

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0047706	(X3) Date Survey Completed 06/16/2026
Name of Provider or Supplier Boone County Health Center	Street Address, City, State 723 West Fairview Street, Albion, NE	
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 surveyor review of laboratory Hepatitis B Surface Antibody (HBsAb) patient results, review of HBsAb performance specifications, and interview with the laboratory manager the laboratory did not verify HBsAb reportable range high enough. 1. Review of HBsAb patient results from 4/16/2026 - 6/16/2026 revealed a patient result from 3/27/2026, resulted as 1600.67 mIU/mL. 2. Review of the laboratory's HBsAb performance specifications revealed the verified reportable range as 0.00 mIU/mL - 420.00 mIU/mL. 3. Interview with the laboratory manager on 6/16/2026 at 2:20 PM, confirmed the laboratory verified 0.00 mIU/mL - 420.00 mIU/mL HBsAb reportable range and confirmed the laboratory did not verify the reportable range higher than 420.00 mIU/mL.</p>