Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2157948	12/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Center For Skin Wellness Llc, The	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 recertification survey was conducted at The Center for Skin Wellness LLC on 12/10/20. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level 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 the CMS Laboratory Personnel Report (Form CMS 209), competency record review, and interview with the Office Manager, the laboratory failed to perform a six month competency evaluation for 1 (Testing Personnel #B) of 1 new employee. Findings included: Record review of the Form CMS 209 revealed that Staff #B worked as Testing Personnel. Record review of the procedure manual revealed the undated procedure titled, "PROFICIENCY TESTING Competency and CLIA competency assessment." The procedure stated "Evaluation and documenting competency of personnel responsible for testing is required at least semi-annually during the first year" When competency records were requested for Testing Personnel #B who had started 3/2020, the laboratory stated they did not have competency records for Testing Personnel #B. Interview on December 10, 2020 at 11:20 AM, the office manager confirmed that competency had not been performed on Testing Personnel #B and stated she did not know that a Moh's surgeon needed competency evaluations.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	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. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to verify the accuracy of testing twice a year for 1 of 1 years (2020) reviewed for subspecialty of Mycology (fungi), and Parasitology (scabies) Findings Included: Review of the procedure manual revealed that the laboratory did not have a procedure for verifying the accuracy of testing for fungi and scabies. Interview on 12/10/2020 at 11:15 AM, the Office Manager confirmed that the peer reviews for fungi and scabies had not been performed in 2020.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 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 with the Office Manager, the laboratory failed to perform preventative maintenance on the cryostat used in the Histopathology laboratory since the date of the last on-site survey, 08/27/2019. Findings included: Observation during the laboratory tour on 12/10/20 at 10:20 AM revealed a sticker on the Leica cryostat that stated the preventive maintenance was due 04/2020. Record review of the laboratory's "Cryostat Maintenance" procedure revealed that "preventative maintenance and grounding checks are done and documented annually." On 12/10/20 at 10:25 AM, the Office Manager stated that the preventative maintenance had been missed due to Coronavirus.
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 interview with the Office Manager, the facility failed to ensure Histopathology Hematoxylin and Eosin (H&E) quality control (QC) stain was documented and acceptable before reporting patient results from 09/20/19 to 12/9 /2020. Findings included: Record review of the procedure manual revealed a procedure titled "Stain Maintenance Auto-Stainer." The procedure stated "A QC worksheet is documented daily on the stain quality and any corrections or changes made." Record review of the "Quality Control Staining" revealed that the H&E QC

	had not been documented from 09/20/19 to 12/9/20. On 12/10/20 at 11:25 PM, the Office Manager confirmed the H&E quality control documentation was missing. This is a repeat deficiency.