Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2028847	10/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Great Lakes Medical Laboratories Inc	13530 Michigan Avenue Suite 248, Dearborn, 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	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Technical Supervisor (TS), the laboratory failed to follow its established safety policy for 10 bottles of chemically hazardous materials. Findings include: 1. On 10/13/2025 at 1:30 pm, the surveyor observed flammable reagents stored in a non-flammable cabinet including: a. Three (3) unopened bottles of Dynamic Xylene b. Three (3) unopened bottles of Dynamic 100% Ethyl Alcohol c. Three (3) unopened bottles of Dynamic 95% Ethyl Alcohol d. One (1) bottle of astraldiagnostics Quick III fixative with Methanol 2. A review of the laboratory's policy titled "Safety" revealed that the first paragraph under "Purpose" states: "The Laboratory Department endorses the standard Safety Management Programs and guidelines as recommended by the College of American Pathologists and the Department of Human Services of the State of Michigan." 3. An internet search of the Safety Data Sheets (SDS) for Dynamic Xylene, Dynamic 95% Ethyl Alcohol, Dynamic 100% Ethyl Alcohol, and astraldiagnostics Quick III Fixative (methanol) revealed that all products are classified as highly flammable liquids and vapors. Each requires storage in a locked flammable storage cabinet to ensure proper safety and compliance with flammable material storage requirements. 4. During an interview conducted on 10/13/2025 at 5:00 pm, the TS confirmed that, according to the laboratory's policy and the Safety Data Sheets (SDS) for the reagents, the flammable chemicals were not stored in a flammable safety cabinet as required.
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 and interview with the Technical Supervisor (TS), the laboratory failed to ensure that 14 reagents were labeled with expiration dates and content identification for Histopathology and Non-GYN Cytology tissue examination. Findings include: 1. On 10/13/2025 at 1:25 pm, during a tour of the laboratory, the surveyor observed 14 reagents that were not labeled with expiration dates and 4 without content identification as follows: a. 13 reagents onboard the VIP Tissue Tek stored in secondary containers were not labeled to reflect expiration dates and 4 were not labeled with contents: 1. Secondary container labeled "10% Formalin 1" without an expiration date. 2. Secondary container labeled "10% Formalin 2" and no expiration date. 3. Secondary container labeled "80% ALC 3" without an expiration date. 4. Secondary container of unknown contents labeled "95% 4" without an expiration date. 5. Secondary container of unknown contents labeled "95% 5" without an expiration date. 6. Secondary container labeled "ALC 100% 6" without an expiration date. 7. Secondary container labeled "ALC 100% 7" without an expiration date. 8. Secondary container labeled "ALC 100% 8" without an expiration date. 9. Secondary container with contents and strength illegible without an expiration date. 10. Secondary container labeled "XXL Xylene 10" without an expiration date. 11. Secondary container labeled "Xylene 15" without an expiration date. 12. Secondary container labeled "100%" with illegible contents 13. Secondary container labeled "Tap H2O 17" without an expiration date. b. A secondary container labeled "Formalin" stored on countertop without an expiration date. 2. A request made on 10 /13/2025 at 1:35 p.m. for the reagent log documenting lot numbers, receipt dates, and expiration dates was not provided prior to survey exit. 3. An interview on 10/13/2025 at 1:45 pm with TS confirmed that reagents were not labeled with expiration dates and content identification.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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. This STANDARD is not met as evidenced by: . Based on observation and interview with the Technical Supervisor (TS), the laboratory failed to ensure that two bottles of reagents used for Histopathology tissue examination were not available for use beyond their expiration dates. Findings include: 1. On 10/13/2025 at 1:45 pm, the surveyor observed the following expired reagents: a. 1 bottle 3% Acetic Acidic Solution with an expiration date of 4/12/2025. b. 1 bottle of astraldiagnostics Methanol Quick III fixative with an expiration date 9/15 /2024. 2. An interview with TS on 10/13/2025 at 1:45 pm confirmed the reagents were expired.

D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: . Based on observation and interview with the Technical Supervisor (TS), the laboratory failed to perform and document maintenance for the laboratory hood for 26 (August 2023 through October 2025) of 26 months reviewed. Findings include: 1. On 10/13/2025 at 1:50 pm, the surveyor observed the laboratory hood and noted that no maintenance or certification stickers were affixed to the equipment. 2. The surveyor requested maintenance records for the laboratory hood; however, no documentation was provided for review. 3. On 10/13/2025 at 5:00 pm an interview conducted with the TS confirmed that service or certification had not been performed on the laboratory hood.