

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1105247	(X3) Date Survey Completed 01/10/2024
Name of Provider or Supplier Pinnacle Dermatology - Plymouth	Street Address, City, State 3655 Plymouth Blvd, Suite 110, Plymouth, MN	
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	The Pinnacle Dermatology laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on January 10, 2024. The following standard-level deficiencies were cited: 493.1105 Retention requirements 493.1252 Test systems, equipment, instruments, reagents, materials, and supplies .
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain Histopathology equipment maintenance and quality control records for at least two years for the single Histopathology test performed by the laboratory between November 2021 and August 2022. Findings are as follows: 1. The laboratory performed tissue gross and slide interpretation for Mohs Micrographic surgery under the subspecialty of Histopathology as confirmed by the Histotechnician (HT)) during a tour of the laboratory at 1:05 p.m. on 01/10/24. 2. The previous laboratory director and Mohs surgeon left the practice in August 2022. 3. The retired CLIA Manual, left by the previous laboratory director, did not include the following documentation from November 2021 through August 2022: -Cryostat maintenance records -Microscope maintenance records -Reagent and stain records -Quality control records 4. The laboratory was unable to locate the missing documentation upon request. 5. In an interview at 2:45 p.m. on 01/10/24, the Laboratory Director confirmed the above finding. .</p>

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 observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of two Histopathology stains were not used after the expiration date had been exceeded in 2024. Findings are as follows: 1. The laboratory performed tissue gross and slide interpretation for Mohs Micrographic surgery under the subspecialty of Histopathology as confirmed by the Histotechnician (HT)) during a tour of the laboratory at 1:05 p.m. on 01/10/24. 2. A Thermo Scientific Linistat slide stainer was observed as in use during the tour. 3. One of two stain bottles stored in the flammable storage cabinet was expired. See below. Vintage Hematoxylin Lot 153142 Expiration date 12/31/23 4. The HT indicated the Hematoxylin stain loaded on the slide stainer was obtained from the expired bottle. 5. The expired Hematoxylin was used to stain slides for eight Mohs patients on 01/03/24 and for nine Mohs patients on 01/10/24 as indicated in the Mohs Lab Case Log and by the HT. 6. In interviews at 1:10 p.m. and 2:35 p.m. on 01/10/24, the HT confirmed the above finding. .