 1% Alcoholic f. One (1) bottle of Gill 3 Hematoxylin 2. A review of the laboratory's policy Standard Operating Procedures, section titled "Hazardous Materials", revealed: a. "ALL HAZARDOUS MATERIALS AND REAGENTS ARE TO BE STORED IN THE FIRE SAFETY CABINET." b. "Current hazardous materials including: 1. Xylene 2. Denatured ethanol (alcohol) 3. Hematoxylin 4. Eosin 5. Mounting medium 6. Isopropyl alcohol 7. Reagent alcohol " 3. An interview conducted with the MT on 08/06/2025 at 1:10 PM confirmed that hazardous chemical reagents were not stored in the fire safety cabinet as required by laboratory policy.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or</p>

procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Mohs Technician (MT), the laboratory failed to verify the accuracy of its testing at least twice annually for Periodic Acid-Schiff (PAS) testing for 3 (of 3 biannual periods reviewed. Findings include: 1. A review of the laboratory's twice annual verification of accuracy documentation revealed lack of documentation of twice-annual verification of accuracy testing for PAS testing during the following periods: a. Second (2nd) biannual period of 2023 b. First (1st) biannual period of 2024 c. Second (2nd) biannual period of 2024 2. On 08/06/2025 at 1:00 PM, a request was made to the MT to review the PAS patient log and confirm the number of patients tested during the above periods. The MT reviewed the log and reported that 19 patients underwent PAS testing during these timeframes. 3. An interview conducted on 08/06/2025 at 1:10 PM, the Mohs Technician (MT) confirmed that verification of accuracy testing for PAS had not been performed for the above periods.

D6084

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(2)

provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Mohs Tech (MT), the laboratory director failed to notify the Department of Health and Human Services (HHS) and the State Agency (SA) of termination of Periodic Acid-Schiff (PAS) testing after cessation of testing for 9 of 9 months since testing ceased. Findings include: 1. A record review of the laboratory's Quality Control and Maintenance Records revealed that PAS testing was discontinued in November of 2024. 2. As of the date of survey, 08/06/2025, no documentation was available to demonstrate that HHS or the SA had been notified of the termination of PAS testing which exceeds the required six (6) month notification period by three (3) months. Notification requirements at 493.51(c) state laboratories are to notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance. 3. During an interview conducted on 08/06/2025 at 1:30 PM, the Mohs Technician (MT) confirmed that PAS testing was discontinued in November 2024 and that no notification had been made to HHS or the SA.