Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2092598	05/17/2019
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
D5805	TEST REPORT CFR(s): 493.1291(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 the laboratory's test reports for Mohs testing, test records for Mohs testing and interview with the facility personnel, the laboratory failed to include the test result on one test report reviewed during the survey. Findings include: 1. The laboratory performs Mohs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 250. The laboratory utilizes an electronic medical record (EMR) system to document the test procedure and test results. 2. One out of four Mohs test reports reviewed during the survey (WM18-34) failed to include the final test result for Mohs. The EMR reviewed for this patient indicated, "Microscopic examination of the tissue revealed". 3. The facility personnel confirmed that the EMR for case# WM18-34 failed to include the final test result.
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 monthly Quality Assessment (QA) documentation, review of electronic test records and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified with electronic test reports. Findings include: 1. The laboratory performs Mohs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 250. The laboratory utilizes an electronic medical record (EMR) system to document the test procedure and test results. 2. No documentation was provided for review during the survey to indicate the laboratory established policies and procedures to monitor the Mohs test results entered into the EMR. 3. The laboratory failed to document the test results in the EMR for one out of four patient records reviewed during the survey. See D5805 for findings. 4. The facility personnel confirmed that the laboratory's established QA procedures failed to monitor the test report information entered into the EMR.