

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0698872	(X3) Date Survey Completed 02/21/2025
Name of Provider or Supplier Davie Dermatology, Pa	Street Address, City, State 108 Dornach Way, Advance, NC	
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 observation, review of manufacturer's instructions, review of the laboratory's 2023 and 2024 temperature logs, and interview with testing personnel (TP #1) on 2/21/25, the laboratory failed to define an acceptable temperature range for the refrigerator used to store immunohistochemical (IHC) reagents. Findings: During a tour of the laboratory at approximately 12:05 p.m., surveyors observed IHC reagents stored in a refrigerator in a room outside the laboratory. Review of manufacturer's instructions for the Bio SB TintoFast MART-1 and Cytokeratin AE1/AE3 IHC stains revealed storage requirements of 2 to 8 degrees Celsius (35.6 to 46.4 degrees Fahrenheit). Review of the 2023 and 2024 refrigerator logs revealed the logs did not include an acceptable range. During an interview at approximately 12:15 pm, TP #1 confirmed other laboratory logs included acceptable temperature ranges but this one refrigerator log did not.</p>
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b)(3) The criteria for proper storage of reagents and specimens, as specified under</p>

493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on observation, review of manufacturer's instructions, review of the laboratory's 2023 and 2024 temperature logs, and interview with testing personnel (TP #1) on 2/21/25, the laboratory failed to ensure corrective actions were taken and documented when IHC reagents were stored at temperatures outside the manufacturer's specified range. Findings: During a tour of the laboratory at approximately 12:05 p.m., surveyors observed IHC reagents stored in a refrigerator in a room outside the laboratory. Review of manufacturer's instructions for the Bio SB TintoFast MART-1 and Cytokeratin AE1/AE3 IHC stains revealed storage requirements of 2 to 8 degrees Celsius (35.6 to 46.4 degrees Fahrenheit). Review of the 2023 and 2024 refrigerator temperature logs revealed recorded temperatures consistently outside the manufacturer's specified storage temperature range of 35.6 to 46.4 degrees Fahrenheit with no corrective action documented. Examples: a. September 2023 - recorded temperatures less than or equal to 34 degrees Fahrenheit 5 of 16 days; b. November 2023 - recorded temperatures less than or equal to 34 degrees Fahrenheit 20 of 20 days; c. May 2024 - recorded temperatures less than or equal to 34 degrees Fahrenheit 19 of 19 days; d. November 2024 - recorded temperatures less than or equal to 34 degrees Fahrenheit 14 of 19 days. During an interview at approximately 12:15 pm, TP #1 stated the lab previously had a dedicated lab refrigerator for storage of the IHC reagents. She stated they had concerns about inaccurate temperature readings in the dedicated refrigerator, so the IHC reagents were moved to a different refrigerator outside the laboratory which is also used to store Botox. She confirmed there were multiple days with out-of-range temperatures and no corrective action documented.