Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410607	07/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Montana Skin Cancer And Dermatology Center (Mscdc)	1905 W College Street, Bozeman, 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 2020, 2021 and 2022 Competency Review and Personnel Training, and interview with laboratory Testing Personnel (TP) #9 , the laboratory failed to perform competency for year 2021. Findings: 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 year 2021 for 6 out of 10 testing personnel (TP#3, TP#5, TP#6, TP#7, TP#8 and TP#9). 2. Interview on July 7, 2022 at 10:00 AM with TP#9, confirmed the lack of documentation to prove competency assessments for 6 of 10 testing personnel for year 2021.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel (TP) #9, the laboratory failed to perform quality control (QC) tissue slides to check for positive and negative reactivity of immunohistochemical stains used from April 1, 2022 to July 7, 2022. Findings: 1. A review of Mohs logs lacked record of QC positive and negative reactivity for Mart-1 and CK5 IHC staining each day of use on patient's frozen tissues. 2. Review of Novodiax instruction for use (IFU) for Mart-1 and CK5 Antibody Reagent revealed, "Quality Control Procedure: Positive and negative controls should be run simultaneously with patient specimens." 3. Review of laboratory procedure "Novodaix Protocol for frozen Tissue" lacked quality controls processing and documentation instructions. 4. Interview with TP #9 on July 7, 2022 at 10:30 AM, confirmed the laboratory failed to perform positive and negative quality control (QC) each day of IHC staining with Mart-1 or CK5 Antibody Reagents from April 1, 2022 to July 7, 2022.