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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D0685911            | <b>(X3) Date Survey Completed</b><br><br>03/28/2018 |
| <b>Name of Provider or Supplier</b><br><br>Skin And Cancer Associates Llp  | <b>Street Address, City, State</b><br><br>1460 North University Dr, Coral Springs, 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>  |
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| <b>D5209</b>              | <p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br/>CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on personnel record review and interview with the laboratory director, the laboratory failed to perform annual competency reviews of testing personnel for 2016 and 2017. Findings include: Review of personnel records for 2016 and 2017 revealed that there was no documentation of competency evaluations for 2 of 3 testing personnel. During an interview on 03/28/18 at 12:00 p.m., the laboratory director confirmed that no annual competency evaluations done for 2 of 3 testing personnel in 2016 and 2017.</p> |
| <b>D5413</b>              | <p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b><br/>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:<br/>Based on record review and interview with the histology technician, the laboratory</p>                           |

failed to document the room temperature and humidity in the room where the cryostat is during 2016, 2017 and 2018 and in histopathology room for 2016 and 2017. Findings include: 1-Review of the cryostat installation requirements revealed that there is a requirement for the maximum temperature of 22 C and humidity no greater than 60%. Review of temperature logs revealed that there were no records of room temperature or humidity in 2016, 2017, and 2018. 2-Review of the quality control records of histopathology room revealed that there were no records of temperatures nor humidity for years 2016 and 2017 3-During an interview on 03/28/18 at 11:00 a. m., the histology technician confirmed that there were no records of room temperature or humidity during 2016, 2017, and 2018 for the cryostat room and for histopathology room there were not records of temperature or humidity for years 2016 and 2017.