

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2116007	(X3) Date Survey Completed 08/12/2026
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
D0000	A recertification survey was performed on August 12th, 2026, at CT Skin Health LLP, the laboratory was found out of compliance with the following conditions: 493.1441 Condition: Laboratories performing high complexity testing; laboratory director. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation and staff interview, the laboratory failed to ensure ten of ten tissue marking dyes did not exceed the manufacturer expiration date during use in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 08/12/2026 at 12:15 PM of the histopathology tissue grossing stations revealed the following expired 'Surgipath Tissue Marking & Margin Dye's' in use: a. 1 of 1 violet dye with lot # 042424 and expiration date of 04/24/2025. b. 1 of 1 green dye with lot # 042324 and expiration date of 04/23/2025. c. 1 of 1 red dye with lot # 040224 and expiration date of 04/02/2025. d. 1 of 1 yellow dye with lot # 043024 and expiration date of 04/30/2025. e. 1 of 1 blue dye with lot # 043024 and expiration date of 04/30/2025. f. 1 of 1 orange dye with lot # 022124 and expiration date of 02/21/2025. g. 1 of 1 black dye with lot # 022824 and expiration date of 02/28/2025. 2. Surveyor observation on 08/12/2026 at 1:25 PM of the Micrographic Surgery (MOHS) laboratory tissue grossing stations revealed the following expired marking dye's in use: a. 1 of 1 red dye with lot # 215 and expiration date of 08/2018. b. 1 of 1 yellow dye with lot # 092 and expiration date of 04/2018. c. 1 of 1 black dye with lot # 082

and expiration date of 04/2018. 3. Staff interview on 08/12/2026 at 1:30 PM with the laboratory supervisor confirmed the above findings. 4. The laboratory performs 35,000 tests annually in the subspecialty of histopathology.

D5427

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(c)

(c) Documentation. The laboratory must document all activities specified in this section.

This STANDARD is not met as evidenced by:

Based on surveyor observation, record review and staff interview, the laboratory failed to document the verification of test performance for the Tissue-Tek DRS 2000 Periodic acid-Schiff (PAS) automatic slide stainer, the hematoxylin and eosin (H&E) Prisma Plus automatic slide Stainer and the NeoPath Pro immunohistochemistry (IHC) automatic slide stainer prior to placing in use in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 08/12/2026 at 9:15 AM of the histopathology laboratory revealed the following instruments were in use: a. One of one Tissue-Tek DRS 2000 automatic slide stainer; serial number (SN): 49290965-0105. b. One of one Tissue-Tek Prisma Plus automatic slide stainer; SN: 474014380919. c. One of one NeoPath Pro automatic slide stainer; SN: NPP420129. 2. Record review on 08/12/2026 of the laboratory's instrument verification binders revealed lack of documentation of verification studies performed for the Tissue-Tek DRS 2000 PAS stainer and the H&E Prisma Plus Automatic Slide Stainer. 3. Record review on 08/12/2026 of the laboratory's performance verification binder for the NeoPath Pro IHC slide stainer revealed the following: a. Lack of documentation of antibody reactions/observations and laboratory director review/approval for 18 of 46 antibodies/clones as follows: i. Antibody BAP-1; Clone BSB-109 ii. Antibody BCL-2; Clone EP36 iii. Antibody CD10; Clone RBT-CD10 iv. Antibody CD68; Clone BSB-8 v. Antibody MCH-1; Clone g168-278 vi. Antibody MSH-2; Clone BSB-147 vii. Antibody BCL-2; Clone BSB-S viii. Antibody BCL-6; Clone EP278 ix. Antibody CD138; Clone B-838 x. Antibody CD31; Clone IA10 xi. Antibody CD4; Clone BSB-179 xii. Antibody CD56; Clone 123C3.D5 xiii. Antibody CD79a; Clone JCB117 xiv. Antibody CEA; Clone BSB-13 xv. Antibody Cytokeratin LMW; Clone CAM5.2 xvi. Antibody Kappa Light Chain; Clone BSB-58 xvii. Antibody Tpall; Clone Polyclonal xviii. Antibody BCL-6; Clone EP278 b. Lack of documentation of antibody reactions /observations for 28 of 46 antibodies/clones as follows: i. Antibody BerEP4; Clone Ber-EP4 ii. Antibody CP20; Clone L26 iii. Antibody CD21; Clone 2g9 iv. Antibody CD3; Clone LN10 v. Antibody CD45 LCA; Clone PD7/26/16 & 2B11 vi. Antibody CD5; Clone 4C7 vii. Antibody CD30; Clone SON6D/B5 viii. Antibody CD8; Clone SP16 ix. Antibody Chromogranin A; Clone LK2H10+PHE5 x. Antibody CK20; Clone KS20.8 xi. Antibody CK5/6; Clone GK5/6.007 xii. Antibody CK7; Clone OV-TL12/30 xiii. Antibody Desmin; Clone D33 xiv. Antibody ER; Clone SP1 xv. Antibody HMB45; Clone HMB45 xvi. Antibody Lambda; Clone N10/2 xvii. Antibody MART-1; Clone M2-7C10TM2-9E3 xviii. Antibody MUM-1; Clone BC5 xix. Antibody P16; Clone BC42 xx. Antibody P63; Clone A4A xxi. Antibody PARICK; Clone AE1/AE3 xxii. Antibody PAX5; Clone BC24 xxiii. Antibody PR16; Clone 16 xxiv. Antibody PRAME; Clone None xxv. Antibody S100; Clone 4C4.9 xxvi. Antibody PR16; Clone 16 xxvii. Antibody SMA; Clone IA4 xxviii. Antibody SOX10; Clone BC34 c. Lack of documentation of 20 cases ran per antibody, as specified in the laboratory's 'IHC Antibody Worksheet: To validate our testing methods, minimum of 20 cases were run in our facility using the NeoPath automated

