

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0935056	(X3) Date Survey Completed 07/12/2023
Name of Provider or Supplier Mid America Pathology Services	Street Address, City, State 725 Lakefront Ct Suite B, Carmel, IN	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation, document review, and interview, the laboratory failed to perform and document maintenance (per manufacturer's instructions) for two of two pieces of laboratory equipment (Embedder-Sakura and Stainer-Leica). Findings include: 1) During tour of the laboratory on 7/12/23 at 10:45 am, a Sakura Embedder (Serial number=47091777) and a Leica Stainer (Serial number=0845) were observed to be in use. 2) Review of manufacturers' instructions for the Embedder and Stainer read: a) Embedder-Sakura (section 6.1)- "...6.1 Cleaning the instrument Clean interior stainless steel surfaces with detergent and rinse with water. Clean the head covers by wiping with a damp cloth....Wipe the control panel carefully with a damp cloth. 6.1.1... Wash containers...Remove the wash containers and clean with detergent. 6.1.2... Reagent containers...Wash in warm water with detergent 6.1.3...Slide racks...Clean with detergent or laboratory cleaning agent as required 6.1.4...Periodically check the wax tray at the bottom of the oven and clean it if excessive wax dripping has occurred..." b) Stainer-Leica (page 7.1)- "...Routine Maintenance Chart...Daily...1) Replenish Paraffin...2) Remove Spilled Paraffin/Debris from insulated workspace and hot plate area...3) Turn off compressor...4) Remove condensate from cooling plate..." "...Periodic and As Required...1) Clean Paraffin Bath, Paraffin Chamber and Filter, Forceps Wells, Exterior Surfaces and Ventilation Panels, Waste Drawer, and Chamber storing Base Molds; add clean Paraffin...2) Clean Magnifying Lens Assembly...3) Clean exterior surfaces..." 3) Review of maintenance logs for the above equipment, SP-2 (General Supervisor) indicated none were available. 4) In interview on 7/12/23 at 3:28 pm, SP-2 (General Supervisor) confirmed the above manufacturers'</p>

maintenance procedures were not being performed nor documented. SP-2 also confirmed the laboratory had no policies on the above procedures. 5) Total annual Histopathology tests=35,000.

D6084

LABORATORY DIRECTOR RESPONSIBILITIES

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

The laboratory director must ensure that the physical plant and environmental conditions 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 observation, document review, and interview, the laboratory director failed to ensure hazardous waste/toxic chemicals (100% Alcohol, Acetone, and Schiff Reagent) were not being disposed of down a sink where an eyewash was mounted for one of two eyewashes observed in the laboratory. Findings include: 1) During tour of the laboratory on 7/12/23 at 10:45 am, an eyewash was observed mounted on a sink where hazardous waste/toxic chemicals (100% Alcohol, Acetone, and Schiff Reagent) were being disposed. 2) The following MSDS (Material Safety Data Sheets) sheets read: a) 100% Alcohol (page two of eight): "...Eye contact: Immediately flush eye with water for at least 15 minutes..." b) Acetone (page one of seven): "...IF IN EYES: Rinse cautiously with water for several minutes..." c) Schiff Reagent (page two of seven): "...Eye Contact IF IN EYES: Rinse cautiously with water for several minutes..." 3) In interview on 7/12/23 at 10:45 am, SP-2 (General Supervisor) confirmed an eyewash was mounted on a sink where the three above hazardous chemicals were also being disposed. 4) Total annual Histopathology tests=35,000.