Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2092598	06/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Omni Dermatology, Inc	11851 N 51st Ave Ste E130, Glendale, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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, Hematoxylin, past the expiration date. Findings include: 1. The laboratory performs the Hematoxylin and Eosin (H&E) stain on patient slides in conjunction with Mohs, with an approximate annual test volume of 540. 2. During the survey conducted on June 25, 2024, direct inspection of the Hematoxylin reagent, lot #160919, indicated an expiration date of May 31, 2024. 3. The laboratory used the expired reagent during one day of testing conducted on 6/19/2024. Approximately 19 patients were tested using the expired reagent. 4. The facility personnel interviewed on 6/25/2024 at 10:20 AM confirmed the expired reagent indicated above was in use at the time of the survey.
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, review of patient slides and interview with the facility personnel, the laboratory failed to accurately report the Mohs test result for one out of four patient records reviewed. Findings include: 1. The laboratory performs Mohs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 540. 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 failed to correctly enter (manually transcribe) the number of Mohs stages in the EMR for one patient record reviewed during the survey, case# WM23-38. The Mohs log, patient slides and Mohs map for this patient indicated a total of 1 stage, and the operative note (final test result) entered in the EMR indicated a total of 2 stages. 4. The facility personnel interviewed on 6/25/2024 at 10:00 AM confirmed that the laboratory failed to accurately report the final test result 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 review of Mohs test reports and interview with the facility personnel, the laboratory failed to establish policies and procedures for amending pathology reports. Findings include: 1. The laboratory performs Mohs testing on patient specimens under the sub-specialty of histopathology, with an approximate annual test volume of 540. The laboratory utilizes an electronic medical record (EMR) system to maintain patient records 2. Review of the Mohs test report for case# WM23-38 indicated the date of service as 2/17/23, and the test report was originally signed by the physician who made the diagnosis on 2/20/23. Information maintained in the EMR indicated the test report was amended and listed the 'amendment sign-off' date as 6/27/23. 3. The laboratory failed to provide documentation as to why the test report indicated above was amended on 6/27/23. 4. No documentation was presented for review during the survey to indicate the laboratory established policies and procedures for amending pathology reports. 5. The facility personnel interviewed on June 25, 2024 at 10:10 AM confirmed the laboratory failed to establish policies and procedures for amending pathology reports, and failed to identify why the Mohs test report indicated above was amended on 6/27/23.