Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0977972	01/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
South Bend Medical Foundation/Fcl-Allied Physician	53990 Carmichael Dr Suite 200, South Bend, 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
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow their procedure to document the acceptability of the quality control for Toluidine Blue (special stain) used in the subspecialty of Histopathology for two (PT#1 and PT#2) of seven patients reviewed from 1-23-2024 to the date of the survey was conducted on 1-27-2025. Findings Include: 1. Review of documents titled "Surgical Pathology Requisition" indicated the following patients had slides examined by a pathologist without review of "acceptable stain quality" indicated by an unchecked stain quality box documented on the requisitions on 7-15-2024 and 11-27-2024 for two of seven patients: Patients Date of Collection PT #1 07-15-2024 PT #2 11-27-2024 2. Review of Policy and Procedure document titled "Performing Frozen Sections" revised by SP-01 (Quality Supervisor) on April of 2021, under procedures II. Identification of Specimens required, "A. Pathologist will ensure the specimen requisition or other identifying reports" (page 1 of 5) and "B. If the quality of the slide preparation (frozen section ...) is not adequate for intra-operative diagnosis, it is documented in the requisitions." (page 2 of 5). 3. In an interview on 1-27-2025 at 1:50 pm, SP-01 (Quality Supervisor) acknowledged the requisition documentation did not indicate acceptable stain quality for PT#1 and PT#2. 4. The annual test volume for Histopathology is 200.