

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2116007	(X3) Date Survey Completed 08/28/2024
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on surveyor observation, record review and staff interview, the laboratory failed to establish and follow a step by step written policies and procedures to ensure correct specimen embedding of tissue specimens while utilizing the tamper embedding tools in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 08/28/2024 at 9:30 AM of the histology laboratory area revealed two 'Leica HistoCore Arcadia H Paraffin Embedding Stations' containing one tamper embedding tool within the holding compartment. 2. Record review on 08/28/2024 of the 'Embedding Center Use and Maintenance' procedure, effective 07/01/2016 revealed lack of documentation of a step-by-step procedure for the use of tamper embedding tools and proper procedure for cleaning to prevent cross contamination between tissue specimens. 3. Staff interview on 08/28/2024 at 10:30 AM with the histology laboratory supervisor confirmed the above findings. 4. The laboratory performs 35,000 tests annually in the subspecialty of histopathology. B. Based on surveyor observation, record review and staff interview, the laboratory failed to establish and follow a step by step written policies and procedures for the newly validated immunohistochemistry stains prior to patient testing in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 08/28/2024 at 9:45 AM of the histology laboratory area revealed the presence of a Leica Bon Max Immunohistochemistry (IHC) stainer in use. 2. Record review on 08/28/2024 of the laboratory's antibody validation binder revealed five antibodies (SOX10, AE1/AE3, CK 5/6, MELA , S100) that were approved between 03/22/2024 through 04/08/2024</p>

by the laboratory director. 3. Record review on 08/28/2024 of the laboratory procedure manual revealed lack of documentation of a written procedure manual for the newly validated antibodies for the Immunohistochemistry antibody staining listed in B-2 above. 4. Staff interview on 08/28/2024 at 10:45 AM with the histology laboratory supervisor confirmed the above findings. 5. The laboratory performs 35,000 tests annually in the subspecialty of histopathology.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on surveyor observation, record review and staff interview, the laboratory failed to provide an updated written procedure manual that is approved, signed and dated by the laboratory director (LD) before use in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 08/28/2024 at 2:10 PM of the laboratory's Periodic Acid-Schiff (PAS) immunohistochemistry manual staining station revealed a PAS staining procedure posted on the wall that lack documentation of an approval by the laboratory director (LD). 2. Record review on 08/28/2024 of the laboratory's 'Staining Procedure for Manual Periodic Acid - Schiff Reaction' SOP# 8.00 with an approval date of 12/28/2016 by the LD revealed a discrepancy between the staining protocol versus the currently used staining protocol posted on the wall. 3. Staff interview on 08/28/2024 at 02:45 PM with the histology laboratory supervisor confirmed the above findings. 4. The laboratory performs 35,000 tests annually in the subspecialty of histopathology.

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 staff interview, the laboratory failed to define and provide evidence of monitoring and documenting humidity requirements and room temperature in the subspecialty of histopathology. Findings include: 1. Record review on 08/28/2024 of the laboratory's maintenance records revealed lack of documentation of daily humidity levels and room temperature for the general histology laboratory area. 2. Record review on 08/28/2024 of the laboratory's standard operating procedure revealed lack of documentation of written policies and procedures defining the acceptable humidity and room temperature requirements. 3. Record review on 08/28/2024 of the 'Sakura Tissue-Tek Film Automated Coverslipper' manual revealed the following humidity and temperature requirements: a. Relative humidity: 30 to 85% (non-condensing). b. Operating temperature range: 10 to 40 degrees Celsius. 4. Record

review on 08/28/2024 of the 'Sakura Tissue-Tek DRS 2000 Automatic Slide Stainer' manual revealed the following humidity and temperature requirements: a. Relative humidity: 30% to 85% (non-condensing). b. Operating temperature range: 10 to 40 degrees Celsius. 5. Record review on 08/28/2024 of the 'Leica HistoCore Arcadia C Cold Plate and HistoCore Arcadia H Paraffin Embedding Station' manual revealed the following humidity and temperature requirements: a. Relative humidity: 20% to 8% (non-condensing). b. Operating temperature range: 20 to 30 degrees Celsius. 6. Record review on 08/28/2024 of the 'Leica ASP300S Advanced Smart Processor Vacuum Tissue Processor' manual revealed the following humidity and temperature requirements: a. Relative humidity: 10% to 80% (non-condensing). b. Operating temperature range: 15 to 35 degrees Celsius. 7. Record review on 08/28/2024 of the 'Leica RM2125 Rotary Microtome' manual revealed the following humidity and temperature requirements: a. Relative humidity: Maximum 80% (non-condensing). b. Operating temperature range: 10 to 35 degrees Celsius. 8. Record review on 08/28/2024 of the 'Leica Bond Max' Immunohistochemistry Stainer manual revealed the following humidity and temperature requirements: a. Relative humidity: 30 to 80% (non-condensing). b. Operating temperature range: 5 to 35 degrees Celsius. 9. Staff interview on 08/28/2024 at 2:30 PM with the histology laboratory supervisor confirmed the above findings. 10. The laboratory performs 35,000 tests annually in the subspecialty of histopathology.