

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0690730	(X3) Date Survey Completed 10/16/2024
Name of Provider or Supplier Associated Dermatology & Skin Cancer Clinic	Street Address, City, State 50 S Last Chance Gulch, Suite 3, Helena, 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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the testing personnel (TP #1), laboratory staff failed to document the intended staining characteristics for each day Tzanck stain was performed on 34 out of 34 patient smears from January 9, 2023, to October 16, 2024. Findings: 1. The laboratory failed to provide documentation of the intended staining characteristics for each day Tzanck stain was performed on patient smears from January 9, 2023, to October 16, 2024. 2. Based on the test volume sheet dated January 9, 2024, 34 patient smears were stained with Tzanck stain. 3. An interview on October 16, 2024, at 10:30 AM with TP #1 confirmed the laboratory staff failed to perform and document the intended staining characteristics for each day Tzanck stain was performed on 34 out of 34 patient smears from January 9, 2023, to October 16, 2024.</p>