Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D2331108	07/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Services Pc	2121 N 117th Ave Ste 100a, Omaha, 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	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (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. This STANDARD is not met as evidenced by: Based on surveyor review of performance specifications of blood bank Grifols DG Reader analyzer and interview with the general lab supervisor the laboratory failed to verify precision on the Grifols DG Reader prior to reporting patient test results. The findings include: 1. Surveyor review of performance specifications of blood bank Grifols DG Reader analyzer revealed precision was not performed. 2. Interview with the general lab supervisor, on 7/9/2026 at 11:30 AM, confirmed the laboratory failed to perform precision on the blood bank Grifols DG Reader prior to reporting patient test results. 3. The laboratory reported ninety four ABO/Rh (D) and ninety six antibody detection blood bank tests on the Grifols DG Reader analyzer from 1/1/2026 - 7/9/2026.