Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2313466	08/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Ct Skinhealth Llp	260 Long Ridge Road, Suite D180, Stamford, CT	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow their established policies and procedures to perform and document peer review to assess testing personnel (TP) skills and competency. Findings include: 1. Record review on 08/11/2026 of the laboratory's 'Proficiency Testing (PT) Program' policy section 'b. Frequency:' revealed 'a: conduct PT every quarter (four times a year).' 2. Record review on 08/11/2026 of the laboratory's 'Dermatopathology Proficiency Review' log revealed the following: a. Lack of documentation of quarterly TP peer review for 2025. b. Lack of documentation of quarterly TP peer review for 1st and 2nd quarter in 2026. 3. Staff interview on 08/11/2026 at 12:02 PM with the laboratory's chief financial officer confirmed the above findings. 4. The laboratory performs 23,000 tests annually in the subspecialty of histopathology.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish competency assessment policy and procedures to assess competency for the regulatory responsibilities for the clinical consultant (CC), technical supervisor (TS), general supervisor (GS) and testing personnel (TP) in the subspecialty of histopathology. Findings include: 1. Record review on 08/11/2026 of the laboratory's procedure manual binder revealed lack of an established competency assessment policy and procedure to assess competency for the regulatory positions of CC, TS, GS, and TP and defining frequency of such assessments. 2. Record review on 08/11/2026 of the laboratory's personnel report 'CMS 209' form revealed 3 of 3 CC currently working in the laboratory. 3. Record review on 08/11/2026 of the laboratory's 'Competency Assessment and Training Program' revealed the lack of documentation of competency assessments for the regulatory positions of 3 of 3 CC, TS, GS, and TP. 4. Staff interview on 08/11/2026 at 12:02 PM with the laboratory's chief financial officer confirmed the above findings. 5. The laboratory performs 23,000 tests annually in the subspecialty of histopathology.