

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 15D2045592 | (X3) Date Survey Completed 07/31/2023 |
| Name of Provider or Supplier Sbmf/Logansport | Street Address, City, State 1101 Michigan Ave, Logansport, 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, record review and interview, the laboratory failed to perform and document maintenance for two of two microscopes (Olympus BX45 BX45TF and BX40F) used for reading histology slides for five of five (PT1-PT5) patients reviewed. Findings include: 1. During tour of the laboratory on 7-31/2023 at 10:33 am, two microscopes were available for reading histology slides. Olympus BX45, serial number BX45TF was in the main laboratory and Olympus BX45, serial number BX40F was in the pathologist's room. 2. Review of patient records indicated the following patients had slides read without documentation of maintenance for the microscope: a. PT1 test date 3/22/2023, b. PT2 test date 4-4-2023, c. PT3 test date 5-15-2023, d. PT4 test date 6-19-2023, and e. PT5 test date 7-25-2023 3. On 7-31-23 at 1:00 pm upon request for maintenance logs for the two microscopes, SP1 verified that there were no maintenance logs for the Olympus BX45, serial number BX45TF and Olympus BX45, serial number BX40F. 4. Review of the facilities procedure "Microscope Preventive Maintenance", approved and signed by the Laboratory Director on 7-27-2022, page 1of 5, Section II, read, "Pathology microscopes only require an annual preventative maintenance. Monthly and quarterly maintenance is not necessary." This procedure does not contain instructions for daily maintenance of microscopes. 5. The annual test volume for Histology is approximately 1,000 tests.</p> |
| D6084 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2)</p> |

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, record review and interview, the laboratory director failed to ensure three of three hazardous waste/toxic chemicals (Alcohol, "EOSIN Y", Clorox Commercial Solutions Clorox Germicidal Bleach) were not being disposed of down a sink where one of one eyewash was mounted for use. Findings include: 1. During tour of the laboratory on 7-31-2023 at 10:38 am, the following was observed: a) An eye wash station was mounted on the faucet of one of one sink in the laboratory. b) Hazardous waste/toxic chemicals were being used in the laboratory: "Alcohol, Reagent Anhydrous GR ACS", "EOSIN Y" and "Clorox Commercial Solutions Clorox Germicidal Bleach". 2. On 7-31-23 at 10:38 am, SP7 (Medical Technologist) confirmed chemicals used in the processing of staining histology slides are disposed of in the sink with the eye wash. 3. Review of Material Safety Data sheets (MSDS) for each chemical indicates the following for the eye: a) MSDS for "Alcohol, Reagent Anhydrous GR ACS " pg. 2 of 17, Section 4 reads, "After eye contact: rinse out with plenty of water. Call in ophthalmologist." b) MSDS for "EOSIN Y" page 2 of 7, Section 4, 4.1, reads, "Rinse thoroughly with water for at least 15 minutes and consult a physician." c) MSDS for " Clorox Commercial Solutions Clorox Germicidal Bleach" pg. 3 of 10, Section 4, reads, "Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after 5 minutes, then continue rinsing eye. Call poison control center, or doctor for treatment advice." 4. Annual volume of Histopathology tests is 1,000.