Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0697872	07/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Associated Dermatologists, Pc	6296 E Grant Rd, Ste 180, Tucson, 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 policy manual and Mohs log, review of patient slides and interview with the facility personnel, the laboratory failed to follow established procedures to ensure positive identification of patient's dermatopathology specimens. Findings include: 1. The laboratory performs Mohs testing under the sub-specialty of histopathology, with an approximate annual test volume of 400. It is the practice of the laboratory to assign a unique accession number to each patient specimen. The accession number is included on the Mohs log, the patient slide(s) and the patient test report. 2. The laboratory's established policy titled, "Test Procedures" listed under section 7.1 states, "Write the patient's last name, accession number, and the number of specimen pieces on the slide before placing the sections on the slide to ensure the identity of the patient". 3. The Mohs slides reviewed during the survey for patient E.O., tested on 6/09/2017, failed to include the accession number (T17-117)on the slides. 4. The facility personnel confirmed that the Mohs slides from the patient indicated above failed to include the accession number per laboratory policy.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on lack of competency policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures to assess employee competency. Findings include: 1. The laboratory began grossing patient specimens in July 2017. 2. No documentation was presented for review to indicate the laboratory established policies and procedures to assess the competency of individuals who perform the gross evaluation on histopathology specimens. 3. The facility personnel confirmed that the laboratory did not have a policy established to assess the competency of testing personnel who perform the gross evaluation on histopathology specimens.
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 Mohs procedure manual presented during the survey and interview with the facility personnel, the laboratory failed to have the Mohs procedure manual approved, signed, and dated by the current laboratory director. Findings include: 1. The Mohs procedure manual presented for review during the survey conducted on July 19, 2018 failed to include the approval, signature and date of the current laboratory director. 2. The individual listed as Laboratory Director on the CMS-209, Laboratory Personnel Form submitted during the survey was assigned the position of Laboratory Director on 5/02/2017, according to the CMS Database. 3. The facility personnel acknowledged that the Mohs procedure manual was not signed and dated by the current laboratory director at the time of the survey.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to document the acceptability of staining materials used for patient testing performed in the sub-specialty of histopathology. Findings include: 1. The laboratory processes and interprets histopathology slides from patient specimens with an approximate annual test volume of 14,500. The laboratory began this form of testing in July 2017 and performs the Hematoxylin and Eosin (H&E) stain on each specimen in addition to the following special stains, if requested: PAS, Trichrome, Fite's, Colloidal Iron, Fontana Masson, Iron, Gram Stain, and Congo Red. 2. No documentation of the H & E stain acceptability was presented for review for case number AD17-000937 from 08/31/2017. 3. No documentation of the PAS and

	Colloidal Iron stain acceptability was presented for review for case number AD17-000937 from 08/31/2017. 4. The facility personnel confirmed that the laboratory failed to document the H & E and special stain acceptability each day of use on the date indicated above.