

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2302180	(X3) Date Survey Completed 05/12/2026
Name of Provider or Supplier Dermeve Pc	Street Address, City, State 607 Washington Road, Lower Level, Mt Lebanon, PA	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Histotechnologist (HT), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Olympus BX45 microscope used to perform histopathology microscopic slide examinations from 11/08/2024 to 05/12/2026. Findings include: 1. The manufacturers operating environment specifications stated, "Olympus BX45 microscope: 5-40 degrees Celsius (ambient temperature); maximum 80 % relative humidity." 2. On the day of the survey, 05/12/2026 at 10:30 am, the laboratory failed to provide documentation for the monitoring of room temperature and humidity to ensure operating conditions were met for the following instruments used to perform histopathology microscopic examinations from 11/08/24 to 05/12 /2026: - 1 of 1 Olympus BX45 microscope 3. The laboratory performed 517 histopathology slide examinations in 2025 (CMS 116, estimated annual volume, dated 05/12/2026). 4. The HT (CMS 209, personnel #2, dated 05/12/2026) confirmed the findings above on 05/12/2026 at 10:45 am.</p>
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedures, lack of documentation, and interview with the Histotechnologist (HT), the laboratory failed to follow the established written policy that required the review of 1 of 1 procedure manual to be performed annually by the Laboratory Director (LD) from 01/01/2025 to date of survey. Findings include: 1. The laboratory's Quality Assessment Manual stated, "The Laboratory Director should also review, sign, and date each laboratory procedure annually and at other times if required by state law, major changes in procedure, or other circumstances affecting laboratory performance". 2. On the day of the survey, 05/12/26 at 10:00 am, the laboratory could not provide documentation for the annual review of 1 of 1 procedure manual performed by the LD in 2025. 3. The HT (CMS 209, personnel #2, dated 05/12/2026) confirmed the above findings on 5/12/26 at 10:45am.