

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2118010	<b>(X3) Date Survey Completed</b>  09/11/2025
<b>Name of Provider or Supplier</b>  Wellspan Dermatology	<b>Street Address, City, State</b>  296 St Charles Way, York, 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>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on review of laboratory records and procedures, lack of documentation, and interview with the Practice Manager (PM), the laboratory failed to document the Quality Control (QC) for 4 of 7 months when human chronic gonadotropin (hCG) examinations were performed from 03/18/2025 to 7/3/2025, using the Cardinal Health Rapid hCG Urine Tests Cassette. Findings include: 1. The laboratory's procedure titled, Urine Pregnancy Test-Cardinal hCG Cassette Rapid Test states, "It is recommended that a positive hCG control (containing &gt; or = to 25 mIU/ML hCG in urine) and a negative hCG control (containing "0" mIU/ML hCG) be evaluated to verify proper test performance with each new lot, each new shipment, monthly as a check on storage, each new untrained operator and as otherwise required by your lab internal quality system procedures." 2. Further review of laboratory records revealed the laboratory started rapid hCG urine testing on 3/18/2025. 3. On day of survey 9/11/2025 at 12:10 pm, the laboratory could not provide documentation of QC performed for new lot, new shipment, or monthly for 4 of 7 months when urine hCG examinations were performed from 3/18/2025 to 7/3/2025. 4. The PM confirmed the findings above on 9/11/2025 at 12:45 pm. B. Based on observation in the laboratory, lack of documentation, and interview with the Practice Manager (PM), the laboratory failed to monitor daily temperatures to ensure proper storage conditions for the Cardinal Rapid HCG kits for 177 of 177 days from 3/18/2025 to 9/11/2025. 1. On the day of survey 9/11/2025, at 12:00 pm, during a tour of the lab, it was observed that the location where Cardinal Rapid HCG kits are stored was not monitored for proper temperature conditions. 2. The manufacturer stated storage requirements for the Cardinal Rapid hCG kits are 2C to 30C. 3. The laboratory failed to provide</p>

temperature documentation for the area where the Cardinal Rapid HCG kits were stored for 177 of 177 days from 3/18/2025 to 9/11/2025. 4. The PM confirmed the findings above on 9/11/2025 at 12:15 pm.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

(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.

This STANDARD is not met as evidenced by:

A. Based on observation in the laboratory, review of laboratory temperature records, and interview with the Practice Manager (PM), the laboratory failed to monitor room temperatures to ensure reagent stability and proper operating conditions for 591 of 715 days from 09/23/2023 to 09/11/2025. Findings include: 1. On the day of survey, 9/11/2025, at 11:30 am, during the tour of the laboratory, the surveyor observed the following reagents stored in the laboratory: - Tissue Tek OTC Compound. Storage requirements 15C to 30C. - Tissue Marking Dyes. Storage requirements 15C to 30C. 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document room temperatures for 591 of 715 days from 09/23/2023 to 09/11/2025 when the laboratory was closed. 3. The PM confirmed the findings above on 9/11/2025 at 11:45 am. B. Based on observation in the laboratory, lack of documentation, and interview with the Practice Manager (PM), the laboratory failed to monitor daily temperatures and humidity to ensure proper operating conditions were met for 1 of 1 Olympus BX46 microscope used to perform MOHS microscopic histopathology examinations from 9/23/2023 to 9/11/2025. 1. Review of the manufacturer's instructions revealed the following acceptable operating temperature and humidity range for the Olympus BX45 microscope: - Temperature 5C to 40C - Humidity 0 to 80% Relative Humidity 3. On the day of the survey, 9/11/2025, the laboratory failed to provide temperature and relative humidity documentation to ensure proper operating conditions were met for 1 of 1 Olympus BX46 microscope used to perform MOHS microscopic histopathology examinations from 9/23/2023 to 9/11/2025. 4. The PM confirmed the findings above on 9/11/2025 at 11:55 am.