Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2032624	(X3) Date Survey Completed 04/26/2022
Name of Provider or Supplier Incyte Pathology - Gritman Medical Center Branch	**Street Address, City, State** 700 S Main St, Moscow, ID	

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	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory compliance officer on 4/26/2022, the laboratory failed to perform maintenance on the Leica CM1850 cryostat as defined by the manufacturer and with at least the minimum specified frequency. The findings include: 1. The Leica CM1850 cryostat manual states that the instrument must have the plastic coupling oiled and the specimen cylinder lubricated weekly. 2. A record review of the cryostat maintenance and turnaround log identified that the laboratory failed to document the weekly maintenance required by the manufacturer for the Leica cryostat CM1850. 3. An interview with the laboratory compliance officer on 4/26/2022 at 5:04 pm confirmed that the laboratory failed to document performance of weekly maintenance on the Leica cryostat CM1850. 4. The laboratory reports performing 3 frozen section procedures annually.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of laboratory records and an interview with the laboratory compliance officer on 4/26/2022, the laboratory failed to document daily Hematoxylin and Eosin (H&E) stain quality. The findings include: 1. A review of the cryostat maintenance and turnaround log identified that the laboratory failed to document H&E stain quality each day of testing. 2. An interview with the laboratory compliance officer on 4/26/2022 at 5:22 pm confirmed that the laboratory failed to document H&E stain quality daily. 3. The laboratory reports performing 3 frozen section procedures annually.