Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1047946	03/16/2023
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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview with the testing person (TP), the laboratory failed to have an eyewash station in the area where Mohs surgery patient slides were processed. Findings: 1. It was observed that the area where patient slides from Mohs surgery were prepared and stained did not contain an eyewash station to aid in flushing out the eyes of testing personnel should they be splashed with staining reagents. 2. During the survey on March 2, 2023 at 1:00 PM, the LD confirmed that an eyewash station was not located in the area where patient slides were processed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the procedure and laboratory records and interview with the testing person (TP), the laboratory failed to document the biannual accuracy /proficiency verification of the Mohs surgeon in 2021 and 2022. Findings: 1. The procedure titled "Diagnostic Proficiency Review" stated that "Each Mohs surgeon, including the Mohs laboratory director, will submit cases on a bi-annual basis for review to verify accuracy/proficiency of the diagnosis and testing procedure. The

	cases will be reviewed for stain quality, diagnosis, and completeness of tissue margins. This will be documented on the Mohs case review log. " 2. The procedure went on to state that if "the review must take place off-site" then the "accession number, number of slides, and patient MRN will be logged on the slide tracking log that is created for all slides not in the laboratory." 3. Review of laboratory records showed that there were no Mohs case review logs and no slide tracking log documenting biannual accuracy/proficiency verification. 4. In an email received on 03 /16/2023 at 12:42 PM, the TP confirmed that biannual accuracy/proficiency verification was not documented for the Mohs surgeon in 2021 and 2022.
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 review of the procedure manual and interview with the nurse, the laboratory's procedure manual failed to include instructions for how the Mohs surgery maps were entered into the patient record. Findings: 1. The laboratory surveyed was a satellite location in Columbia, Maryland (MD) and the main laboratory was located in Baltimore, MD. 2. All patient records were stored at the Baltimore location. 3. The nurse stated that the staff would collect all the paperwork, including the Mohs maps, make sure all records were complete and matched each patient identity, then transport all paperwork to the Baltimore facility to scan into the electronic medical records (EMR). 4. There was no procedure for how the Mohs maps were matched with each patient, transported to the Baltimore facility, and entered into the EMR. 5. During the survey on 03/02/2023 at 12:00 PM, the nurse confirmed that there was no written procedure for the process of reconciling patient records, transporting them to Baltimore, then entering them into the EMR.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)

	Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the testing person (TP), the staining containers located in the automated stainer were not labeled to indicate which staining reagent was contained within. Findings 1. The laboratory used an automated slide stainer to apply the hematoxylin and eosin stain to patient slides. 2. The individual containers holding each staining reagent within the automated stainer were not labeled with the identity or expiration date of each staining reagent contained within. 3. During the survey on 03/02/2023 at 1:00 PM, the TP confirmed that the individual containers in the automated stainer were not labeled with the identity or expiration date of the staining reagents contained within.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 review of staining reagent logs, observation, and interview with the testing person (TP), the laboratory did not ensure that staining reagents were not used beyond their expiration date. Findings: 1. The laboratory had a "Reagent Log" to document the name of the staining reagent, lot number, expiration date, opened date, and TP's initials. 2. The log showed that lot number 2104313 of the Eosin Y expired on 02/18 /2023 and no new lot number was documented. 3. The log showed that lot number 2017009 of the bluing reagent expired on 06/23/2021 and no new lot number was documented. 4. The log listed lot number K160-21 of Scott's tap water solution with an expiration date of 06/17/2023 and no opened date. 5. The log listed lot number 092108 for histoclear with no expiration or opened date. 6. It was observed that the bottle of Eosin Y stored in the flammable cabinet was expired. 7. During the survey on 03/02/2023, the TP confirmed that the "Reagent Log" was not complete and expired staining reagents were stored in the flammable cabinet.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the testing person (TP), the laboratory failed to document preventive maintenance (PM) for the fume hood and automatic slide stainer. Findings: 1. The laboratory used an automated slide stainer that was contained within a fume hood to apply the hematoxylin and eosin stain to patient slides. 2. There was no procedure defining what PM was required for the fume

	hood and automatic slide stainer. 3. There was a sticker affixed to the fume hood indicating that PM was overdue. 4. During the survey on 03/02/2023 at 1:00 PM, the TP confirmed that the facility the laboratory was located in was responsible for performing PM on all equipment and was unsure the last time PM was performed for the fume hood and automatic slide stainer.
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: Note: This is a repeat deficiency. The laboratory was cited during the recertification survey completed on March 11, 2021 for not documenting training and approval of contract histotechnicians (HTs) prior to testing patient specimens. The laboratory's plan of correction stated that the deficiency was corrected on March 18, 2021. Based on review of maintenance and personnel records and interview with the testing person (TP), the laboratory director failed to document training, qualifications, and approval of the contract HTs prior to testing patient specimens. Findings: 1. The procedure titled "Responsibilities and Duties for Mohs Staff" stated that the HT must "be a histology technician with at least one year of current general histology experience. HT (ASCP) registry is preferred, but not required." The procedure went on to state that the "histology technician will have documented training in the method used by the specific Mohs surgeon they are assisting. This documentation will be signed as completed by the Mohs director." 2. Review of the maintenance records showed that at the end of 05/2021 and beginning of 06/2021 the laboratory had three contract HTs processing slides. 3. Review of the personnel records showed that training and HT (ASCP) certification records were only present for one of the three contract HTs. 4. In an email received on 03/15/2023 at 9:07 AM, the TP confirmed that the laboratory did not have a record of the training, qualifications and approval of the contract HTs performing slide processing in 05/2021 and 06/2021.