	stainer and detection system'. 4. Staff interview on 08/12/2026 at 1:00 PM with the laboratory supervisor confirmed the above findings. 5. The laboratory performs 35,000 tests annually in the subspecialty of histopathology.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure that testing personnel (TP) had the required 24 semester hours educational credits in biology, chemistry and/or clinical or medical laboratory sciences to perform high complexity macroscopic gross examination of biopsy specimens in the subspecialty of histopathology. Refer to D6102
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure that testing personnel (TP) had the required educational qualification to perform high complexity macroscopic gross examination of biopsy specimens in the subspecialty of histopathology. Findings Include: 1. Record review on 08/12/2026 of the laboratory's TP#1 employment records revealed the following: a. Date of hire: 10/13/2025 b. Official undergraduate academic transcript from 'Southern Connecticut State University' with the following: i. Bachelor of Science in Exercise Science ii. Total semester hours: 120.5 iii. Total semester hours in chemistry: 8.00 iv. Total semester hours in biology: 12.00 c. Lack of documentation for an additional 4 semester hours in biology, chemistry or medical laboratory technology to meet the educational qualification requirements for high-complexity TP. 2. Record review on 08/12/2026 of TP#1 '90 Day Review of New Employee' competency assessment revealed the following: a. 'Exceeds expectations' for grossing procedure. b. Signed off by the laboratory supervisor on 01/14/2026. 3. Staff interview on 08/12/2026 at 10:00 AM with the laboratory supervisor confirmed the above findings. 4. The laboratory performs 35,000 tests annually in the subspecialty of histopathology.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

	This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory director failed to provide an approved standard operating procedure for the NeoPath Pro immunohistochemistry (IHC) automatic slide stainer prior to placing in use in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 08/12/2026 at 9:15 AM of the histopathology laboratory revealed one of one NeoPath Pro IHC automatic slide stainer in use with a serial number of NPP420129. 2. Record review on 08/12/2026 of the laboratory's 'SOP FOR NEO-Path' standard operating procedure revealed lack of documentation of the Laboratory Director's approval date and signature. 3. Staff interview on 08/12/2026 at 1:15 PM with the laboratory supervisor confirmed the above findings. 4. The laboratory performs 3,114 IHC tests annually in the subspecialty of histopathology.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that testing personnel (TP) had the required 24 semester hours educational credits in biology, chemistry and/or clinical or medical laboratory sciences to perform high complexity macroscopic gross examination of biopsy specimens in the subspecialty of histopathology. Refer to D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted

occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure that testing personnel (TP) had the required educational qualification to perform high complexity macroscopic gross examination of biopsy specimens in the subspecialty of histopathology. Findings Include: 1. Record review on 08/12/2026 of the laboratory's TP#1 employment records revealed the following: a. Date of hire: 10/13/2025 b. Official undergraduate academic transcript from 'Southern Connecticut State University' with the following: i. Bachelor of Science in Exercise Science ii. Total semester hours: 120.5 iii. Total semester hours in chemistry: 8.00 iv. Total semester hours in biology: 12.00 c. Lack of documentation for an additional 4 semester hours in biology, chemistry or medical laboratory technology to meet the educational qualification requirements for high-complexity TP. 2. Record review on 08/12/2026 of TP#1 '90 Day Review of New Employee' competency assessment revealed the following: a. 'Exceeds expectations' for grossing procedure. b. Signed off by the laboratory supervisor on 01/14/2026. 3. Staff interview on 08/12/2026 at 10:00 AM with the laboratory supervisor confirmed the above findings. 4. The laboratory performs 35,000 tests annually in the subspecialty of histopathology.