

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2300666	(X3) Date Survey Completed 01/06/2025
Name of Provider or Supplier Upper Valley Community Health Services	Street Address, City, State 3729 Woodking Dr Ste 1, Idaho Falls, ID	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory documents, a lack of a verification of performance specification documentation and an interview with the chief compliance officer (CCO) on 1/6/2025, the laboratory failed to perform verifications on the Abbott Afinion 2. The findings include: 1. A review of laboratory documents and a lack of performance specification verification documentation for Albumin/Creatinine Ratio (ACR) testing on the Abbott Afinion 2 identified that the laboratory failed to verify the manufacturer's specifications for ACR testing before beginning patient testing. 2. An interview with the CCO on 1/6/2025 at 2:01 pm confirmed that the laboratory failed to verify manufacturer's performance specifications. 3. The laboratory reports performing 50 ACR tests annually.</p>
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and</p>

This STANDARD is not met as evidenced by:

Based on a review of the Sysmex 430 instrument verification and an interview with the chief compliance officer (CCO) on 1/6/2025, the laboratory director failed to ensure that the verification of instrument performance specifications were adequate. The findings include: 1. A review of the new instrument verification of the Sysmex 430 identified that the laboratory director failed to review and approve the verification results for accuracy, precision, and reportable range to ensure that they were adequate before beginning patient testing. 2. An interview with CCO on 1/6/2025 at 2:01 pm confirmed that the laboratory director failed to review and approve the verification. 3. The laboratory reports performing 1,200 hematology tests annually.