Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0990466	03/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Billings Dermatology Pc	2294 Grant Road, Billings, 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 announced CLIA recertification survey on March 24, 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.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and an interview with the practice manager (not listed on the CMS 209 Laboratory Personnel Report form), the laboratory failed to perform one of the two required twice-yearly accuracy verifications of its Mohs and routine testing procedures for years 2024 and 2025. Findings: 1. A review of the "Peer Review Calendar" log revealed: 2024: One Mohs case (M23-525) was sent for review on 3-11-24 and one routine case (T24-0342) was sent for review on 3/12/24; no Mohs and routine cases were sent for accuracy verification review during July-December 2024. 2025: One Mohs case (M24-187) and one routine case (T25-0160) was sent for review on 3/17/25; no Mohs and routine cases were sent for accuracy verification review during July-December 2025. 2. A review of the "Mohs Surgery Policies and Procedures" failed to address the twice-yearly accuracy verification. 3. A review of the "Form CMS-116" dated 3/17/26 under "Total Estimated Annual Test Volume" for histopathology revealed 2618 patient tests were performed using Mohs and routine testing procedures. 4. An interview on March 24, 2026, at 12:35 PM with the practice manager (not listed on the CMS 209 Laboratory Personnel Report form) confirmed the laboratory did not perform one of the two twice-yearly accuracy verifications of its Mohs and routine testing procedures for years 2024 and 2025.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: I. Based on observation of the slide staining process in the laboratory and interview with the practice manager (not listed on the CMS 209 Laboratory Personnel Report form), the laboratory failed to label one of one secondary containers with the identity of the reagent, preparation date, and expiration date. Findings: 1. Observation of the laboratory on March 24, 2026, at 1:49 PM revealed one glass container with clear liquid. The container failed to be labeled with the reagent's identity, preparation date, and expiration date. 2. An interview with the practice manager (not listed on the CMS 209 Laboratory Personnel Report form) on March 24, 2026, at 1:49 PM stated the liquid in the secondary container was Histo-Clear and confirmed the container was not labeled. II. Based on observations in the laboratory, record review, and an interview with the practice manager (not listed on the CMS 209 Laboratory Personnel Report form), the laboratory failed to follow the requirement in its Safety Manual to label eight of eight reagents with the appropriate hazards and warnings when aliquoted into secondary containers. Findings: 1. Observation of the laboratory on March 24, 2026, at 1:55 PM revealed: a. Leica TP 1020 (automated tissue processor): Ten of twelve reagent containers were not labeled with the chemcial hazards for formalin, 70% alcohol, 95% alcohol, 100% alcohol, and xylene. b. Leica AutoStainer XL (automated slide stainer): Thirteen of eighteen reagent containers were not labeled with the hazards for xylene, hematoxylin, acid alcohol, eosin, 70% alcohol, 95% alcohol, and 100% alcohol. 2. A review of the laboratory's "Safety Manual" revealed the laboratory staff failed to follow its written "hazard communication plan" and ensure secondary containers were labeled with the appropriate hazards and warnings. 3. An interview with the practice manager (not listed on the CMS 209 Laboratory Personnel Report form) on March 24, 2026, at 1:56 PM confirmed the secondary containers were not labeled with the chemical hazards and warnings as directed by the Safety Manual.