Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2041624	01/26/2022
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
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 lack of competency policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures to assess employee competency. Findings include: 1. The laboratory performs the gross evaluation on patient specimens in the sub-specialty of Histopathology. 2. No documentation was presented for review to indicate the laboratory established policies and procedures to assess the competency of individuals who perform the gross evaluation on histopathology specimens. 3. The facility personnel confirmed that the laboratory did not have a policy established to assess the competency of testing personnel who perform the gross evaluation on histopathology specimens.
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 testing performed under the sub-specialty of Histopathology at least twice annually during 2021. Findings include: 1. The laboratory performs Mohs and Biopsy interpretation under

	the sub-specialty of Histopathology, with an approximate annual test volume of 9,380. 2. No documentation was presented for review during the survey conducted on January 26, 2022 to indicate the laboratory verified the accuracy of the microscopic interpretation (reading) of Mohs specimens at least twice annually during 2021. 3. No documentation was presented for review during the survey conducted on January 26, 2022 to indicate the laboratory verified the accuracy of the microscopic interpretation (reading) of Biopsy specimens at least twice annually during 2021. 4. The facility personnel confirmed that the laboratory failed to verify the accuracy of Mohs and biopsy testing at least twice annually during 2021.
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 (A) failed to perform and document quality assessment activities as indicated in laboratory policy and (B) failed to perform and document accuracy verification activities as indicated in laboratory policy. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Histopathology with an approximate annual test volume of 9,380. A1. The laboratory's established policy titled, "Method Accuracy Verification For Routine Pathology (Procedure #6)" states, "Every quarter the laboratory staff will pick 2 random cases to review all aspects of grossing, processing, staining and microtomy." A2. No quarterly QA documentation was presented for review from January 2019 through the date of the survey conducted on January 26, 2022. A3. The facility personnel confirmed that the laboratory failed to perform and document the quarterly QA review as stated in policy. B1. The laboratory's established policy titled, "Mohs Slide Review - Procedure #5" states, "Two Mohs cases will be randomly pulled every six months for review by a certified Dermatopathologist (4 cases per year)..." B2. No documentation was presented for review from 2021 to indicate the laboratory followed their established policy indicated above to verify the accuracy of the Mohs testing. See D5217 for findings. B3. The facility personnel acknowledged that the laboratory failed to follow their established policy and provide documentation of accuracy verification procedures as indicated above.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by:

	Based on review of pathology test records and interview with the facility personnel, the laboratory failed to maintain a record system that includes the identity of the individual who performs the gross description on histopathology specimens. Findings include: 1. The laboratory performs the gross description on skin biopsies under the sub-specialty of Histopathology, with an approximate annual test volume of 8,804. The laboratory utilizes an EMR (Electronic Medical Record) to maintain patient test records and test reports. 2. One test report reviewed during the survey (ID21-7495) failed to include the identity of the testing personnel who performed the gross description. The laboratory failed to indicate the identity of the testing personnel who performed the gross description on any other laboratory records. 3. The facility personnel confirmed that the laboratory failed to maintain a record system at the time of the survey conducted on January 26, 2022 that includes the identity of the testing personnel who performed the gross description on patient specimens.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test results maintained in the electronic medical record (EMR), review of the laboratory log used to record patient test results, review of the Mohs map and interview with the facility personnel, the laboratory failed to accurately report the Mohs test result for one patient. Findings include: 1. The laboratory performs Mohs testing under the sub-specialty of Histopathology, with an approximate annual test volume of 576. It is the practice of the laboratory to manually document the Mohs test information onto the laboratory log titled "Mohs Accession Log", as well as documenting the test information on each individual Mohs map, and then to manually enter the test result into the EMR for each patient tested. The EMR is the final test report destination. 2. Review of the Mohs Operative Note (final test report) maintained in the EMR for patient, M21-619 performed on 9/13/21, indicated the Mohs site as "Right inferior medial malar cheek". 3. Review of the Mohs Accession Log listed the site for the Mohs case referenced above as "Right NLF". 4. Review of the Mohs map for the case referenced above listed the site as "Right nasal labial fold". 5. The facility personnel interviewed during the survey confirmed that the site terminology was not accurately entered in the EMR for the patient indicated above.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) documentation, review of electronic test records and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified with electronic test reports. Findings include: 1. The laboratory performs Mohs testing and Biopsy interpretations in the sub-specialty of Histopathology, with an approximate annual test volume of 9,380. The laboratory utilizes an electronic medical record (EMR) system to document the test procedure and test results. The information is manually transcribed by laboratory personnel into the EMR. 2. No QA documentation was provided for review during the survey to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified with dermatopathology test results manually entered into the EMR. 3. The laboratory failed to enter the correct Mohs test site in the EMR for one patient record reviewed during the survey. See D5801 for findings. 4. The facility personnel confirmed that the laboratory failed to establish QA policies and procedures to monitor, assess and correct problems identified with the postanalytic systems, specifically test report information manually entered into the EMR.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the deficient practices identified during the survey, the laboratory director failed to ensure that a quality assessment program is established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5291 and D5891 for findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of education credentials and training documentation for one testing personnel who performs testing in the sub-specialty of Histopathology and interview with the facility personnel, the laboratory director failed to ensure that all testing personnel have the appropriate education and experience, receive the appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: 1. The laboratory performs testing under the sub-specialty of Histopathology, with an approximate annual test volume of 9,380. 2. During the survey conducted on January 26, 2022, no

	education credentials were presented for review for one testing personnel who performs the gross evaluation on patient specimens. The testing personnel began patient testing in July 2020. 3. No initial training documentation was presented for review for one testing personnel hired in July 2020, who performs the gross evaluation on patient specimens in the sub-specialty of Histopathology. 4. The facility personnel confirmed that the laboratory failed to have documentation of the appropriate education and initial training for the testing personnel indicated above.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation of a semi-annual competency evaluation for one testing personnel and interview with the facility personnel, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semi-annual competency evaluation documentation was presented for review for one testing personnel who began grossing patient specimens in July 2020. 2. The facility personnel confirmed that the technical supervisor failed to document a semi-annual competency evaluation for the testing personnel indicated above.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on lack of testing personnel competency evaluation documentation and interview with the facility personnel, it was determined that the technical supervisor failed to evaluate and document the performance of two out of two testing personnel at least annually. Findings include: 1. During the survey conducted on January 26, 2022, no documentation of an annual competency assessment for was presented for review for two out of two testing personnel who perform the gross description on patient specimens. The testing personnel began testing patient specimens in May 2019 and July 2020.. 2. The facility personnel confirmed that no annual competency evaluation was performed for the testing personnel indicated above.