Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D2333809	04/29/2026
Name of Provider or Supplier	**Street Address, City, State**	
Incyte Pathology - St Patrick Branch	500 W Broadway St, Missoula, MT	

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
D0000	The Montana CLIA Program conducted an initial survey on April 29, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be in compliance with condition-level CLIA requirements. However, the following standard-level deficiencies were identified during the survey.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) (a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following: (a)(6)(i) Immunohematology reports as specified in 21 CFR 606.160(d). (a)(6)(ii) Pathology test reports for at least 10 years after the date of reporting This STANDARD is not met as evidenced by: Based on record review, patient result reports, and interviews with the laboratory director (LD1) and technical consultants (TC1) (not listed on the CMS-209 Laboratory Personnel Report form), the laboratory failed to retain the digital images used for diagnosis for two of two pathology reports for at least two years from February 5, 2026, to April 29, 2026. Findings: 1. A review of patient result reports (PS-26-03310) revealed digital images were examined onsite and used for the final diagnosis report and addendum report as stated: A. MICROSCOPIC EXAMINATION: Histologic sections of all submitted blocks (or IHC as applicable) are digitally scanned and examined. These findings, together with the gross examination, support the pathologic diagnosis. FINAL DIAGNOSIS PERFORMED BY: Pathologist (LD1) Feb 5 2026 11:29 AM B. ADDENDUM MICROSCOPIC EXAMINATION: Histologic sections of all submitted blocks (or IHC as applicable) are digitally scanned and examined. These findings, together with the gross examination, support the pathologic diagnosis. ADDENDUM #1 PERFORMED BY: Pathologist (LD1) Mar 19 2026 5:44 AM 2. During an interview with LD1 on April

	29, 2026, at 10:45 AM, the state surveyor asked to review the digital images for case PS-26-03310. LD1 stated the images had been deleted and were not retained. 3.A review of the "Laboratory Document and Material Control" policy confirmed the laboratory failed to retain digital images used for pathologic diagnosis for at least two years as the policy states: Material/Record: Digital images used for primary diagnosis; Period of Retention: 30 days if original glass slides are available. 4. During an interview with TC1 (not listed on the CMS 209 Laboratory Personnel Report form) on April 29, 2026, at 10:50 AM, the state surveyor requested the number of digital cases performed onsite. An email response from TC1 on April 7, 2026, at 10:37 PM stated, "These cases are incorporated into the laboratory's overall annual pathology volume tracking and are not differentiated from conventional microscopy case volumes." 5. Based on the Test Volume Sheet, 21,520 pathology patient tests were performed from April 29, 2025, through April 29, 2026.