

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2094124	(X3) Date Survey Completed 02/08/2023
Name of Provider or Supplier Forefront Dermatology-Pp East Kenosha	Street Address, City, State 8501 75th St Ste J, Kenosha, WI	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, observation of reagents in use in the laboratory, and interview with the regional clinic manager, the laboratory used expired xylene substitute on sixty-eight of the sixty-eight days of testing from April 4 through December 15, 2022. Findings include: 1. Review of the 'Quality Control Assessment of Mohs Tissue Staining Procedure' logs (QC log) from April 4 through December 15, 2022 showed testing personnel documented the lot number and expiration dates of the reagents used for 68 days of patient testing. Review of the records for xylene substitute showed personnel recorded the following information: Lot number / Dates recorded 08220 / April 4 - October 4, 2022 08230 / October 10 - December 15, 2022 Expiration Date (Year - Month - Day) / Dates recorded 22 - 2 - 28 / April 4 - July 21, 2022 28 - 2 - 28 / July 25 - December 15, 2022 2. Review of the 'Chemical Log Sheet' showed the log included reagents received between March 16, 2020 and November 16, 2022. There is no record for Sub-X (Xylene Substitute) lot 08220 or 08230. The log showed lot 062322 was received on November 16, 2022. The 'Date Opened' column was blank for this reagent. 3. Observation of the xylene substitute reagent available in the laboratory on February 8, 2023 at 9:35 AM revealed the reagent lot number was 062322, expiration date 2024-06-23. Personnel had not labeled the bottle with an opened date. 4. Interview with the regional clinic manager on February 8, 2023 at 9:40 AM confirmed testing personnel recorded the Sub-X Xylene Substitute expiration dates as Year - Month - Day on the QC Log. The same</p>

interview confirmed testing personnel recorded inaccurate expiration dates on the QC Log and confirmed the logs showed testing personnel used expired Sub-X xylene substitute for patient testing from April 4 through December 15, 2022.

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 surveyor review of laboratory procedures and records, observation of reagents in the laboratory, and interview with the clinic regional manager, the laboratory director did not ensure personnel maintained the reagent quality assurance records as required for five of five reagents reviewed to identify failures in quality. Findings include: 1. Review of the laboratory procedure, 'Quality Control Policies and Documentation' showed the procedure included the following statements: "Reagents must be on the chemical log sheet to include product name, supplier, and quantity, lot #, date received, date opened and expiration date." "The reagents and embedding media are checked daily for intended reactivity and expiration dates." 2. Review and comparison of the 'Quality Control Assessment of Mohs Tissue Staining Procedure' logs (QC log) from April 4 through December 15, 2022 and the 'Chemical Log sheets' in use in from March 16, 2020 to November 16, 2022 showed the following: Eosin Stain: Personnel documented the use of lot 062722 starting August 2, 2022 on the QC log. Personnel documented the use of lot 070122 on August 23, 2022 on the QC log. The Chemical Log Sheet showed no record for lot 062722 or 070122. Observation of the bulk stain in the laboratory on February 8, 2023 at 9:35 AM revealed lot number 070122 was opened on August 22, 2022. The expiration date printed on the bottle is 2024-07-01. Hematoxylin Stain: Personnel documented the use of lot 092332 on April 4, 2022 with an expiration date 23-03-24 on the QC log. The QC log showed the lot number changed to 09232 on May 16, 2022 and the expiration date changed to 03-03-24 on May 19, 2022. The expiration date changed again to 23-3-29 on June 6, 2022. The Chemical Log Sheet showed no record of Hematoxylin stain with lot number 092332 or 09232. The recorded lot number on the Chemical Log sheet was 092321, opened on October 9, 2021 with a March 23, 2023 expiration date. Observation of the stain in the laboratory on February 8, 2023 at 9:35 AM revealed the current lot number was 092321 with an expiration date of March 23, 2023. Sodium Bicarbonate: Personnel documented the use of lot 011322 starting April 26, 2022 with an expiration date 23-07-13 on the QC log. The log showed the lot number changed to 113822 on May 16, 2022 and the expiration date changed to 28-07-13 on June 20, 2022. Testing personnel recorded the lot number as 011382 as of November 21, 2022. The Chemical Log Sheet showed no record for Sodium Bicarbonate. Reagent Alcohol: Personnel documented the use of lot BC3611XE on April 4, 2022 with an expiration date 23-02-27 on the QC log. The log showed the expiration date changed to 25-02-29 on May 16, 2022. The recorded lot number starting on August 2, 2022 was BC361118XE. On October 10, 2022 testing personnel recorded a new lot, BC1942XC, with expiration date 24-7-13. The Chemical Log Sheet showed lot BC3611XE was opened on February 14, 2022 with an expiration date 23-12-27. Lot BC1942XC was recorded as received on 09-2022 with a 24-07-12 expiration date, no date opened was recorded. Xylene Substitute: Personnel documented the use of lot 08220 starting on April 4, 2022 with an expiration date 22-02-28 on the QC log. The log showed the expiration

date changed to 28-8-28 on July 25, 2022 and the lot number changed to 08230 on October 10, 2022. The Chemical Log Sheet showed no record of lot number 08220 or 08230. The Chemical Log Sheet showed lot 062322 received on November 16, 2022 with an expiration date of 2024-6-23. Observation of the Xylene Substitute in the laboratory on February 8, 2022 at 9:35 AM revealed a bottle of lot 062322 with expiration date of 2024-06-23. 3. Interview with the clinic regional manager on February 8, 2022 at 9:40 AM confirmed the 'Chemical Log Sheet' and 'Quality Control Assessment of Mohs Tissue Staining Procedure' quality assurance processes were not maintained and may have contributed to the use of expired xylene substitute (See D5417). Further interview confirmed the lot number and expiration dates on the quality control log were not consistent and did not correlate with the chemical log, and that personnel did not complete the chemical log as required.