Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1083664	01/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Omni Dermatology Inc	4801 E Mcdowell Rd Ste 150, 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 the laboratory's Mohs log, Mohs maps, patient slides and final test reports maintained in the patient's Electronic Medical Record (EMR), and interview with the facility personnel, the laboratory failed to follow policies and procedures that ensure positive identification of patient's dermatopathology specimens from the time of collection through completion of testing and reporting of test results. Findings include: 1. The laboratory performs Mohs testing under the sub-specialty of histopathology, with an approximate annual test volume of 200. It is the practice of the laboratory to assign a unique accession number to each Mohs specimen. The unique accession number is included on the Mohs log recorded by laboratory personnel, patient's Mohs map, patients' slides and final test report maintained in the patient's Electronic Medical Record (EMR). 2. The laboratory failed to ensure positive identification of patients' specimens for Mohs testing throughout the entire test process on 11/28/2022. A total of 4 patients were tested on 11/28/2022 and three out of four patient records reviewed from that date failed to include the correct accession number on the Mohs maps and patient slides: - The Mohs map and slides for patient C. M. were labeled with accession# M22-166. The correct accession# was M22-266 as indicated on the Mohs log and final test report in the EMR. - The Mohs map and slides for patient P.E. were labeled with accession# M22-167. The correct accession# was M22-267 as indicated on the Mohs log and final test report in the EMR. - The Mohs map and slides for patient J.K. were labeled with accession# M22-168. The correct accession# was M22-268 as indicated on the Mohs log and final test report in

	the EMR. 3. The facility personnel interviewed on 1/25/2023 at 10:05am acknowledged that the laboratory failed to ensure positive identification of the patient's specimens from the time of collection through completion of testing and reporting of results, as evidenced by the specimen identification errors that occurred on 11/28/2022.
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 established quality assessment (QA) policies and interview with the facility personnel, the laboratory failed to monitor, assess and correct problems identified in the general laboratory systems. Findings include: 1. The laboratory performs testing under the sub-specialty of Histopathology, with an approximate annual test volume of 200. 2. The laboratory's established policy QA policy presented for review failed to include information to monitor, assess and when indicated, correct problems identified in the general laboratory systems, including but not limited to, ensuring the positive identification of patient specimens. See D5203 for findings. 3. The facility personnel interviewed on 1/25/23 at 10:35am confirmed that the laboratory's QA processes at the time of the survey failed to monitor, assess and correct problems identified in the general laboratory systems.
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 patient slides 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 in the sub-specialty of Histopathology, with an approximate annual test volume of 200. 2. The laboratory utilizes an electronic medical record (EMR) system to document the Mohs test procedure and Mohs test results. The final test result information is manually transcribed by laboratory personnel into the patient's EMR. 3. The laboratory's established policy titled, "General Laboratory Systems Quality Assessment Policy" states, "MA and manager will review Mohs maps on a monthly basis, to assure Mohs test results are entered in

	the EMR and accurate to reflect both Mohs maps and EMR system". 4. The laboratory failed to correctly enter (manually transcribe) the number of Mohs stages in the EMR for one patient record reviewed during the survey, case# M21-146. The Mohs log, patient slides and Mohs map for this patient indicated a total of 4 stages, and the operative note (final test result) entered in the EMR indicated a total of 5 stages. 5. The facility personnel interviewed on 1/25/2023 at 9:50am confirmed that the laboratory failed to follow established QA policies and procedures to monitor, assess and correct problems identified with the postanalytic systems, specifically test report information which is manually entered into the EMR (electronic test report).
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 established QA policies, review of electronic test records and interview with the facility personnel, the laboratory failed to follow established policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include: 1. The laboratory performs Mohs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 200. It is the practice of the laboratory to scan the Mohs map into the patient's Electronic Medical Record (EMR). 2. The laboratory's established policy titled, "General Laboratory Systems Quality Assessment Policy" states, "MA and manager will review Mohs maps on a monthly basis, to assure Mohs test results are entered in the EMR and accurate to reflect both Mohs maps and EMR system." 3. No monthly QA documentation was provided for review for each month of 2022, to indicate the laboratory followed the policy and procedure indicated above to monitor, assess and, when indicated, correct problems identified with dermatopathology test results that are manually transcribed into the EMR and to ensure Mohs maps are scanned into the patient's EMR. 4. During the survey performed on 1/25/2023, review of patients' Mohs maps maintained in the EMR revealed the laboratory failed to scan one out of four Mohs map, case# M21-146, into the patient's EMR, as indicated by laboratory policy. 5. The facility personnel interviewed on 1/25/2023 at 10:30am confirmed that the laboratory failed to perform monthly QA activities in 2022 as stated above, to monitor, assess and correct problems identified with the postanalytic systems and failed to ensure Mohs maps are scanned into the patient's EMR as indicated in laboratory policy.
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.