Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2041624	07/24/2025
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of test procedures on 7/24/25 at 11:07 AM for testing performed in the subspecialty of Histopathology and interview with the facility personnel, the laboratory failed to establish a written test procedure for Frozen Section Biopsy testing. Findings include: 1. The laboratory performs testing in the subspecialty of Histopathology with a reported annual test volume of 12,292. 2. No documentation was presented for review during the survey conducted on 7/24/2025 to indicate the laboratory established a written test procedure for Frozen Section Biopsy testing. 3. The facility personnel interviewed on 7/24/25 at 11:07 AM confirmed the laboratory failed to establish a written test procedure for Frozen Biopsy testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on review of temperature records, review of the manufacturer's specifications for laboratory equipment and interview with the facility personnel, the laboratory failed to define an operating humidity range for the laboratory that is consistent with the manufacturer's requirements for one tissue processor, one automatic slide stainer and one immunohistochemical (IHC) stainer, and the laboratory failed to monitor and document the ambient humidity of the laboratory from 6/06/24 through 7/24/25. Findings include: 1. The laboratory utilizes one Tissue-Tek VIP 5 tissue processor, one Leica Autostainer XL and one StatLab Quantum HDX IHC stainer to process and stain tissue specimens. The laboratory reports an annual test volume of 12,292 in the subspecialty of Histopathology. 2. The manufacturer's ambient humidity requirements for operating each piece of equipment are as follows: - Leica Autostainer XL - 20% - 80% - Tissue-Tek VIP 5 Tissue Processor - 30% - 85% - StatLab Quantum HDX IHC Stainer - 0% - 80% 3. The laboratory failed to define an ambient humidity range consistent with the manufacturer's requirements for the area of the laboratory where the equipment indicated above is utilized. 4. The laboratory failed to monitor and document the ambient humidity of the laboratory on each day of patient testing from 6 /06/24 through 7/24/25. 5. The facility personnel interviewed on 7/24/25 at 11:41 AM confirmed the laboratory failed to define an acceptable humidity range for the area of the laboratory where the tissue processor and tissue stainers are operated, and confirmed the lab failed to monitor and document the ambient humidity of the laboratory during the timeframe indicated above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 direct observation of Gram stain reagents for staining histopathology slides and interview with the facility personnel on 7/24/25 at 11:50 AM, the laboratory tested 34 patient specimens with expired Gram stain reagents between 7/01/24 through 7/24/25. Findings include: 1. The laboratory processes dermatopathology tissues and performs the microscopic interpretation of slides in the subspecialty of Histopathology with a reported annual test volume of 12,292. 2. Direct observation of the Gram Stain reagents on 7/24/25 at 11:50 AM revealed each of the 4 stain components included in the Gram Stain kit utilized by the laboratory was expired as follows: - Optimized Tartrazine Counterstain, lot# 181604, expiration date 9/30/24 - Gentian Violet, lot# 182228, expiration date 1/31/25 - Universal Iodine Solution, lot# 182375, expiration date 3/31/25 - Carbol Fuchsin, lot# 182316, expiration date 6/30 /24 3. The laboratory performed and reported Gram Stain test results using the expired stain reagents on 34 patients between 7/01/24 and 7/24/25. 4. The facility personnel interviewed on 7/24/25 at 11:50 AM confirmed the expired Gram Stain kit indicated above was used for patient testing past the manufacturer's expiration date and was in use at the time of the survey.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

	(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on lack of established IHC control procedure documentation and interview with the facility personnel on 7/24/25 at 11:25 AM, the laboratory failed to establish control procedures for the immunohistochemical (IHC) stains, MART-1, SOX-10-2x, Ki-67 and Pan-Cytokeratin. Findings include: 1. The laboratory performs testing in the sub-specialty of Histopathology, with a reported annual test volume of 12,292. 2. The laboratory began using IHC stains in June 2024 and performs the IHC stains, MART-1, SOX-10-2x, Ki-67 and Pan-Cytokeratin on dermatopathology specimens, as determined by the diagnosing physician. 3. No evidence was presented for review during the survey conducted on 7/24/25 to indicate the laboratory established positive and negative control procedures for the IHC stains indicated above, including but not limited to, the number, type and frequency of testing control materials and the laboratory's practice of using previously known patient specimens as positive and negative control material. 4. The facility personnel interviewed on 7/24/25 at 11:25 AM confirmed the laboratory failed to provide documentation of established, approved QC procedures for the IHC stains listed above and stated that the laboratory uses previously known patient specimens for positive control tissue and utilizes non-reactive areas of the same tissue for negative controls.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures for review on 7/24 /25, lack of documented QA activities and interview with the facility personnel, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1256 and 493.1281 through 493.1289, and failed to document QA activities for the analytic systems from June 2024 through July 2025. Findings include: 1. The laboratory failed to provide evidence of established QA policies and procedures specific to the analytic systems specified in 493.1251 through 493.1256 and 493.1281 through 493.1289. 2. The laboratory failed to provide evidence of QA documentation from June 2024 through July 2025 to indicate the laboratory monitored, identified and corrected problems found in regards to missing Frozen Section test procedures. Refer to D5401 3. The laboratory failed to provide evidence of QA documentation from June 2024 through July 2025 to indicate the laboratory

	monitored, identified and corrected problems found in regards to a lack of humidity records for the laboratory. Refer to D5413 4. The laboratory failed to provide evidence of QA documentation from June 2024 through July 2025 to indicate the laboratory monitored, identified and corrected problems in regards to using Gram Stain reagents past the expiration date. Refer to D5417 5. The laboratory failed to provide evidence of QA documentation from June 2024 through July 2025 to indicate the laboratory monitored, identified and corrected problems in regards to establishing a Quality Control procedure for IHC stains. Refer to D5441 6. The facility personnel interviewed on 7/24/25 at 12:00 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the analytic systems, and failed to document QA activities from June 2024 through July 2025. 7. The laboratory performs testing in the subspecialty of Histopathology with a reported annual test volume of 12,292.
D5805	TEST REPORT CFR(s): 493.1291(c) (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 pathology test reports for biopsy interpretations and frozen biopsy interpretations and interview with the facility personnel, the laboratory failed to include the gross description on 3 out of 3 pathology reports and failed to include the microscopic description on 1 out of 1 frozen biopsy test report reviewed during the survey. Findings include: 1. The laboratory performs the diagnostic interpretation of dermatopathology specimens in the subspecialty of Histopathology, with a reported annual test volume of 12,292. It is the practice of the laboratory to maintain histopathology test reports in the patient's Electronic Medical Record (EMR). 2. Three out of three dermatopathology test reports (ID24-8684, ID25-3143 and ID25-3037) failed to include the gross description. The gross description (including weighing, measuring, describing color, specific orientation for diagnostic interpretation, and other characteristics of the tissue) must be included on the pathology test report. 3. One out of one frozen biopsy test reports (FS25-02) maintained in the patient's EMR failed to include the microscopic description. 4. The facility personnel interviewed on 7/24/2025 at 10:40 AM acknowledged that the gross description was missing for the 4 biopsy test reports, and the frozen biopsy test report was missing the microscopic description, as referenced above.