

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2028847	(X3) Date Survey Completed 07/17/2023
Name of Provider or Supplier Great Lakes Medical Laboratories Inc	Street Address, City, State 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to retain temperature monitoring records for at least 2 years for 12 (January - December 2022) of 19 months reviewed. Findings include: 1. A review of the laboratory's temperature monitoring records revealed a lack of records between January - December in 2022. 2. When queried on 7/13/2023 at 12:43 pm, the Laboratory Director was not able to provide the surveyor the documents requested. 3. An interview on 7/13/2023 at 12:43 pm, the Laboratory Director confirmed the laboratory did not retain temperature monitoring records from January - December in 2022.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with the Laboratory Director (LD), the</p>

laboratory failed to ensure staining reagents used in histopathology testing's pour-off tubes were labeled with the concentration, preparation, and expiration dates for 4 (Schiff Stain Solution, Iron, Gomori Prussian Blue Stain, and MassonTrichrome, and Aniline Blue Stain) of 4 staining kits observed in the laboratory. Findings include: 1. The surveyor observed the following pour-off tubes in the laboratory that did not include the preparation and expiration dates for the special stains on 7/13/2023 at 8:23 am during a tour of the laboratory: a. Schiff Stain Solution - pour off tube labeled with only the name. b. Iron, Gomori Prussian Blue Stain Kit - pour off tubes labeled with L41 and Red. c. Masson Trichome - pour off tubes labeled with Bouin fluid, Weigert Iron Hematox, Biebrich Scarlet Acid, and Phos, Phos Acid. d. Aniline Blue Stain Kit - pour off tubes labeled with Aniline Blue 2. The surveyor observed the labeling on the Acetic Acid pour-off tube for the Aniline Blue staining did not contain the concentration, preparation, and expiration date on 7/13/2023 at 8:23 am during a tour of the laboratory. 3. An interview on 7/13/2023 at 8:23 am the Laboratory Director confirmed the reagents listed above did not have all the required elements on the pour-off tubes.