

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0894223	(X3) Date Survey Completed 04/24/2025
Name of Provider or Supplier Tideway Dermatology	Street Address, City, State 930 Revolution St, Havre De Grace, 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	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review, surveyor observation, and interview with the histotechnologist (HT), the laboratory failed to follow written procedures for performing testing on patient skin and nail scrapings for fungal elements and parasites, using a potassium hydroxide (KOH) solution. Findings: 1. The procedure, "KOH Policy and Procedure" states that patient skin and nail samples should be mixed with "1-2 drops of 20% KOH." 2. During a tour of the laboratory at 10:10 AM, it was observed that the opened and in-use bottle of KOH was labeled as "Potassium Hydroxide 10%." This did not match the concentration of 20% KOH to be used as listed in the written procedure. 3. During an interview on 04/24/2025 at 11:15 AM, the HT confirmed that the concentration of KOH used for patient testing was not what was listed in the written procedure, and that testing personnel were not following the laboratory 's procedure for KOH testing.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on procedure manual review and interview with the histotechnologist (HT), the laboratory failed to ensure that all of the laboratory 's written procedures were approved, signed, and dated by the LD before use. Findings: 1. During a tour of the laboratory at 10:10 AM, it was observed that the clipboard containing the patient log for testing skin and nail samples with potassium hydroxide (KOH) also held three different procedures for performing KOH testing: "KOH Guidelines," "KOH Procedure," and "KOH Policy and Procedure." 2. Three of the three procedures on the KOH clipboard were not approved (signed and dated) by the laboratory director. 3. A review of the laboratory 's approved procedure manual showed that it did not include a copy of the three KOH procedures found on the clipboard. 4. During an interview on 04/24/2025 at 11:15 AM, the HT confirmed that the three KOH procedures were not approved by the laboratory director.

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 record review, observation, and interview with the histotechnologist (HT), the laboratory failed to ensure that histopathology stains and reagents were not used after they exceeded their expiration date. Findings: 1. The laboratory performs a slide examination of skin and nail scrapings for fungal elements and parasites, using a potassium hydroxide (KOH) solution to dissolve tissue cells and keratinized material. 2. During a tour of the laboratory at 10:10 AM it was observed that the in-use bottle of KOH (lot number 2202) had expired on 07/21/2024. 3. A review of the "KOH Log" showed that 14 patients were tested using the expired KOH reagent between 08/07/2024 and 04/17/2025. 4. The laboratory also uses tissue marking dye, to stain patient tissue samples prior to processing for Mohs surgery. 5. During a tour of the laboratory at 11:08 AM it was observed that five of five in-use bottles of tissue marking dyes were expired: "Black" (lot number 167158, expiration date 02/28/2025), "Yellow" (lot number 166232, expiration date 02/28/2025), "Green" (lot number 168109, expiration date 03/31/2025), "Red" (lot number 168107, expiration date 02/28/2025), and "Blue" (lot number 166704, expiration date 01/31/2025). 6. During an interview on 04/24/2025 at 11:15 AM the HT confirmed that the laboratory failed to ensure that histopathology stains and reagents were not used after they exceeded their expiration date.