Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D2156587	04/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Associates In Dermatology Pllc	1028 N Dixie Ave, Ste 140, Elizabethtown, KY	

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 record review and staff interview on 04/11/2019, the laboratory failed to establish a policy describing the step-by-step procedure for interpreting and reporting results for all stages performed during Mohs surgical procedures. Findings include: Review of the policy and procedure manual revealed the laboratory failed to include a procedure describing the location site for the Mohs procedure, description of tissue obtained by the Mohs procedure, findings of frozen section analysis for each incision stage including the stage describing a clear tumor margin, and repair of the surgical site. Testing Personnel acknowledged in an interview at 10:45 AM on 04/11/2019, the

	laboratory failed to establish a policy describing the step-by-step performance of the Mohs surgical procedure.
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 record review and staff interview on 04/11/2019, the laboratory failed to establish a written policy for an ongoing mechanism to review, monitor, assess, and correct problems when an error is identified in the postanalytic phase of test reporting. Findings include: Review of test report for Patient #2 revealed five stages of tissue were removed, processed, and analyzed on the left nasal ala. The report failed to include the findings for Stage 5. Review of test report for Patient #4 revealed two stages of tissue were removed, processed, and analyzed on the right nasal dorsum. The report failed to include the findings for Stage 2. Review of the policy and procedure manual revealed the laboratory failed to include a Postanalytic Systems Quality Assessment to review test reports and when errors are identified to investigate, resolve through corrective action, and monitor and assess the corrective action to prevent recurrence. Testing Personnel acknowledged in an interview at 10:45 AM on 04/11 /2019, the laboratory failed to establish a Quality Assessment to review Mohs surgical reports to ensure reports were complete for removal, processing, analyzing, and reporting findings of tissue specimens.