Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2041624	03/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ironwood Dermatology	10211 N Oracle Rd, Oro Valley, 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
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 lack of accuracy verification documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2017 and 2018. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Histopathology, with an approximate annual test volume of 6,065. 2. No documentation was presented for review during the survey conducted on March 27, 2019 to indicate the laboratory verified the accuracy of Mohs testing at least twice annually during 2017. 3. No documentation was presented for review during the survey conducted on March 27, 2019 to indicate the laboratory verified the accuracy of Biopsy interpretation at least twice annually during 2018. 4. The facility personnel stated that it is the practice of the laboratory to send 4 Mohs cases every 2 months, and 6 Biopsy cases annually to another qualified physician for accuracy verification, however the laboratory failed to send the cases for verification in 2017 and 2018 as indicated.
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 quality assessment (QA) policies and interview with the facility personnel, the laboratory failed to perform and document quality assessment activities as indicated in laboratory policy. Findings include: 1. The laboratory presented a monthly Quality Assessment checklist for review during the survey which monitored patient test management, quality control, safety policies, proficiency testing, personnel and QA reviews. The form was retired by the laboratory on July 27, 2017. 2. No other QA documentation was presented for review to indicate the laboratory performed and documented QA activities as indicated above from the time the form was retired in July 2017 through the date of the survey conducted on March 27, 2019. 3. The facility personnel confirmed that the laboratory did not have documentation of QA activities stated above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of patient logs, direct observation of stain reagents and interview with the facility personnel, the laboratory used Gram Stain reagents and Colloidal Iron stain reagents past the expiration date. Findings include: 1. The laboratory performs a Gram stain, if warranted, on patient slides in conjunction with biopsy slide interpretation. 2. During the survey conducted on March 27, 2019, direct inspection of the reagents that make up the Gram Stain revealed the laboratory used the reagents past the expiration date. The Gram Stain reagents observed during the survey include: Gentian Violet, lot #15050518, expiration date 9/05/16; Gram's Decolorizer, lot# 14070745, expiration date 7/2016; Universal Iodine Solution, lot# 16110838, expiration date 5/08/16; Optimized Tartrazine Counterstain, lot# 17011062, expiration date 1/10/18; and Carbol Fuchsin Solution, lot# 40523, expiration date 03/2018. 3. Direct observation of Glacial Acetic Acid used for the Colloidal Iron stain indicated the reagent was expired on 09/02/18 (lot# 6245). 4. The facility personnel confirmed that the expired reagents indicated above were still in use on the day of the survey. The number of patients tested using the expired reagents could not be determined at the time of the survey.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's test reports and interview with the facility personnel, the Mohs test reports failed to include the address of the laboratory where the reading of the dermatopathology slides was performed . Findings include: 1. The Mohs test reports reviewed during the survey were missing the address of the laboratory where the reading of the dermatopathology slides was performed. 2. The facility personnel confirmed that the laboratory address was missing from the Mohs test reports indicated above.