Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2114594	07/31/2025
Name of Provider or Supplier	**Street Address, City, State**	
Northwest Texas Healthcare System,Inc	8960 Hillside Road, Amarillo, 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 compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a validation survey conducted July 30 - 31, 2025.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) (d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based upon review of policies and procedures, patient test records and interview of facility personnel found the laboratory failed to have written instructions available to the laboratory's clients for the appropriate collection, handling, transportation and storage of specimens submitted for Tacrolimus testing for 5 of 5 patients tested between January 1, 2025 and May 28, 2025. The findings included: 1. Review of policies and procedures found that the laboratory did not have a written instructions available to the laboratory's clients for the appropriate collection, handling, transportation and storage of specimens used for testing Tacrolimus available to outside clients. 2. Review of patient test records found the laboratory received and tested 5 patient specimens for Tacrolimus between January 1,2025 and May 28, 2025. 3. During interview of the technical consultant conducted July 30, 2025 at 2:20 PM, she confirmed that the laboratory had no written instructions available to clients for specimens submitted for testing at this location.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed.

	This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the laboratory establishment of patient normal range for Prothrombin Time conducted 05/03/23, and interview of facility personnel, the laboratory failed to have documentation that patient samples used to establish the new patient normal range were not on medication that could have affected the test. The findings included: 1. Review of the Reagent lot Roll-Over Studies for the CA-500/600 Systems found on page XIV-1 under verification of reference range: "20 normal individuals, 10 males and 10 females spanning the age range. 20 is the minimum requirement for a statistically valid study. Fresh samples preferred but frozen platelet poor plasma may be used if prepared and thawed per CLSI guidelines. Note medication history. After review of data, history may be used for excluding questionable results." 2. A review of the laboratory's lot rollover for the MNPT from 05/03/2023 (current lot 564631) found the laboratory tested 20 patients, however, the laboratory failed to have documentation that the samples used for the establishment were from patients who were not taking medications that could affect the assay. 3. During interview of the technical consultant conducted July 31, 2025 at 11:54 AM, she confirmed that the laboratory did not use an equal number of males and female patients across the age range of service but would randomly select the 20 patient results that were within normal limits, and used those results to establish the new MNPT. There was no documentation of the age, sex or medication history for the samples used.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based upon review of proficiency testing records, personnel records, and interview of facility personnel, the laboratory director failed to specify in writing, the responsibilities delegated to one of one technical consultant. The findings included: 1. Review of proficiency testing records found the technical consultant was attesting to the routine integration of proficiency testing specimens into the routine workload, and reviewing results received. 2. Review of the personnel records for the technical consultant found no written delegation of duties for attesting to the routine integration of proficiency specimens. 3. During interview of the technical consultant conducted July 30, 2025 at 12:42 PM, she confirmed there was no written delegation of duties for her responsibilities as technical consultant.