Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2120936	06/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Medstar Mohs Laboratory	5530 Wisconsin Ave Suite 730, Chevy Chase, 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
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 proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory failed to ensure that PT was performed at least twice annually for the specialty of histopathology. Findings: 1. During an interview on 06/06 /2025 at 10:45 AM the LD stated that once a year the laboratory sends out patient slides from completed Mohs surgery cases to another dermatologist to review in order to meet the requirement for PT. 2. Record review showed that the laboratory recorded the case numbers of the slides which were sent out on a "Mohs Quality Improvement and Consensus Sheet" (Mohs QI form). 3. Two Mohs QI forms were reviewed. One sheet listed seven cases which were originally tested in 2022 (more than two years ago and outside the scope of this CLIA survey) and four cases tested in 2023 (M23-17, M23-24, M23-53, and M23-74). The second sheet listed six cases from 2024 (M24-006, M24-013, M24-040, M24-046, M24-63, and M24-321) and six cases from 2025 (M25-05, M25-048, M25-067, M25-070, M25-082, and M25-093). 4. The sheets did not document the date that the slides were sent out for PT. 5. During an interview on 06/06/2025 at 11:00 AM, the LD confirmed that PT slides were not sent out twice a year.
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 proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory failed to ensure that the written procedure manual included a procedure for performing PT. Findings: 1. The laboratory performs H&E staining procedures to evaluate histopathology slides for Mohs surgery patients. 2. During an interview on 06/06/2025 at 10:45 AM the LD stated that the laboratory sends out several patient cases and slides once a year to another dermatologist to evaluate. 3. Record review showed that the PT was documented on a "Mohs Quality Improvement and Consensus Sheet" (Mohs QI form) which had columns labeled, "Case ID," "Path Req (if applicable)," "Grossing (+/-)," "Staining (+/-)," "Diagnostic Consensus (+/-)," "Comments," and "Reviewer." 4. A review of the laboratory's procedure manual showed that it did not include a procedure for how the laboratory performs PT for the discipline of histopathology, including how many cases to send to the second dermatologist and how to interpret the results documented on the Mohs QI form. 5. During an interview on 06/06/2025 at 11:00 AM, the LD confirmed that the laboratory failed to include a procedure for performing PT in the laboratory's written procedure manual.
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. Daily stain QC for the H&E stain is recorded on the "Hematoxylin and Eosin Staining Quality Control" log. 2. A review of daily stain QC logs from seven days of testing from 12/04/2023 to 12/20/2023 showed that on one of seven days (12/06/2023) the results of the stain QC was not documented on the "Hematoxylin and Eosin Staining Quality Control" log. 3. A review of patient logs showed that there were six patients tested on 12/06/2023 (case # M23-345 through case # M23-350); and 4. A review of daily stain QC logs from six days of testing from 09/11/2024 to 09/30/2024 showed that on one of six days (09/18/2024) the results of the stain QC was not documented on the "Hematoxylin and Eosin Staining Quality Control" log. 5. A review of patient logs showed that there were four patients tested on 09/18/2024 (case # M24-229 through case # M24-232). 6. During an interview on 06/06/2025 at 11:00 AM, the LD confirmed that daily stain QC was not consistently documented.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require

	corrective action; and This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory director (LD), the LD failed to ensure that all PT reports were reviewed and evaluated to identify any problems that required corrective action. Findings: 1. Record review showed that the laboratory recorded the case numbers of the slides which were sent out for PT on a "Mohs Quality Improvement and Consensus Sheet" (Mohs QI form). The form had several labeled columns (cross-refer to D5401 for details) and a place where the second dermatologist put their initials after documenting the results of their review. 2. A review of two Mohs QI forms which listed the case numbers of slides tested from 2023 through 2025 (cross-refer to D5217 for details) showed that there was no documentation that the completed PT forms had been evaluated by the LD after their return to the laboratory. 3. During an interview on 06/06/2025 at 11:00 AM the LD confirmed that they had not signed PT results, indicating that they had been reviewed to identify any problems that required corrective action.