

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D2298036	<b>(X3) Date Survey Completed</b>  01/22/2025
<b>Name of Provider or Supplier</b>  Tvl- Twin Falls	<b>Street Address, City, State</b>  512 Pole Line Road, Suite 2b, Twin Falls, ID	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training and competency assessment records and an interview with the technical consultant (TC) on 1/22/2025, the laboratory failed to follow written policies and procedures to assess testing personnel, clinical consultant (CC) and TC competency since opening in 2024. The findings include: 1. A review of the CMS 209 form identified four testing personnel, one clinical consultant and one technical consultant. 2. A review of training records identified the laboratory failed to have documentation of initial training for one testing personnel in 2024. 3. A review of competency assessment records identified the laboratory failed to have documentation of six month competency for two testing personnel in 2024. 4. A review of competency assessment records identified the laboratory failed to have documentation of competency for the CC and TC. 5. An interview with the TC on 1/22/2025 at 10:30 am confirmed the above findings. 6. The laboratory reports performing 636 hematology tests annually.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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</p>

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:

Based on a review of laboratory temperature logs, the Sysmex XN-550 users manual and an interview with the technical consultant (TC) on 1/22/2025, the laboratory failed to establish and monitor room temperature since beginning testing in May, 2024. The findings include: 1. A lack of the laboratory room temperature logs identified the laboratory failed to establish and monitor room temperature per the Sysmex XN-550 manufacturer requirements. 2. A review of the Sysmex XN-550 user manual identified an operating temperature range of 15 to 35C. 3. An interview with TC on 1/22/2025 at 12:02 pm confirmed that the laboratory failed to monitor room temperature. 4. The laboratory reports performing 636 hematology tests annually.