Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410607	04/23/2024
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
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 a review of testing records, personnel records, and an interview with testing personnel (TP) #8, the laboratory failed to perform twice yearly accuracy verification of its method to detect the presence or absence of fungi, MOHS surgery procedure, and immunohistochemical (IHC) test method for years 2022 and 2023. Findings: 1. A review of personnel records revealed the laboratory failed to perform one of the two accuracy verifications for its method to detect the presence or absence of fungi and MOHS surgery procedures for years 2022 and 2023. 2. A review of personnel records lacked documentation of twice annually accuracy verification for IHC testing for QXS-Enh Mart-1 and QXS-Enh CK5 for years 2022 and 2023. 3. A review of the laboratory's procedures failed to define its twice yearly accuracy verification and evaluation parameters. 4. Interview on April 23, 2024, at 10:30 AM with testing personnel (TP) #8 confirmed the laboratory failed to perform twice annually accuracy verification of its method to detect the presence or absence of fungi, MOHS surgery procedure, and immunohistochemical (IHC) staining method for years 2022 and 2023.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of testing records, procedures and an interview with testing personnel (TP) #8, the laboratory failed to verify the performance specifications of two out of two immunohistochemical (IHC) tests before reporting patient test results from April 23, 2022, to April 23, 2024. Findings: 1. A review of testing records revealed the laboratory testing menu included IHC testing for QXS-Enh Mart-1 and QXS-Enh CK5 from April 23, 2022, to April 23, 2024. 2. The laboratory lacked documentation of the IHC tests' performance specifications (accuracy and precision) that were comparable to those established by the manufacturer of Novodiax Q-Stain QXS-Enh Mart-1 Antibody Reagent and Novodiax Q-Stain QXS-Enh CK5 Antibody Reagent prior to reporting patient test results. 3. A review of the laboratory's procedures failed to define a process to verify new instruments or assays prior to reporting patient test results. 4. Interview on April 23, 2024, at 11:30 AM with testing personnel (TP) #8 confirmed the laboratory failed to verify the manufacturer's performance specifications of Mart-1 and CK5 immunohistochemical (IHC) tests prior to reporting patient test results from April 23, 2022, to April 23, 2024.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of testing records, procedures, and an interview with testing personnel (TP) #8, the laboratory failed to perform a positive and negative quality control check for immunohistochemical (IHC) stains each time of use before reporting three out of three patient test results and failed to document the results of negative controls performed from April 23, 2022, to April 23, 2024. Findings: 1. A review of patient testing records for the IHC test (QXS-Enh Mart-1) revealed the laboratory failed to perform a positive and negative quality control for each time the test was performed on: a. October 3, 2022 (AB22-512) lacked a negative control. b. March 8, 2023 (AB23-125 and AB23-129) lacked one positive and one negative control. c. March 24, 2023 (MB23-109 and MB23-110) lacked one negative control. 2. A review of the "Stain Quality Assurance Log" lacked documentation of reactions for each IHC negative and positive control performed from April 23, 2022, to April 23, 2024. 3. An interview on April 23, 2024, at 1:30 PM with testing personnel (TP) #8 confirmed the laboratory failed to perform a positive and negative quality control check for each time the IHC test (QXS-Enh Mart-1) was performed for three out of three patient tests and document the results of negative controls performed from April 23, 2022, to April 23, 2024.