Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2130280	07/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
White Mountain Dermatology	50078 Ehrenberg Rd, Ehrenberg, AZ	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's established Quality Assessment policies and interview with the facility personnel, the laboratory failed to establish policies related to accuracy verification for Dermatopathology testing performed by the laboratory. Findings include: 1. The laboratory performs slide interpretation for Mohs testing under the sub-specialty of Histopathology, with an approximate annual test volume of 12. 2. No documentation was presented during the survey to indicate the laboratory had an established policy related to the verification of accuracy process for the testing indicated above, including but not limited to, information specific to the frequency of the review, number of cases reviewed, individual or laboratory performing the review and a remedial action plan in the event of a noted discrepancy. 3. The facility personnel confirmed that the laboratory did not have an established policy in place at the time of the survey for the verification of accuracy process for Dermatopathology testing performed by the laboratory.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper

	use. This STANDARD is not met as evidenced by: Based on direct inspection of histopathology stain reagents and interview with the facility personnel, the laboratory failed to properly label stain reagents used in conjunction with patient testing. Findings include: 1. The laboratory performs the Hematoxylin & Eosin (H&E) stain on histopathology specimens, with an approximate annual test volume of 12. 2. The laboratory personnel stated during the survey conducted on July 17, 2018 that the stain reagents were kept in their original bottles and the bottles were refilled as necessary. 3. Direct inspection of the Hematoxylin reagent by the surveyor indicated the bottle was labeled with Lot# 374013 and an expiration date of 11/2017. 4. Direct inspection of the Eosin reagent by the surveyor indicated the bottle was labeled with Lot# A190 103114 and an expiration date of 11 /03/2014. 5. The facility personnel confirmed that the reagent containers indicated above were refilled with reagents from another laboratory location and were not labeled with the correct lot number and expiration date at the time of the survey.