

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2272601	(X3) Date Survey Completed 09/15/2023
Name of Provider or Supplier Dockside Dermatology Llc	Street Address, City, State 8601 Veterans Hwy #201, Millersville, 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 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 and record review and interview with the laboratory director (LD), the laboratory did not ensure that there is an approved policy for all duties and tasks performed in the laboratory. Findings: 1. Record review showed that the laboratory documents monthly eye wash "operational checks" (maintenance) on an "Eye Wash Station Log." Laboratory staff check "Y" if the eye wash is "in good working condition." 2. Procedure manual review showed that the laboratory did not have an approved, written procedure for how to perform monthly eye wash maintenance, including how to check if the eye wash station is "in good working condition." 3. Record review showed that the laboratory has a blank log for documenting when histology slides are sent out to another doctor to review as part of the laboratory's proficiency testing (PT) program. 4. Procedure manual review showed that the laboratory did not have an approved, written procedure for how to perform and evaluate PT. 5. During an interview on 09/15/2023 at 2:50 PM, the LD confirmed that the laboratory's procedure manual did not include a policy for all duties and tasks performed in the laboratory.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,</p>

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 procedure manual review and interview with the laboratory director (LD), the laboratory did not ensure that there is an approved policy for all tests performed in the laboratory. Findings: 1. During an interview on 09/15/2023 at 2:30 PM, the LD stated that the laboratory performs KOH (potassium hydroxide) and scabies testing on their dermatology patients. 2. A review of the laboratory's procedure manual showed that the laboratory did not have an approved, written procedure for how to perform KOH or scabies testing. This was confirmed by the LD at 2:50 PM on the day of the survey.

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 laboratory director (LD), the laboratory did not ensure that the in-use histology stain reagents are labeled with the date that they are opened. Findings: 1. During a tour of the laboratory at 1:15 PM, it was observed that the opened and in-use histology stain reagents in the laboratory flammable cabinet were not labeled with the date that they were opened and put in to use. These include: Gill 3 Hematoxylin (lot# 169445, expiration date 09/30/2024); Eosin-Y (lot# 164413, expiration date 01/31/2025); Hematoxylin "Type One" (lot# 154106, expiration date 01/31/2024); Eosin-Y "Type One" (lot# 155325, expiration date 02/29/2024); 95% Alcohol (lot# 2300304, expiration date 01/08/2026); 100% Alcohol (lot# 2300610, expiration date 01/12/2026); Scott's Tap Water (lot# M160-20, expiration date 06/23/2024); and UltraClear Xylene Substitute (lot# 2307894, expiration date 07/2025). 2. During an interview on 09/15/2023 at 2:50 PM, the LD confirmed that the histology stain reagents in-use were not labeled with the date that they were opened.

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 record review and interview with the laboratory director (LD) and histotechnician, the laboratory failed to ensure that the lot numbers and expiration dates of reagents used for histology testing are documented. Findings: 1. The laboratory performs histology testing on dermatology skin and tissue specimens. 2. Record review showed that the laboratory had no written documentation of lot numbers and expiration dates of reagents used to stain skin and tissue specimens for interpretation by the doctor. 3. During a telephone interview at 2:27 PM on the day of the survey, the histotechnician stated that the laboratory did not have a reagent log which documented the lot numbers and expiration dates of staining reagents used in the laboratory. This was confirmed by the LD.

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:

Based on procedure manual and record review and interview with the laboratory director (LD), the LD failed to ensure that 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. Findings: 1. The laboratory currently has 2 testing personnel (TP) listed on the "Laboratory Personnel Report" (CMS-209) who perform the grossing of tissue specimens for histology testing. 2. The procedure "Responsibilities and Duties for Mohs Technician" states, "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." 3. Record review showed that 1 of 2 TP had received their first competency assessment, however there was no documentation of the initial training for 2 of 2 TP. 4. During an interview on 09/15/2023 at 2:50 PM, the LD confirmed that they did not ensure that the the initial training of the TP was documented.