Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2167256	07/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Northwest Emergency On Georgia	4121 S. Georgia Street, 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 Pat 493, Requirements for Laboratories as a result of a validation survey conducted July 29 - 30, 2025.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Review of policies and procedures, quality control records, patient test records and interview of facility personnel found the laboratory failed to follow it's own individualized quality control plan (IQCP) for testing quality control materials when testing 159 patient specimens for Strep A using the Cepheid Gene Xpert in January 2025. The findings included: 1. Review of the laboratory's IQCP procedure found on page 3: "The laboratory will perform QC at least once every 31 days and for each new lot and shipment." 2. Review of quality control records found no documentation of quality controls performed for Cepheid Gene Xpert Strep A cartridges lot 40911. 3. Review of patient test records found the laboratory tested 159 patient specimens for Strep A between 01/01/2025 and 01/30/2025. 4. During interview of the Technical Consultant conducted July 29, 2025 at 4:10 PM, she confirmed that the laboratory did not perform quality control testing with each new lot, shipment and every 30 days as defined in their own procedure.

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 29, 2025 at 12:01 PM, she confirmed that the laboratory 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 29, 2025 at 10:26 AM, she confirmed there was no written delegation of duties for her responsibilities as technical consultant.