

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2116007	(X3) Date Survey Completed 10/05/2022
Name of Provider or Supplier Ct Skin Health, Llp	Street Address, City, State 4 Corporate Dr, Suite 386, Shelton, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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: Based on record review and staff interview, the laboratory failed to assess the competency of the laboratory's Clinical Consultants (CC), Technical Supervisor (TS) and General Supervisor(GS) in the subspecialty of Histopathology. Findings include: 1. Review of the laboratory's personnel competency records on 10/05/22 revealed the lack of documentation for the following personnel competency assessment in 2020 and 2021. a. 4 of 4 CC. b. 1 of 1 TS. c. 1 of 1 GS. 2. Record review on 10/05/22 of the laboratory's "Histopathology & Mohs Surgery" procedure manual (page 31) revealed "the laboratory director, clinical consultant, technical supervisor, and general supervisor must be reviewed once every year by another qualified staff member (the Mohs supervisor {BS &2+ years experience} or an MD)". 2. Staff interview with the laboratory supervisor on 10/05/22 at 10:10 AM confirmed the laboratory did not have competency assessment records for CC, TS and GS in 2020 and 2021. 3. The laboratory performs 21,120 tests in the sub-specialty of Histopathology.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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</p>

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 record review and staff interview, the laboratory failed to perform manufacturer recommended maintenance in its required frequency to ensure the proper functioning of the laboratory equipment. Findings include: 1. Record review of the laboratory's "Fume Hood Monthly Maintenance Log" on 10/05/22 revealed the laboratory failed to replace the fluorescent lamps biannually in 2020, 2021 and to-date in 2022. 2. Record review of the fume hood (Model# B1115484 and SN# P83313) operator's manual on 10/05/22 revealed to replace the fluorescent lamps biannually for the proper functioning of the equipment. 3. Staff interview on 09/29/2022 at 12:40 PM with the testing personnel #3 (TP#3) confirmed the above findings. TP#3 further commented he/she was not aware it is a required maintenance to be done semiannually..