

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0216260	<b>(X3) Date Survey Completed</b>  05/24/2023
<b>Name of Provider or Supplier</b>  University Of Maryland Dermatologists Pa	<b>Street Address, City, State</b>  419 W Redwood Street Suite 260, Baltimore, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>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. During the survey on 05/24 /2023 at 12:00 PM, the TP confirmed that biannual accuracy/proficiency verification was not documented for the Mohs surgeon in 2021 and 2022.</p>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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</p>

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 05/24/2023 at 12:00 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 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 used 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 2002233 of Eosin expired on 01/27/2022. The next documented lot number for Eosin was L22515 with an expiration date of 09/09/2023, but the opened date was not filled in. 3. The log showed that lot number 129138 of hematoxylin expired on 02/28/2023. The next documented lot number for hematoxylin was 160052 with an expiration date of 04/30/2024, but the opened date was not filled in. 4. The log showed that lot number 2104101 of Scott's bluing expired on 02/12/2022. The next documented lot number was L16021 which was opened on 06/13/2022, about 4 months after the previous lot number expired. 5. During the survey on 05/24/2023 at 12:00 PM, the TP confirmed that the "Reagent Log" showed that expired stains were used for patient testing.

**D5473**

CONTROL PROCEDURES  
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the procedure and the hematoxylin and eosin (H & E) stain quality control (QC) log and interview with the testing person (TP), the laboratory failed to document slide staining quality each day patients were tested. Findings: 1. The procedure titled "Identification, Labeling and Storage of Mohs Surgery Slides" stated

"The daily quality control slide will be examined by the Mohs surgeon and the quality of the staining will be documented in the log that has been created for this purpose."  
2. The H & E Quality Control Log stated "The Mohs surgeon will identify the QC slide as adequate (+) or inadequate (-). Slides that are marked inadequate (-) will have a comment identifying deficiencies" and included columns to record the date, the accession number of the slide used for QC, the "Slide Quality" results, and the Mohs surgeon's initials. 3. Review of the QC log from 05/19/2021 - 05/24/2023 showed that the "Slide Quality" was not documented or initialed by the Mohs surgeon from 06/28/2021-12/27/2021 and from 10/17/2022-12/27/2022. 4. During the survey on 05/24/2023 at 12:00 PM, the TP confirmed that the H & E stain quality was not consistently documented by the Mohs surgeon each day of patient testing.

**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 procedure and the quarterly quality control (QC) log and interview with the testing person (TP), the laboratory director failed to maintain the established quality assessment (QA) procedure by not performing quarterly reviews. Findings: 1. The procedure titled "Quarterly Records" stated that "The quarterly record form documents that quality control forms, including Mohs maps, have been completed by the Mohs technician/surgery staff. The Mohs director signs off each quarter to verify this has been completed." 2. The "Mohs Director Quarterly Q.C. Log Check" (quarterly log) stated "The Mohs director will initial that records are complete for each quarter. Incomplete records or problems identified will be described below with the corrective action taken." 3. The quarterly log was last completed and initialed by the laboratory director on 04/13/2021. 4. During the survey on 05/24/2023 at 12:00 PM, the TP confirmed that the last quarterly QA review was performed on 04/13/2021.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with the testing person (TP), documentation of competency evaluations for the TP were missing for 2021 and 2022. Findings: 1. Personnel records for the current TP did not include recent competency evaluation documentation. 2. During the survey on 05/24/2023 at 12:00 PM, the TP confirmed that documentation of competency for the TP was missing for 2021 and 2022.