Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0690730	03/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Associated Dermatology & Skin Cancer Clinic	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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel files for 2019 and 2020, General Laboratory Quality Systems Procedure, and interview with testing personnel (TP#6) the laboratory failed to perform competency of 4 out of 6 testing personnel semiannually during the 1st year of employees tests patient specimens and annually thereafter. Findings include: 1. Review of Personnel Records lacked documentation to prove either semiannually competency during the 1st year of patient testing or annual competency of testing personnel for years 2019 and 2020 for 4 out of 6 testing personnel (TP#2, TP#3, TP#5 and TP#6). 2. Review of General Laboratory Quality Systems Procedure states "Training: All new employee training will be documented and competency evaluation at 6 months and 1 year. All laboratory employees will be evaluated every year unless requested earlier by the laboratory manager or laboratory director." 3. Interview on March 4, 2021 at 1:30 PM with testing personnel (TP#6) verified lack of documentation to prove competency assessments.
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 review of personnel files and proficiency records for 2019, 2020 revealed, and interview with testing personnel (TP#6) confirmed, the laboratory failed to establish a means to verify the accuracy of its MOHS testing procedures twice a year. Findings include: 1. Review of proficiency records of 2019 and 2020 revealed the laboratory failed to enroll and establish a means to prove accuracy twice a year for MOHS testing procedures. 2. Review of personnel files lacked correlation documentation for 2019 and 2020 to prove twice a year accuracy of MOHS testing procedures. 3. Interview on March 4, 2021 at 2:30 PM with testing personnel (TP#6) verified lack of documentation to prove accuracy twice a year for MOHS testing procedures.