

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2265294	(X3) Date Survey Completed 03/28/2023
Name of Provider or Supplier Red River Women's Clinic	Street Address, City, State 302 Hwy 75 N, Suite 108, Moorhead, MN	
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>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to complete a performance verification (PV) for the single non-waived test implemented by the laboratory in 2022. Findings are as follows: 1. The laboratory performed Rhesus (Rh) typing as confirmed by Testing Personnel 2 (TP2) during a tour of the laboratory at 1:05 p.m. on 03/28/23. 2. Eldon Biologicals EldonCard Blood Typing Kits were observed as present and available for use during the tour of the laboratory. Rh testing using the EldonCard kits was implemented on 08/10/22 as indicated by TP2 and confirmed in laboratory patient testing records. 3. PV documentation for EldonCard Rh testing was not found during review of laboratory records. The laboratory was unable to provide PV documentation upon request. 4. The patient testing log found in the Lab Log manual indicated 118 patients received Rh testing since implementation on 08/10/22 through date of survey, 03/28/23. See below Year Number of patients tested 2022 68 2023 50 5. In an interview at 1:20 p.m. on 03/28/23, TP2 confirmed the above finding. .</p>