

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2262921	<b>(X3) Date Survey Completed</b>  07/17/2024
<b>Name of Provider or Supplier</b>  Premier Dermatology Clinic	<b>Street Address, City, State</b>  3 Plaza Dr, Toms River, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the review of Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of Histopathology testing in the calendar years 2022 and 2023. The LD confirmed on 7 /17/24 at 12:30 pm that the laboratory did not perform BA for Histopathology as stated above.</p>
<b>D5401</b>	<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: a) Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Director (LD), the laboratory failed to follow the PM for Competency Assessment (CA) from 6/21/22 to the date of the survey. The finding includes: 1. There was no documented evidence that CA was performed on testing personnel. 2. The LD confirmed on 7/17/24 at 12:30 pm that the laboratory did not follow the PM. b) Based on surveyor review of the Procedure Manual (PM), and interview with the LD, the laboratory failed to have a policy on how to store and how long to maintain</p>

	<p>histopathology slides from 6/21/22 to the date of the survey. The LD confirmed on 7/17/24 at 12:30 pm that the laboratory did have a policy on histopathology slide storage and retention.</p>
<p><b>D5415</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Staining Station and interview with the Laboratory Director (LD) the laboratory failed to label the identity of all staining jars used for Histopathology testing from 6/21/22 to the date of the survey. The LD confirmed on 7/17/24 at 12:35 pm that all staining jars were not labeled.</p>
<p><b>D5417</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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 observation of Histology reagents and interview with the Laboratory Director (LD), the laboratory failed to discard expired Histopathology reagents from 8/2/22 to the date of survey. The findings include: 1. Avantik Tissue marking dyes were expired as follows: a) Blue marking day lot # 140452 expired 1-3-2024 b) Yellow marking dye lot # 143908 expired 2-29-2024 c) Green marking day lot # 144651 expired 2-29-2024 2. Avantik Hematoxylin lot # 135954 expired 5-31-2023 3. Platinumline Scott's Tap Water Substitute Lot # 2121022 expired 8-2-2022 4. Approximately 500 patients were tested with expired reagent. 5. The LD confirmed on 7/17/24 at 12:30 pm that the laboratory used expired reagents.</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of a Procedure Manual (PM) and interview with the Laboratory Director (LD), the LD failed to have an approved PM for Histopathology testing from 6/21/22 to the date of the survey. The findings include; 1. The name and address listed in the PM was "World of histology 644 Miami lakes dr #22b Miami lakes FL 33014" the laboratory is located in New Jersey. 2. The name of the supervisor listed in the PM was not listed on the CMS form 209. 3. The PM was not</p>

approved by the LD 4. The LD confirmed on 7/17/24 at 1:10 pm that the LD did not ensure an approved PM was available.