

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 53D2279002	<b>(X3) Date Survey Completed</b> 12/04/2024
<b>Name of Provider or Supplier</b> Wellspring Health Access	<b>Street Address, City, State</b> 918 E 2nd St, Casper, WY	
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 review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to ensure the individual testing the proficiency samples and the laboratory director attested to the routine integration of the American Proficiency Institute (API) proficiency tests into the patient workload for 3 of 3 Immunochemistry proficiency testing events reviewed from October 2023 through November 2024. The findings were: 1. Review of the 2023 API Immunochemistry Event #3, the 2024 Immunochemistry Event #1, and the 2024 Immunochemistry Event #2 records showed the testing personnel and laboratory director failed to sign the attestation statements. 2. Interview with testing personnel #1 on 12/4/24 at 2:15 PM confirmed no further documentation was available.</p>
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test</p>

system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing records and staff interview, the laboratory failed to maintain a copy of each step in the testing and reporting process for 3 of 3 American Proficiency Institute Immunohematology proficiency testing events reviewed from October 2023 through November 2024 (2023 Event #3, 2024 Event #1, 2024 Event #2). The findings were: 1. Review of the laboratory's proficiency testing records showed no evidence the attestation statements, submission forms, and documentation of the testing results had been maintained. 2. Interview with testing personnel #1 on 12/4/24 at 2:15 PM confirmed no further documentation was available.