

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0357411	(X3) Date Survey Completed 07/26/2023
Name of Provider or Supplier South Bend Medical Foundation/Sjrmc	Street Address, City, State 611 E Douglas Rd, Mishawaka, 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: D5429: 493.1254 Standard: Maintenance and function checks Based on observation, record review and interview, the laboratory failed to perform and document maintenance for one of three microscopes (Olympus BX41 [serial number NF0002522]) used for reading histology and cytology slides for one (PT1) of six patients reviewed. Findings include: 1. On 7/26/203 at 10:44 am, during a tour of the laboratory a microscope Olympus BX41 (serial number NF0002522) was observed ready for slide review in the "Frozen Room". 2. Review patient records indicated Patient PT1 had histology testing performed on February 28, 2023, using the Olympus BX41 (serial number NF0002522). 3. On 7-26-23 at 1:00pm, upon request for all maintenance logs for the Olympus BX41 (serial number NF0002522), SP2 verified that there were no maintenance logs for this microscope. 3. "Microscope Preventive Maintenance" procedure, no approval date by the laboratory director, reads on page 1 of 5, "C. Wipe the oil objective, condenser, and stage with a lens paper after using the microscope. Do not leave the objective/condenser with oil on it..." 4. The annual test volume for Histology and Cytology tests is approximately 800.</p>