

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0972210	<b>(X3) Date Survey Completed</b>  04/09/2018
<b>Name of Provider or Supplier</b>  Rsb Dermatology Inc	<b>Street Address, City, State</b>  1500 E Hillsboro Blvd Ste 204, Deerfield 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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory director, the laboratory failed to verify the accuracy of Mohs slides for 1 out of 2 years and histopathology 2 out of 2 years. Findings include: Review of laboratory's verification accuracy records showed there is no documentation for year 2016 for Mohs slides and for histopathology, there is no documentation for years 2016 and 2017. Interview with the laboratory director at 11:00 a.m. on 04/09/2018 confirmed that there is no documentation of the accuracy verification for Mohs during 2017 and for histopathology for 2016 and 2017.</p>
<b>D5293</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory failed to document the quality assessment activity during 2016 and 2017 for histopathology, and for Mohs during 2017. Findings include: 1-Review of the quality assessment policy stated that it is required the laboratory to document the quality</p>

assessment activity. 2-Review of quality assessment records revealed that there were no documentation of the quality assessment activity for years 2016, 2017 for histopathology and 2017 for Mohs 3-During an interview on 04/09/18 at 11:30 a.m., the laboratory director confirmed that there were no documentation of quality assessment activity for 2016 and 2017 for histopathology and neither for Mohs during 2017.

**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 with the histology technician, the laboratory failed to document the room temperature and humidity in the room where the cryostat is during 2016, 2017 and 2018. Findings include: 1-Review of the cryostat installation requirements revealed that there is a requirement for the maximum temperature of 23 C; for humidity state that can affect the performance. Review of temperature logs revealed that there were no documentation of room temperature nor humidity in 2016, 2017, and 2018. 2-During an interview on 04/09/18 at 11:00 a.m., the histology technician confirmed that there were no documentation of room temperature or humidity during 2016, 2017, and 2018 for the cryostat room.