Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0100947	05/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermcare Pc	25 Tamarack Avenue, Danbury, 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 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 provide an approved MOHS written procedure in the subspecialty of histopathology. Findings include: 1. Record review on 05/12/2022 of the 'Advanced DermCare Histology Q.A., Q.C., SOP's' binder revealed lack of an approved MOHS micrographics standard operating procedure. 2. Staff interview on 05/12/2022 at 1:15 PM with the laboratory manager confirmed the above finding and stated that "he cannot find the MOHS procedure in the laboratory". 3. The laboratory performs 800 MOHS surgeries annually in the subspecialty of Histopathology.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review, surveyor observation and staff interview, the laboratory failed to follow its H&E staining procedure in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 05/12/2022 1:09 PM of the Tissue Tek Prisma Automated Slide Stainer current program versus record review of the 'Advanced DermCare Histology Q.A., Q.C., SOP's Binder, Tissue Staining Program Number 2: H&E' approved procedure revealed the following: a. 20 of 20 numbered reagent stations did not match the written procedure. b. 5 of 20 reagent incubation times did not match the written procedure. 2. Staff interview on 05/12/2022 at 1:20 PM with the laboratory manager confirmed the above finding and stated that "he forgot to update the SOP to reflect what's on the Tissue Tek Prisma Automated Slide Stainer". 3. The laboratory performs 8000 H&E staining 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 provide evidence of monitoring and documenting humidity requirements in the subspecialty of histopathology. Findings include: 1. Record review on 05/12/2022 of the 'Equipment Quality Control Form 4: Cryostat/Microtome Maintenance Record' for the years of 2020, 2021, and 2022 revealed lack of documentation of humidity levels. 2. Record review on 05/12/2022 of the 'Avantik Cryostat QS11/QS11UV Instruction Manual' revealed the following: a. Operating conditions at a max. rel. humidity of 60% 3. Staff interview on 05/12/2022 at 11:17 AM with the laboratory manager confirmed the above and stated, "He was unaware that documentation of air humidity is a requirement for proper function of the lab equipment". 4. The laboratory performs 800 MOHS surgeries annually in the subspecialty of Histopathology.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the

	following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to provide evidence of appropriate issuance and maintenance of corrected and/or amended reports when problems were identified in the subspecialty of Histopathology and specialty of Microbiology. Findings include: 1. Record review on 05/12/2022 of final patient test reports revealed the lack of documentation of any corrected reports by the laboratory. 2. Staff interview on 05/12/2022 at 1:45 PM with the laboratory manager confirmed the above findings and commented that multiple patient reports have been corrected however the laboratory has no mechanism of accessibility. 3. The laboratory performs 9,130 tests annually in the subspecialty of Histopathology and 350 tests annually in the specialty of Microbiology.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish a written policy to assess and monitor problems identified in the post analytic systems in the subspecialty of histopathology. Findings include: 1. Record review on 05/12/2022 of the 'Advanced Dermcare Histology Q.A., Q.C., SOP's Binder' revealed no written policy for post analytical systems and what corrective actions must be taken to correct the problem. 2. Staff interview on 05/12/2022 at 1:45 PM with the laboratory manager confirmed the above and revealed that there's no ongoing mechanism to identify and trace back corrected/amended reports when needed. 3. The laboratory performs 9,130 tests annually in the subspecialty of Histopathology and 350 tests annually in the Microbiology.