

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 53D2279002	<b>(X3) Date Survey Completed</b> 06/29/2023
<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>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 lack of documentation and staff interview, the laboratory failed to ensure a policy and procedure was established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure they were competent and maintained their competency to process specimens, perform test procedures, and report test results promptly and proficiently. The findings were: 1. Review of the laboratory's documentation failed to show a policy and procedure to monitor each individual's competency had been developed. 2. Interview with the practice manager and testing personnel #1 on 6/29/23 at 10:30 AM confirmed the laboratory had not developed a policy to ensure the competency of the laboratory personnel. .</p>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by:                      . Based on procedure manual review, lack of documentation, and staff interview, the</p>

laboratory failed to establish a quality assessment plan for general laboratory, pre-analytic, and post-analytic systems for the Eldoncard test system for determining a patient's Rh blood type. The laboratory estimated it would perform approximately 100 Rh blood type tests per year. The findings were: 1. The laboratory procedure manual failed to include a quality assurance plan that included the items the laboratory reviewed, the frequency of the review, and the method used to document the review in the following areas: a. General laboratory tasks which include proficiency testing review, testing personnel competency procedures, and complaint documentation and resolution. b. Pre-analytic tasks which include specimen collection, patient identification verification, and specimen labeling. c. Analytic tasks which include review of quality control and test record logs. d. Post-analytic tasks which include test report accuracy. 2. Interview with the practice manager and testing personnel #1 on 6/29/23 at 10:30 AM confirmed the laboratory had not established a quality assessment plan. .

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
. Based on lack of documentation and staff interview, the laboratory failed to have a written procedure for the Eldoncard test system for determining Rh blood type. The laboratory estimated it would perform approximately 100 Rh blood type tests per year. The findings were: 1. Review of the laboratory's procedure manuals showed no evidence the laboratory had developed a policy and procedure for the Eldoncard test system for determining Rh blood type. 2. Interview with the practice manager and testing personnel #1 on 6/29/23 at 10:30 AM confirmed the laboratory did not have a written procedure for the Eldoncard test system. .

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
. Based on lack of documentation and staff interview, the laboratory failed to verify the accuracy and precision of the Eldoncard test system for determining Rh blood type prior to patient testing. The laboratory estimated it would perform approximately 100 patient blood types per year. The findings were: 1. Review of the laboratory's records

showed no evidence a verification study had been completed for the Eldoncard test system. 2. Interview with the practice manager and testing personnel #1 on 6/29/23 at 10:30 AM confirmed the verification study had not been completed.