

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2227667	<b>(X3) Date Survey Completed</b>  08/01/2025
<b>Name of Provider or Supplier</b>  Warren Skin Care Center, Pa	<b>Street Address, City, State</b>  2597 Schoenersville Rd Room 303, Bethlehem, PA	
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>D3007</b>	<p>FACILITIES CFR(s): 493.1101(b)</p> <p>(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of temperature records, and interview with the histotechnician, the laboratory failed to ensure that 1 of 1 thermometer /hygrometer used to monitor operating conditions when histopathology examinations were performed from 07/11/2025 to 08/01/2025 was accessible during the time of the survey. Findings include: 1. On the day of survey 08/01/2025 at 10:26 am, while touring the laboratory, the surveyor discovered the 1 of 1 thermometer/hygrometer used to monitor operating conditions when histopathology examinations were performed from 07/11/2025 to 08/01/2025 was not accessible in the laboratory during the time of the survey. 2. The laboratory failed to produce the thermometer /hygrometer used to monitor the room temperature and humidity of the laboratory when requested by the surveyor on the day of the survey. 3. During an interview with the histotechnician on 08/01/2025 at 10:55 am, the histotechnician confirmed the findings above and stated, "the laboratory moved to the new location on 07/11/2025 and monitored the room temperature and humidity using a portable thermometer /hygrometer that was not onsite during the inspection."</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the histotechnician, the laboratory failed to ensure that 1 of 3 reagents used to perform hematoxylin and eosin (H&E) staining for microscopic histopathology slide examinations was not used beyond the expiration date from 07/28/2024 to date of survey. Findings include: 1. On the day of survey 08/01/2025 at 10:26 am while touring the laboratory, the surveyor discovered the following 1 of 3 expired reagents used to perform H&E staining for microscopic histopathology slide examinations from 07/28/2024 to 08/01/2025: - 1 opened bottle of Mercedes Scientific Hematoxylin Stain Solution, Gill III (Lot #2219919 expired 07/28/2024) 2. The laboratory performed 109 histopathology examinations in 2024 (CMS 116, estimated annual volume, dated 07/26/2025). 3. The histotechnician confirmed the findings above on 08/01/2025 at 10:55 am.