

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1090103	(X3) Date Survey Completed 04/05/2021
Name of Provider or Supplier Premier Dermatology, Pc	Street Address, City, State 44121 Leesburg Pike, Suite 210, Ashburn, VA	
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
D0000	An announced off-site CLIA recertification survey was conducted at Premier Dermatology, PC on April 5, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on March 5, 2021 and virtual record review conducted on March 30, 2021. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency is as follows:
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: A. Based on a review of the laboratory's Chemical Log, policy and procedure manual, MOHS accession log and interview, the laboratory failed to ensure the Eosin stain used for staining MOHS specimens was within manufacturer's expiration date while staining thirty-three (33) Mohs patient specimens from July 5, 2020 until July 29, 2020. Findings include: 1. A review of the laboratory's "Chemical Log" revealed the following: a. 1 gallon of Platinum Line eosin stain (lot number 1818010/expiration date 7/4/2020) received on 9/14/18 with an open date of 9/28/2018; b. 1 gallon of Mercedes eosin stain (lot number 2015337/expiration date 10/6/2022) received on 7/7/2020 with an open date of 7/29/2020. There were no other lots of eosin stain listed with "Open Dates" on the laboratory's "Chemical Log". 2. A review of the laboratory's policy and procedure manual revealed a policy, "Hazardous Chemical Inventory", which stated "The laboratory will follow all manufacturer recommendations with regards to storage of reagents as provided by MSDS sheets. No reagent will be used if contaminated, expired, deteriorated, of substandard quality, or showing evidence of tampering." 3. A review of the laboratory's "MOHS Accession Log" revealed 33</p>

Mohs patient specimens were stained from July 5, 2020 until July 29, 2020 while using the expired eosin stain (lot number 1818010/expiration date 7/4/2020). 4. In an exit interview with the laboratory director (LD) on April 5, 2021 at 8:30 AM, the findings were confirmed. B. Based on a review of the laboratory's Chemical Log, policy and procedure manual, MOHS accession log and interview, the laboratory failed to ensure the hematoxylin stain used for staining MOHS specimens was within manufacturer's expiration date while staining one hundred thirty-two (132) patient specimens from February 23, 2020 until August 5, 2020. Findings include: 1. A review of the laboratory's "Chemical Log" revealed the following: a. 1 gallon of Platinum Line hematoxylin stain (lot number 1864608/expiration date 2/22/2020) received on 9/14/18 with an open date of 9/28/2018; b. 1 gallon of Mercedes hematoxylin stain (lot number 1932518/expiration date 11/26/2021) received on 7/7/2020 with an open date of 8/5/2020. There were no other lots of hematoxylin stain listed with "Open Dates" on the laboratory's "Chemical Log". 2. A review of the laboratory's policy and procedure manual revealed a policy, "Hazardous Chemical Inventory", which stated "The laboratory will follow all manufacturer recommendations with regards to storage of reagents as provided by MSDS sheets. No reagent will be used if contaminated, expired, deteriorated, of substandard quality, or showing evidence of tampering." 3. A review of the laboratory's "MOHS Accession Log" revealed 132 Mohs patient specimens were stained from February 23, 2020 until August 5, 2020 with the expired hematoxylin stain (lot number 1864608/expiration date 2/22/2020). 4. In an exit interview with the laboratory director (LD) on April 5, 2021 at 8:30 AM, the findings were confirmed.