

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2169618	(X3) Date Survey Completed 04/18/2022
Name of Provider or Supplier Great Lakes Foot And Ankle	Street Address, City, State 32743 23 Mile Rd Suite 110, Chesterfield, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #2 (TP2), the laboratory failed to establish written procedures for microscopic tissue evaluations for 6 (October 2021 to April 2022) of 6 months since the laboratory added microscopic tissue examination testing. Findings include: 1. A review of the laboratory's patient test reports revealed the laboratory had added microscopic tissue examination testing in October 2021. 2. A review of the laboratory's procedure manual revealed a lack of an established procedure for the performance of microscopic tissue examinations. 3. An interview on 4/18/22 at 3:53 pm with TP2 confirmed the laboratory had not established a procedure for the performance of microscopic tissue examinations.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p>

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #2 (TP2), the laboratory failed to ensure daily maintenance was performed each day of patient testing for 2 (2/10/21 and 2/24/22) of 9 patient testing dates reviewed. Findings include: 1. A review of 9 patient test records and daily maintenance records revealed the following dates patient testing was performed when daily maintenance for the tissue processor, tissue embedding system, flotation bath, rotary microtome, and automated stainer had not been performed: a. 2/10/21 b. 2/24/22 2. A review of the laboratory's "Tissue Processing- Tissue Tek VIP 5 Tissue Processor" procedure revealed a section titled "General Maintenance" stating, "Every use clean the inside of the retort, retort rim and lid gasket by wiping with gauze. Insept gasket for deterioration. Change water in fume control system. Clean outlet filter- unscrew counterclockwise, remove from retort, remove any debris, thoroughly clean by soaking in clearant, dry and reinstall filter." 3. A review of the laboratory's "Embedding- Tissue TEC 5 Tissue Embedding Console System" revealed a section titled "Procedure" stating, "At the end of embedding, all residual paraffin will be scrapped off the embedding center. The unit can be cleaned with gauze or soft cloth slightly moistened with clearant. Dry and polish with gauze or soft cloth. Waste drawer should be emptied weekly. Clean forcep holder with a cotton swab. Cooling plate should be cleaned and dried after each use. The temperature of the paraffin is taken and recorded every workday. Maintain paraffin temperature 2-4 degrees above the manufacturers recommended melting point." 4. A review of the laboratory's "Flotation Bath- Boekel Round Tissue Bath" procedure revealed a section titled "Quality Control" stating, "Daily cleaning temperature recording" and "Document maintenance of floatation bath." 5. A review of the laboratory's "Microtomy Leica Rotary Microtome RM2235" procedure revealed a section titled "Maintenance" stating, "At the end of the day the microtome will be thoroughly cleaned. All paraffin rolls and tissue debris will be brushed off the machine." 6. A review of the laboratory's "Tissue Tek Prisma Automated Stainer" procedure revealed a section titled "Daily/Every workday" stating, "Keep outside clean by wiping with damp cloth. Rotate reagents as needed. Filter Hematoxylin and Eosin. Check temperature." 7. An interview on 4/18/22 at 3:50 pm with TP2 confirmed the laboratory had not documented maintenance on the dates listed above.