

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D2141070	(X3) Date Survey Completed 06/29/2022
Name of Provider or Supplier Highline Dermatology & Skin Cancer	Street Address, City, State 505 Cascade Loop, Kalispell, 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
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on review of procedures, patient records and slides, and interview with Testing Personnel (TP) # 3, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the preanalytic systems from January 1, 2021 to June 29, 2022. Findings: 1. Review of Specimen Handling, Storage, Preservation and Identification procedure revealed, "3.4.9 Slides are labeled with the Mohs number, patient name, date, stage (roman numeral), piece # (numbers) and slide # (numbers)." 2. Review of patient slides revealed inconsistent labeling: M22-229, M21-178 labels lacked stage #, piece # and slide #; M22-117(II), M22-234 (II) labels lacked piece # and slide #; M22-126 (III)1, M22-126 (II)2, M22-126(II)1, M21-176(II)1-3, lack slide #; and M20-81(I)C, M20-81 (I)B lack piece #. 3. No documentation of corrective action or assessment of the preanalytical system was available for review from January 1, 2021 to June 29, 2022. 4. No quality assurance procedures to monitor, assess, and correct problems identified were available for review. 5. Interview with the TP #3 on June 29, 2022, at 10:00 AM, confirmed these findings.</p>