Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2321219	03/26/2026
Name of Provider or Supplier	**Street Address, City, State**	
University Of Maryland Dermatology	1447 York Road Ste 102, Lutherville, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 procedure manual and quality assurance (QA) record review and interview with the laboratory director (LD), the laboratory failed to follow written procedures for performing quarterly quality control (QC) and maintenance log checks as part of its QA program. Findings: 1. The procedure, "Quarterly Records" states, "The quarterly record form documents that quality control forms, including Mohs maps, have been completed by the Mohs technical/surgery staff. The Mohs director signs off each quarter to verify this has been completed." The laboratory created a "Mohs Director Quarterly Q.C. Log Check" (quarterly log) form which listed the records that should be reviewed. 2. A review of QA records from May 2025 through March 2026 showed that there were no quarterly logs which had been completed or signed by the LD. 3. During an interview on 03/09/2026 at 12:45 PM, the LD confirmed that the laboratory had failed to follow the written procedure for performing quarterly QA reviews.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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 procedure manual review and interview with the laboratory director (LD), the laboratory failed to ensure that the laboratory's written procedure manual was approved, signed, and dated by the LD before use. Findings: 1. A review of the current written procedure manual showed that the procedures were not approved (signed and dated) by the LD. 2. During an interview on 03/09/2026 at 12:45 PM, the LD confirmed that they had failed to sign and date the laboratory's procedure manual to indicate that it had been approved before use.
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 reagent log record review, observation, and interview with the histotechnologist (HT) and laboratory director (LD), the laboratory failed to ensure that histopathology stains and reagents were not used after they exceeded their expiration date. Findings: 1. The laboratory performs Hematoxylin and Eosin (H&E) staining procedures to evaluate histopathology slides for Mohs surgery patients. The laboratory records the "Lot #", "receive date", "Open date", and "Expiration Date" of each reagent on the "Mohs Reagent Log". 2. A review of Mohs reagent logs from May 2025 through March 2026 showed that the laboratory received a bottle of "Eosin-Y 1% Alcoholic" (Eosin-Y) stain (lot # 43080043) on 09/30/2024 which was opened on 05/19/2025 and expired on 08/11/2025, and another bottle of Eosin-Y (lot # 44030376) received on 09/15/2025 which was documented as opened on 09/06/2025 and had an expiration date of 03/19/2026. 3. During a tour of the laboratory at 10:30 AM, it was observed that both bottles of Eosin-Y stain were stored in the laboratory's flammable cabinet. The bottle which expired on 08/11/2025 (lot # 43080043) was observed to be half empty. During an interview at that time, the HT stated that the half-empty and expired bottle was the one being used for patient testing. 4. During an interview on 03/09/2026 at 12:45 PM, the LD confirmed that the laboratory performed testing on patients using expired reagents.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on quality control (QC) and patient log record review and interview with the laboratory director (LD), the laboratory failed to ensure that daily stain QC was consistently documented, recording the quality of the staining characteristics of the Hematoxylin and Eosin (H&E) stain each day of patient testing. Findings: 1. The laboratory performs H&E staining procedures to evaluate histopathology slides for Mohs surgery patients. Daily stain QC for the H&E stain is recorded on the "H & E Quality Control Slide Log" (QC log). 2. A review of daily QC logs from 07/08/2025

	through 03/09/2026 showed that the results of the stain QC were not documented on the QC log on 09/29/2025, 09/30/2025, 10/07/2025, and 03/03/2026; and 3. A review of patient logs from the same time period showed that there were 15 patients tested on 09/29/2025 ("Accession #" LM25-326 through LM25-340); 10 patients tested on 09/30 /2025 ("Accession #" LM25-341 through LM25-350); 13 patients tested on 10/07 /2025 ("Accession #" LM25-365 through LM25-377); and nine patients tested on 03 /03/2026 ("Accession #" LM26-157 through LM26-165). 4. During an interview on 03 /09/2026 at 12:45 PM, the LD confirmed that daily stain QC was not documented each day of use when patient slides were tested.