

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0276503	<b>(X3) Date Survey Completed</b>  08/07/2018
<b>Name of Provider or Supplier</b>  Advanced Dermatology And	<b>Street Address, City, State</b>  3755 7th Terrace, Vero Beach, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's procedure manual failed to include step by step instructions for making the 95% alcohol solution. Findings: Review of the procedure titled "Automatic Staining Procedure Hematoxlin &amp; Eosin" showed the procedure failed to included step by step instructions for making the 95% alcohol solution used for the Hematoxylin and Eosin (H&amp;E) stain. During an interview on 8/07/18 at 10:20 AM, the Location Manager confirmed with Testing Personnel A over the phone that they make up the 95% alcohol solution, and Location Manager acknowledged that there are no written instructions for making the 95%</p>

alcohol solution for the H&E stain. During an interview over the phone on 8/07/18 at 11:33 AM, the Compliance Director stated that there were no records for the preparation of the 95% alcohol solution.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to record the room temperature and humidity of the room where testing was performed from 1/06/17 to 3/29/17. Findings: Review of laboratory's log titled "Laboratory Temp/Humidity Log" showed that the room temperature and humidity of the room where testing was performed was not documented from 1/06/17 to 3/29/17. The log showed the following dates that were listed and initialed in the signature column didn't contain temperature or humidity readings. January 6, 9, 19, 23 and 26, 2017 February 1, 2, 6, 20 and 23, 2017 March 1, 13, 17, 20 and 29, 2017 During an interview on 8/07/18 at 11:40 AM, the Location Manager confirmed with Testing Personnel A over the phone that she believed the temperature and humidity for those dates was recorded on another form. During an interview on 8/07/18 at 11:55 AM, the Location Manager stated she could not find the temperature and humidity readings.

**D5609**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document and maintain a record of the open dates for reagents used in their Hematoxylin & Eosin (H&E) stains. Findings: Record review of the laboratory's log titled "Reagent Log" showed that the laboratory failed to record when the reagents were opened from 8/07/16 to 8/07/18. During an interview on 8/07/18 at 11:09 AM, the Location Manager confirmed they didn't record the open date for their reagents on the log, and that they only recorded the open dates on the reagent bottles.