

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 13D0917694	<b>(X3) Date Survey Completed</b> 10/27/2023
<b>Name of Provider or Supplier</b> High Valley Dermatology And	<b>Street Address, City, State</b> 703 Rigby Lake Dr, Rigby, 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>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation from the American Association of Bioanalysts (AAB) and an interview with the laboratory supervisor on 10/27/2023, the laboratory failed to have testing personnel and the laboratory director attest to the integration of PT samples with routine testing of patient samples in 2023. The findings include: 1. A review of PT results for serum human chorionic gonadotropin (hCG) and potassium hydroxide (KOH) slide examination from AAB identified that the laboratory failed to have the performing testing personnel and the laboratory director attest that the PT samples were tested in the same manner and with patient samples for events one (1), two (2) and three (3) in 2023. 2. An interview with the laboratory supervisor on 10/27/23 at 10:18 am confirmed that the laboratory failed to sign PT attestations in 2023. 3. The laboratory reports performing 730 moderate and high complexity tests annually.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of polices and procedures and an interview with the laboratory</p>

	<p>supervisor on 10/27/2023, the laboratory director failed to approve, sign and date the laboratory policies and procedures. The findings include: 1. A record review of laboratory policies and procedures identified that the laboratory director failed to approve, sign and date laboratory policies and procedures after becoming the laboratory director on 4/5/2023. 2. An interview with the laboratory supervisor on 10/27/2023 at 9:29 am, confirmed that the laboratory director had not approved, signed or dated the laboratory policies and procedures. 3. The laboratory reports performing 730 moderate and high complexity tests annually.</p>
<p><b>D5413</b></p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (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 a record review and interviews with the laboratory supervisor on 10/27/2023, the laboratory failed to document humidity and room temperature as required by manufacturers. The findings include: 1. A review of the manual for the Avantik QS12 cryostat identified that the operational humidity is less than 60%. 2. A review of the laboratory microtome maintenance log identified that the laboratory failed to document humidity in 2022 and 2023. 3. A review of the instructions for use for the One Step Human chorionic gonadotropin test identified a storage temperature of 2-30 C. 4. A review of the upstairs temperature log identified that the laboratory failed to document room temperature in May, June, July, August, September and October of 2023. 5. An interviews with the laboratory supervisor on 10/27/2023 at 10:39 am and 11:02 am respectively confirmed the above findings. 6. The laboratory reports performing 730 moderate and high complexity tests annually.</p>
<p><b>D5417</b></p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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> <p>This STANDARD is not met as evidenced by: Based on a direct observation and an interview with the laboratory supervisor on 10/27/2023, the laboratory failed to discontinue the use of expired potassium hydroxide (KOH) with DMSO. The findings include: 1. During the laboratory tour on 10/27/2023 a direct observation identified that the laboratory failed to discontinue the use of expired 20% KOH with DMSO used in KOH slide examinations. Delasco 20% KOH with DMSO lot K20354 expiration 3-31-2023 2. An interview with the laboratory supervisor on 10/27/2023 at 11:40 am confirmed the above finding. 3. The laboratory reports performing 40 KOH slide examinations annually</p>