Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0092534	04/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Department Of Dermatology	21 South Rd 1st Fl, Ste 120, Farmington, 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 surveyor observation, record review and staff interview, the laboratory failed to provide a written laboratory procedure for the Automated Coverslipper currently in use in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 4/12/2022 at 11:20 AM of the current laboratory equipment revealed a Leica CV5030 coverslipper installed in 2015 and attached to the Leica Stainer. 2. Record review on 4/12/2022 of the laboratory procedure manual revealed: a. A coverslipper procedure for the 'HCM 6000 Automated Glass Coverslipper'. b. Lack of documentation of a procedure for the Leica CV5030 instrument currently in use. 3. Staff Interview on 4/12/2022 at 11:25 AM with Testing Personnel #2 (TP#2) confirmed the above findings. In addition, TP#2 remarked the serial number of the Leica CV5030 translates to the instrument being in service since 2015.
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 record review and staff interview, the laboratory failed to ensure laboratory

	procedures were approved by the laboratory Director (LD) prior to patient use in the subspecialty of histopathology. Findings include: 1. Record review of the following laboratory procedure manuals on 4/12/2022 revealed the lack of documentation of the current LD approval prior to patient testing: a. Immuno Special Staining (IHC) procedure manual b. MOHS procedure manual 2. Record review on 4/12/2022 of the Dermatopathology procedure manual revealed the following procedures are marked as revised with no current laboratory director signature of approval: a. Temperature Quality Control b. Specimen Collection and Handling c. Specimen Grossing d. Embedding Guidelines e. Missing Specimen Procedure f. Automated Hematoxylin and Eosin Staining Procedure 3. Staff interview with testing personnel #2 (TP#2) on 4 /12/2022 at 12:30 PM confirmed the IHC manual had been reviewed by the IHC technical supervisor and TP#2 was unaware the LD needed to review and approve. 4. Staff interview with testing personnel #3 on 4/12/2022 at 1:40 PM confirmed the MOHS procedure manual was not signed and approved by the LD. 5. Staff interview on 4/12/2022 at 11:20 AM with the laboratory supervisor confirmed the procedures in 2 above were revised by a prior histology technologist with no signed approval by the LD.
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 surveyor observation, record review and staff interview, the laboratory failed to provide evidence of monitoring and documenting proper paraffin temperature requirements for the period of April 2020 until April 12 2022. Findings include: 1. Record review on 4/12/2022 of the maintenance logs for the 'ASP 300 processor: Paraffin Temperature' chart revealed: a. The acceptable paraffin temperature range was 59 to 63 degrees Celsius. b. Lack of documentation of daily paraffin temperatures for the period of April 2020 until April 12 2022. 2. Record review on 4/12/2022 of the maintenance logs for the 'ASP 300S processor: Paraffin Temperature' chart revealed: a. The acceptable paraffin temperature range was 59 to 63 degrees Celsius. b. Lack of documentation of daily paraffin temperatures for the period of April 2020 until April 12 2022 3. Record review on 4/12/2022 of the laboratory's 'Temperature Quality Control' procedure revealed "Temperatures of all instruments/equipment on the Daily Q.C. Log should be taken early in the day to allow for corrective action to be taken in the event of an elevated or low temperature". 4. Staff interview with Testing Personnel # 2 on 4/12/2022 at 11:05 AM stated the laboratory discontinued documenting the temperatures and only document when paraffin is changed for the two processors.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of

	all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to evaluate testing personnel (TP) to ensure competency to perform and report Potassium Hydroxide (KOH) test results in the subspecialty of mycology. Findings include: 1. Record review on 4/12/2022 of the laboratory's CMS 209 Laboratory Personnel Report form revealed the laboratory employs 19 moderate complexity TP. 2. Record review on 4/12 /2022 of the laboratory competency assessment records for 2020 and 2021 revealed the lack of documentation of the six required competency assessment criteria for 19 of 19 TP performing the KOH test procedure. 3. Staff interview on 4/12/2022 at 1:55 PM with the laboratory supervisor confirmed the laboratory did not have documentation of competency assessments for the moderate complexity TP.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and staff interview, the technical supervisor (TS) failed to ensure 10 of 10 testing personnel performing macroscopic gross examination of skin specimens were evaluated for training and/or competency by a qualified individual for the period of 2020 and 2021 in the subspecialty of histopathology. Findings include: 1. Record review on 4/12/2022 of the laboratory's training records for 2020 and 2021 revealed the following: a. 2 of 2 TP training documents list 'Accurately performs grossing of' various specimen types with signatures by 2 histology technologists. Lack of documentation of approval by a technical supervisor. b. The training documentation lacked the development of the knowledge and skill to perform macroscopic gross examination of skin specimens prior to patient testing. 2. Record review on 4/12/2022 of the laboratory's competency records for 2020 and 2021 revealed the following: a. 7 of 17 competency assessments for TP 'grossing' lack documentation of review and approval by a technical supervisor. b. 8 of 17 competency assessments for TP 'grossing' have documented signature by the laboratory supervisor and lack documentation of review and approval by a technical supervisor. c. 2 of 17 competency assessments for TP 'grossing' have documented signatures by 2 histology technologists and lack documentation of review and approval by a technical supervisor. d. The above competency records lacked the six required elements of competency assessments. 3. Record review on 4/12/2022 of the laboratory supervisor credentials revealed the highest level of educational qualification was a bachelor degree and does not meet the histopathology requirement of a medical degree to perform training and competency assessments noted in 2b above. 4. Record review on 4/12/2022 of the credentials for the histology technologists revealed the highest level of educational qualification was a bachelor degree and does not meet the histopathology requirement of a medical degree to

	perform training and competency assessments in 1a and 2c above. 5. Staff interview with the laboratory supervisor on 4/12/2022 at 12:45 PM confirmed the above. 6. The laboratory performs 37,960 macroscopic gross examination annually in the subspecialty of histopathology.