Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2280599	03/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Desert Valley Dermatology	3815 E Bell Rd Ste 3100, Phoenix, 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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of Mohs test records and interview with the facility personnel, the laboratory failed to ensure positive identification for 1 out of 6 dermatopathology specimens from the time of collection through completion of testing and reporting of test results. Findings include: 1. The laboratory performs testing in conjunction with the Mohs procedure under the subspecialty of histopathology, with a reported annual test volume of 1,080. It is the practice of the laboratory to assign a unique accession number to each Mohs specimen. The unique accession number is documented on the laboratory's Mohs log, Mohs map, patient's slides and final test report maintained in the patient's Electronic Medical Record (EMR). 2. The laboratory failed to ensure positive identification of a patient's specimen throughout the entire test process for 1 out of 6 Mohs cases reviewed during the survey. Direct observation of the patient's slides, Mohs map and the laboratory's Mohs log listed the accession number as 360-2024. The accession number listed in the patient's EMR was 360-2025. 3. The facility personnel interviewed on 3/25/25 at 12:39 PM acknowledged that the accession number for the patient referenced above was incorrect in the EMR and acknowledged that the laboratory failed to ensure positive identification of a patient's specimen from the time of collection through completion of testing and reporting of results.
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 the microscopic interpretation of Frozen Biopsy specimens and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the subspecialty of Histopathology at least twice annually during 2024. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of the microscopic interpretation of Frozen Biopsy specimens at least twice annually during 2024. 2. The facility personnel interviewed on 3/25/25 at 1:40 PM confirmed the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2024, as indicated above. 3. The laboratory performed 1 frozen biopsy in 2024.
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 humidity records from May 5, 2023 through March 25, 2025, review of the manufacturer's environmental specifications for the Microm HM550 Cryostat and interview with the facility personnel, the laboratory failed to define an operating humidity range that is consistent with the manufacturer's requirements for one cryostat. Findings include: 1. The laboratory utilizes one Microm HM550 cryostat in conjunction with patient testing under the subspecialty of Histopathology. The laboratory reports an annual test volume of 1,080. 2. The manufacturer's environmental specifications for the Microm HM550 cryostat listed an operating relative humidity range of 0%-60%. 3. The laboratory's humidity records reviewed from May 5, 2023 through March 25, 2025 failed to include an acceptable humidity range for the room where the cryostat is utilized for patient testing. 4. The facility personnel interviewed on 3/25/2025 at 1:04 PM confirmed the laboratory failed to define a humidity range for the cryostat that is consistent with the manufacturer's requirements.
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 histopathology stain reagents and interview with the facility personnel, the laboratory used the stain reagent, Avantik Bluing Reagent, past the expiration date on 75 testing days during 2024 and 2025. 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 1,080. 2. During the survey conducted on March 25, 2025, direct inspection of the Avantik Bluing Reagent, lot #144999, indicated an expiration date of March 31, 2024. 3. The laboratory used the expired reagent to process patients' slides on 57 testing days in 2024 and 18 testing days in 2025 throughout the timeframe of 4 /01/24 through 3/25/25. 4. The facility personnel interviewed on 3/25/25 at 2:45 PM confirmed the expired reagent indicated above was used for patient testing past the manufacturer's expiration date and was in use at the time of the survey.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's annual maintenance policy for the microscope and cryostat used for patient testing, lack of annual maintenance records and interview with the facility personnel, the laboratory failed to perform and document annual maintenance of the microscope and cryostat during 2023. Findings include: 1. The laboratory's preventative maintenance policy states, "Preventative maintenance service must be performed annually for the following equipment to ensure optimal performance: Microscope, Cryostat, Autoclave." 2. The laboratory failed to provide records of annual preventative maintenance from 2023 for the microscope and the Microm HM550 cryostat which are used for patient testing in the subspecialty of Histopathology. 3. The facility personnel interviewed on 3/25/25 at 2:17 PM confirmed the laboratory failed to provide documentation of annual maintenance from 2023 for the cryostat used by the laboratory to process tissue specimens and for the microscope used by the laboratory to read patient slides. 4. The laboratory began patient testing on 5/05/23 in the subspecialty of Histopathology, with a reported annual test volume of 1,080.
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 frozen biopsy pathology reports and interview with the facility personnel, the laboratory failed to include the gross description and test result on 2 out of 2 frozen biopsies test records reviewed during the survey. Findings include: 1. The laboratory performs the microscopic interpretation of frozen biopsy specimens in the subspecialty of Histopathology, with a reported annual test volume of 1. It is the practice of the laboratory to maintain histopathology test results in the patient's Electronic Medical Record (EMR). 2. Two out of two frozen biopsy pathology reports (FS01-2024 and FS01-2025) 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. Two out of two frozen biopsy pathology reports (FS01-2024 and FS01-2025) failed to include the final diagnosis. 4. The facility personnel interviewed on 3/25/2025 at 12:54 PM acknowledged that the gross description and final test result (diagnosis) were missing from the patient's EMR for each frozen biopsy specimen referenced above.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 lack of Quality Assessment (QA) documentation from 2023, 2024 and 2025, review of established QA policies and procedures and interview with the facility personnel, the laboratory director failed to ensure that QA programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings include: 1. The laboratory began testing on 5/05/2023 in the subspecialty of histopathology, with a reported annual test volume of 1,080. 2. The laboratory's established QA process requires the performance of a 'Monthly Quality Assurance Checklist' which includes a review of the following: Patient Test Management System, Quality Control Policies, Laboratory Safety Policies, Proficiency Testing Policies, Personnel Policies and Quality Assurance Program. 3. The laboratory's established QA process requires the performance of a 'Monthly Patients Quality Assurance Checklist' which includes an audit of one patient test record to ensure completeness and accurate test records of the following quality systems: Pre-Analytical, Analytical and Post-Analytical. 4. The laboratory failed to provide evidence of documented QA activities from 5/05/23 through the date of the survey conducted on 3/25/25. 5. The facility personnel interviewed on 3/25/25 at 2:33 PM confirmed that the laboratory failed to provide documentation of the QA activities referenced above from May 5, 2023 through March 25, 2025.