

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0357414	<b>(X3) Date Survey Completed</b>  07/10/2024
<b>Name of Provider or Supplier</b>  South Bend Clinic Laboratory	<b>Street Address, City, State</b>  1945 Lincolnway East, South Bend, IN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5429</b>	<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 on one of one Immunology analyzer (Biotek ELx800 /Serial number =208031) for two of two years (July 2022 to July 2024) used for one of twelve patient medical records reviewed (Patient #9). Findings include: 1) During tour of the laboratory on 7/9/24 at 10:29 am, a Biotek ELx800 analyzer was observed in use for Immunology testing. 2) Review of the operator's manual for the Biotek ELx800 read on page 128-135; "...Maintenance...A daily maintenance schedule is the best way to ensure accurate performance and a long life for your instrument. Frequent cleaning of the microplate carrier and all exposed surfaces of the instrument will help to reduce the amount of particulates or dust that can cause erroneous readings. Routine Cleaning Procedure...Purpose...Exposed surfaces may be cleaned (not decontaminated) with a cloth moistened (not soaked) with water or water and a mild detergent...Procedure...1. Turn off and disconnect the instrument from the power supply. 2. Moisten a clean cotton cloth with water, or with water and the mild detergent. Do not soak the cloth. 3. Wipe the plate carrier and all exposed surfaces of the instrument. 4. If detergent was used, wipe all surfaces with a cloth moistened with water. 5. Use a clean, dry cloth to dry all wet surfaces...Replacing the Bulb...The lamp is rated fro an average life of 600 hours. The intensity of the lamp will slowly drop over time until the run time self check detects a low signal level and the instrument displays an error code. The bulb should be replaced and aligned at this time... Decontamination Procedure...Any laboratory instrument that has been used for research or clinical analysis is considered a biohazard and requires decontamination</p>

prior to handling. Decontamination minimizes the risk to all who come into contact with the instrument during shipping, handling, and servicing...Procedure...1. Turn off and unplug the instrument. 2. Prepare an aqueous solution of 0.5% sodium hypochlorite (NaClO), or bleach. As an alternative, 70% isopropyl alcohol may be used if the effects of bleach are a concern...3. Moisten a cloth with the bleach solution or alcohol. Do not soak the cloth. 4. Wipe the keypad (do not soak). Wipe again with a clean cloth moistened with deionized or distilled water. Dry immediately with a clean, dry cloth. 5. Wipe the plate carrier and all exposed surfaces of the instrument. 6. Wait 20 minutes. Moisten a cloth with deionized or distilled water and wipe all surfaces of the instrument that have been cleaned with the bleach solution or alcohol. 7. Use a clean, dry cloth to dry all wet surfaces. 8. Discard the used gloves and cloths using a Biohazard trash bag and an approved Biohazard container..." 3. Review of medical record #9 indicated the following patient was tested for Anti-Sm (Smith Antibody): PT# (pt=patient) Date Result 9 1-2-24 8 Units 4. In an interview on 7/10/24 at 10:25 am, SP-3 (General Supervisor) confirmed the laboratory had not been performing nor documenting maintenance procedures based on manufacturer's instructions and also had no standard operating procedure for maintenance on the Biotek ELx800 analyzer. 5. Annual test volume for Immunology= 11,193.