Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2157948	(X3) Date Survey Completed 08/27/2019
Name of Provider or Supplier Center For Skin Wellness Llc, The	**Street Address, City, State** 6771 Professional Pkwy West Ste 203, Sarasota, 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
D0000	An announced CLIA initial certification survey was conducted at The Center for Skin Wellness LLC on 08/27/19. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 Office Manager, the laboratory failed to record the room humidity for 5 of 5 days (04/23/19, 04/24/2019, 05/31/19, 06/28/19, and 07/26/19) and failed to record room temperature for 2 (06/28/19 and 07/26/19) of 5 days (04/23/19, 04/24/2019, 05/31/19, 06/28/19, and 07/26/19) when Histopathology Hematoxylin and Eosin (H&E) staining was being performed. Findings Included: Record review of the Leica CM1850 Cryostat Instruction Manual dated 12/2003 showed the maximum room temperature should be 35 degrees Celsius and the air humidity should not exceed 60%. A review of the Moh's log showed patient's specimens for H & E stain had been performed on 04/23/19, 04/24/19, 05/31/19, 06/28/19 and 07/26/19. A review of the "2019 Room Temperature" log revealed no temperatures were recorded on 06/28/19 and 07/26/19. In addition, there was no record or log that documented room humidity for any of the dates when staining was performed. Interview on 08/27/19 at 11:00 AM with the Office Manager confirmed

	that room temperatures were not recorded for 06/28/19 and 07/26/19, and the humidity for 04/23/19, 04/24/19, 05/31/19, 06/28/19, and 07/26/19 had not been documented.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to ensure Histopathology Hematoxylin and Eosin (H&E) quality control (QC) stain was documented and acceptable before reporting patient results for 3 (05/31/19, 06/28/19, and 07/26/19) out of 5 (04/23/19, 04/24/19, 05/31/19, 06/28/19, and 07/26/19) days. Findings included: Record review of the Moh's log showed patient's specimens for H & E stain had been logged on 04/23/19, 04/24/19, 05/31/19, 06/28/19, and 07/26/19. A total of 38 patients' specimens for H & E had been stained since 04/23/19. Record review of the procedure revealed a procedure titled "Quality Assurance for Routine Stains" and stated "Each QC will be logged on the stain QC chart. Record review of the "Quality Control Staining "revealed that the H & E QC had not been documented on 05/31/19, 06/28/19, and 07/26/19. On 08/27/19 at 12:00 PM, the Office Manager confirmed the H & E quality control documentation was missing.