

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0885369	<b>(X3) Date Survey Completed</b>  03/07/2018
<b>Name of Provider or Supplier</b>  Emerald Coast Dermatology And Skin Surgery	<b>Street Address, City, State</b>  350 W Redstone Ave, Crestview, 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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, it was determined that the laboratory did not document room temperature and humidity requirements to assure optimal storage temperatures for certain reagents for 2 years ( 2016-2018). Findings included: Review of the manufacturer's procedure indicated that the Multienzyme Cleanser and Paragard Paraffin Repellent should be stored at 22 degrees Centigrade and 35 degrees Centigrade. There was no temperature log available for documenting the temperature of the laboratory room. Interview on 3/7/18 at 11:30 AM, testing person # B confirmed that the temperature and humidity of the laboratory room were not checked and documented.</p>
<b>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result</p>

reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview, the laboratory failed to perform yearly preventive maintenance on the Olympus CX31 microscope for 2 years ( 2016 - 2018 ). Findings included: Observation on 3/7/18 at 10:30 AM showed that the Olympus CX31 microscope did not have a preventive maintenance sticker. Review of the equipment maintenance records for 2016 - 2018 showed no documentation for annual preventive maintenance done on the microscope. Interview on 3/7/18 at 12:00 PM , personnel # A confirmed that the laboratory did not have records to show annual preventive maintenance on the microscope.