Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2119558	10/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Intermountain Park City Specialty Mohs Surgery	900 Round Valley Drive, Ste 200, Park City, UT	

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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on patient test records review, lack of documentation, and interview with staff, the laboratory failed to verify accuracy, precision, analytical specificity and sensitivity for the Immunohistochemical staining process for Mart 1 test kits prior to reporting patient test results. The laboratory performed approximately 10 to 12 tests per year. Findings include: 1. Patient test records review for patient cases 18-365 on 08/09 /2018 and 18-439 on 09/25/2018 document the laboratory performed Mart 1 immunohistochemical (IHC) staining to aid in reporting the histology specimen to be clear of the persistence of melanocytes associated with a melanoma in situ diagnosis through the Mohs micrographic surgical process. 2. The laboratory failed to document the laboratory verified Mart 1 staining test accuracy and precision and verified the test was specific for reporting the presence or absence of melanocytes and possessed sensitivity to document the lab could determine the difference between a positive and negative response in order to provide diagnostic confirmation of melanocytes

	presence or absence. 3. In an interview with staff on 10/11/2018 at approximately 4: 45 P.M. staff confirmed they had not documented verification of test accuracy, precision, specificity or sensitivity prior to reporting patient tests results.
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 patient test records review, lack of documentation, and interview with staff, the laboratory failed to document they checked the staining process for positive and negative reactivity each time of use for Mart 1 immunohistochemical (IHC) stains for 2 of 2 days of IHC staining reviewed. The laboratory performed approximately 8 to 12 stains per year. Findings include: 1. Patient test records review included documentation that Mohs surgical cases 18-365 on 08/09/2018 and 18-439 09/24 /2018 had Mart 1 IHC stains performed to aid in the detection of the presence or absence of melanocytes from Mohs surgery histology specimens. 2. The laboratory failed to document they included Mart 1 control slides of positive and negative reactivity for the presence of melanocytes. 3. In an interview with staff on 10/11/2018 at approximately 4:45 P.M. staff stated they did not document they checked stain reactivity with control slides that demonstrated positive and negative reactivity.