Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0672374	03/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Wichita Falls - Wichita County Public Health	1700 Third Street, Wichita Falls, TX	

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
D0000	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for use (IFU), surveyor direct observation, and confirmed in interview, the laboratory failed to ensure storage requirements were maintained for 43 of 43 phosphate buffered saline (PBS) tubes used for patient specimen collection. Findings include: 1. Review of the manufacturer's IFU titled "Hardy Diagnostics Instructions for Use Phosphate Buffered Saline (PBS)" stated: "Storage: Upon receipt store Cat. no. K146, K163, U137 and U138 at 2-30C and Cat. no. R201 at 2-8C away from direct light" 2. On 03/20/2025 at 1327 hours, the surveyor observed 43 PBS tubes used for patient specimen collection stored on a shelf, exposed to direct light, located inside Room 627 "Storage Room" located in a patient examination area: "PBS Lot#636865 Exp. 08/07/2025" 3. The technical supervisor (as listed on the CMS-209 form) confirmed the PBS tubes used were not stored according to manufacturer instructions during an interview on 03/20 /2025 at 1329 hours in the storeroom. Key : CMS: Centers for Medicare and Medicaid Services