Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2190610	05/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Omni Dermatology	10204 W Happy Valley Pkwy #165, Peoria, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's test procedure for Mohs and interview with the facility personnel, the Mohs test procedure failed to include the laboratory's system for entering results in the patient record and reporting patient results. Findings include: 1. The laboratory began reading and diagnosing patient specimens during the Mohs procedure in the sub-specialty of Histopathology on September 16, 2020, with a reported annual test volume of 384. It is the practice of the laboratory to enter the Mohs test results into the patient's Electronic Health Record (EHR). 2. The Mohs test procedure reviewed during the survey conducted on May 9, 2023 failed to include the

	laboratory's system for entering results in the patient record and reporting patient results, including but not limited to, the acceptable timeframe for the physician who performed the test to electronically sign the test report in the EHR. 3. The facility personnel interviewed on May 9, 2023 at 10:45am confirmed that the Mohs test procedure reviewed during the survey lacked information regarding the laboratory's system for reporting patient test results in the EHR as indicated above.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's test procedure for Mohs and interview with the facility personnel, the laboratory director failed to approve, sign and date the Mohs test procedure before use. Findings include: 1. The laboratory began patient testing in conjunction with the Mohs procedure in the sub-specialty of Histopathology on September 16, 2020, with a reported annual test volume of 384. 2. The Mohs test procedure presented for review during the survey conducted on May 9, 2023 failed to include the approval, signature and date of the current laboratory director. 3. The facility personnel interviewed on May 9, 2023 at 10:30am acknowledged that the Mohs test procedure was not signed and dated by the current laboratory director at the time of the survey.
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 established quality assessment (QA) policies and procedures for review and interview with the facility personnel, the laboratory failed to follow established QA policies and procedures to monitor, assess and correct errors found in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. The laboratory performs the microscopic interpretation of Mohs specimens under the sub-specialty of Histopathology, with an approximate annual test volume of 384. It is the practice of the laboratory to scan the Mohs maps into the patient's electronic health record (EHR). 2. The laboratory's established QA 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. Monthly Mohs check will be signed off by the MA and manager on a monthly basis." 3. Review of the EHR for patient, PM21-06, from testing performed on 2/03/2021 indicated the laboratory failed to scan the Mohs map into the patient's EHR. 4. The laboratory failed to follow the established QA policy indicated above to identify and correct errors with Mohs maps retained in the patient's EHR, as evidenced above for patient PM21-06. 5. The facility personnel interviewed on 5/09/2023 at 10:50am confirmed that the laboratory's QA

	process failed to identify and correct errors identified with Mohs maps missing in the patient's EHR.