Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0528263	08/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Paradise Valley Dermatology	12251 N 32nd St Ste 12, 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 lack of policies and procedures presented for review and interview with the facility personnel, the laboratory failed to establish written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen throughout the testing process. Findings include: 1. The laboratory performs Mohs testing and biopsy interpretation in the sub-specialty of Histopathology with an approximate annual test volume of 3,350. 2. The laboratory utilizes a Mohs log to include documentation of a unique Mohs accession number that is assigned to each Mohs case by the laboratory. 3. No documentation was presented for review to indicate the laboratory established written policies and procedures regarding the labeling of Mohs slides, and to ensure positive identification and optimum integrity of a patient's tissue specimen from the time of collection through completion of testing and reporting of results. 4. Direct observation of the Mohs slides reviewed during the survey conducted on August 6, 2021 revealed the laboratory was labeling Mohs slides with only the Mohs accession number that is assigned to each case. 5. Review of the patient's Mohs test reports documented in the Electronic Medical Record (EMR) failed to include the unique Mohs case number assigned to each Mohs case. The EMR contains an area for the "Mohs Case Number" to be entered by laboratory staff and the laboratory uses this area to document the patients first and last name, as well as the testing date, but not the unique Mohs case number. 6. The Mohs maps utilized by the laboratory contains an area to document the "Mohs #", but seven out of seven Mohs maps reviewed during the survey failed to include any documentation of the Mohs

	case # on the Mohs map. 7. The facility personnel confirmed that the laboratory failed to provide documentation of a policy and procedure indicating the laboratory's labeling process for patients' Mohs slides, and acknowledged that the laboratory failed to positively identify each Mohs specimen tested by documenting the Mohs accession # in the EMR and on the Mohs map.
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 patient test records for Mohs testing and interview with the facility personnel, the laboratory failed to maintain a record system that positively identified the specimen site. Findings include: 1. The laboratory performs patient testing in the sub-specialty of histopathology, with an approximate annual test volume of 3,350. The laboratory performs Mohs testing and utilizes an electronic medical record (EMR) system to document the test records and results in an electronic note, as well as maintaining a scanned copy of the Mohs map. 2. The laboratory maintains a Mohs log to include the following patient specific information for each Mohs case: Mohs#, Slides/Case, Date, Patient Name, Site, and Diagnosis (DX). 3. Five out of five patient's Mohs test records reviewed during the survey for patient testing that occurred on 8/20/2020 listed the incorrect specimen site on the electronic test report and Mohs map compared to the specimen site documented on the Mohs log. The following test records were reviewed as follows: a). The electronic test report and Mohs map for patient, MR# 2083843, indicated the specimen site as 'Nasal Supratip' and the Mohs log indicated the specimen site as 'Sternum'. b). The electronic test report and Mohs map for patient, MR# 2080032, indicated the specimen site as 'Sternum' and the Mohs log indicated the specimen site as 'Left Forearm'. c). The electronic test report and Mohs map for patient, MR# 2012135, indicated the specimen site as 'Left Distal Radial Dorsal Forearm' and the Mohs log indicated the specimen site as 'Right Thigh'. d). The electronic test report and Mohs map for patient, MR# 2014668 (Mohs# 345), indicated the specimen site as 'Right Anterior Distal Thigh'' and the Mohs log indicated the specimen site as 'Left Shin'. e). The electronic test report and Mohs map for patient, MR# 2014668 (Mohs# 346), indicated the specimen site as 'Left Distal Pretibial Region'' and the Mohs log indicated the specimen site as 'Right Shin'. 3. During the survey conducted on August 6, 2021, it could not be determined if the electronic test records and Mohs map listed the incorrect specimen site or if the Mohs log listed the incorrect specimen site for the Mohs cases indicated above. 4. The facility personnel confirmed that the specimen site listed on the Mohs map and in the EMR did not match the specimen site documented in the Mohs log for the patients indicated above.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory's QA processes failed to monitor, identify and correct errors found in the analytic portion of histopathology testing which is performed by the laboratory. Findings include: 1. The laboratory processes and interprets dermatopathology slides from patient specimens for Mohs testing and biopsy interpretations. The laboratory's approximate annual test volume is 3,550. 2. No QA documentation was presented for review during the survey to indicate the laboratory monitored, identified and corrected issues found with the specimen site indicated in the EMR, Mohs map and on the Mohs log for patient testing that occurred on 8/20/2020, see D5787 for specific findings. 3. The facility personnel confirmed that the laboratory failed to monitor, identify and correct errors found with documenting the Mohs specimen site in the EMR, Mohs map and Mohs log as indicated above.