Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1071340	05/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Florida Dermatology Specialists	650 Se Indian Street Ste 4, Stuart, FL	

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, observation and interview, the laboratory procedure manual instructions for making the 95% alcohol used for their Hematoxylin and Eosin Stain were incomplete. Findings: Review of the procedure manual, signed on 1/03/19, under the subject staining solutions states "Statlab Flex 100 diluted down to 95% by adding 5 milliliters (ml.) of distilled water." The procedure failed to mention the amount of Statlab Flex 100 alcohol that is to be used. The container used for staining was filed to the level for reagents used and the volume of liquid measured approximately 280 ml. During an interview on 5/21/19 at 10:40 AM, the Mohs Technician A stated they add

	5 ml. distilled water to the whole container and that the procedure did not mention the amount of alcohol used.
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 record review and interview, the laboratory's final surgical report failed to list the correct address of the location where the Mohs surgical procedure and specimen processing occurred for 2 out of 5 patient reports examined (#1 & 4). Findings: Review of the "Visit Notes" from the Mohs surgery showed for patient #1 and #4, reports examined had the incorrect location listed. During an interview on 5/21 /19 at 12:15 PM, Mohs Technician stated that the "Visit Notes" were the final surgical report, and that 2 of the reports viewed had the wrong address.