Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1047946	03/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
University Of Maryland Dermatologists	5890 Waterloo Road, Columbia, MD	

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
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 remote review of the laboratory's procedure and interview with the histotechnician (HT), the laboratory failed to include detailed instructions for performing peer review. Findings: 1. The "Diagnostic Proficiency Review" procedure stated that each Mohs surgeon will submit cases on a bi-annual basis to be peer reviewed for stain quality, diagnosis, and completeness of tissue margins. 2. The procedure did not include instructions for how to transport the slides when reviewed off site and document the removal of the slides from the laboratory. 3. The procedure did not include instructions for corrective actions to be taken if the peer review finds

	the stain quality, diagnosis, or completeness of tissue margins to be unsatisfactory. 4. During the phone interview on 03/11/2021 at 2:00 PM, the HT confirmed that the procedure manual did not include instructions for the transport of peer review slides and corrective actions to be taken when the peer review determines unsatisfactory performance.
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 remote review of the procedure manual and maintenance logs and interview with the histotechnician (HT), the laboratory failed to define the acceptable humidity ranges for reliable test system operation. Findings: 1. The laboratory's cryostat maintenance log had a row to record the room humidity. Neither the log nor the procedure listed the acceptable humidity range for operation of the cryostat. 2. During the phone interview on 03/11/2021 at 2:00 PM, the HT confirmed that the maintenance log did not include the acceptable humidity ranges for operation of the cryostat.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on remote review of the final test report and interview with the histotechnician (HT), the laboratory failed to indicate on the final report where the testing was performed. Findings: 1. The laboratory has two locations, both of which were listed on the final test reports. 2. The test report did not indicate at which of the two locations the testing was performed. 3. During the phone interview on 03/11/2021 at 2:00 PM, the HT confirmed that the final report did not indicate at which of the two laboratory locations testing was performed.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the quarterly quality assurance (QA) log and interview with the histotechnician (HT), the laboratory director (LD) failed to record the date of each QA review to document that each review was performed in a timely manner. Findings: 1. The laboratory's log titled "Mohs Director Quarterly Q.C. [quality control] Log Check" stated that the LD will review and initial laboratory records and logs on a quarterly basis. 2. The quarterly QC log for 2020 contains the initials of the LD for each quarter, but does not include the date the LD performed each quarterly review to document that each review was performed in a timely manner. 3. During the phone interview on 03/11/2021 at 2:00 PM, the HT confirmed that the quarterly QC log did not contain the date of LD review.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 remote review of laboratory records and interview with the histotechnician (HT), the laboratory failed to document training and approval of a contract histotechnician prior to testing patient specimens. Findings: 1. Remote review of laboratory logs determined that a contract histotechnician performed the slide preparation on 12/31/2020. 2. The personnel records that were reviewed did not list any training for the contract histotechnician. 3. During the phone interview on 03/11 /2021 at 2:00 PM, the HT confirmed that the laboratory director did not record the initial training and assessment of the contract histotechnician's education and experience.