Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0686476	(X3) Date Survey Completed 08/08/2018
Name of Provider or Supplier Skin And Cancer Associates, Llp	**Street Address, City, State** 1480 N 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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of employee competencies from 2016 to 2018 and interview with Laboratory Director (LD) revealed that the laboratory failed to document annual competency for testing personnel (TP) from 2016 to 2018. Findings include: Review of personnel records revealed that for 2 out of 3 testing personnel (TP A and TP B) had no competency evaluations for the years 2016, 2017 and 2018 and for 1 out of 3 (TP C) missing the initial evaluation in 2018 During an interview on 8/08/2018 at 11: 30 AM, with the LD, he confirmed there were no records of annual competency evaluation for 2 out of 3 testing person (TP A and TP B) for the years of reference and no initial evaluation for TP C
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 laboratory director, the laboratory failed to document the room temperature and humidity in 2018. Findings include: Review of the TN50 cryostat manual indicated a requirement for room temperature not greater than 25 C and humidity not above 60 %. Quality control records of histopathology room revealed that there was no documentation of the humidity neither room temperature done since the purchase of the new cryostat in 2018. During an interview on 08/08/18 at 11:30 a.m., the laboratory director confirmed that there was no record of room temperature or humidity for the period of of reference.