

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0469387	<b>(X3) Date Survey Completed</b> 04/10/2025
<b>Name of Provider or Supplier</b> Rural Wellness Anadarko, Inc	<b>Street Address, City, State</b> 1002 E Central Blvd, Anadarko, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 04/09,10/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer, quality risk and compliance manager, laboratory director, technical consultant #2, and laboratory manager during an exit conference performed at the conclusion of the survey.
<b>D5421</b>	<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 a review of records and interview with the laboratory director, the laboratory failed to utilize the demonstrated reportable ranges for two of two new Biosite Triage Meter Pro analyzers introduced into the laboratory in June 2024. Findings include: (1) On 04/09/2025 at 02:30 pm, the laboratory director stated the laboratory began performing D-dimer testing using two new Biosite Triage Meter Pro analyzers on 06/24/2024; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges for D-dimer: (a) Analyzer Serial #99626 - 225-3900 ng/ml (b) Analyzer Serial #99621 - 218-3640 ng/ml (3) Interview with the laboratory director on 04/09/2025 at 3:15 pm confirmed the laboratory was using the manufacturer's reportable range of 100-5000 ng/ml instead of the reportable ranges that had been demonstrated by the laboratory.</p>

**D5775**

**COMPARISON OF TEST RESULTS**

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results for Routine Chemistry testing performed using two test methods during the review period of June 2023 through the current date. Findings include: (1) On 04/09/2025 at 02:45 pm, the laboratory director stated the laboratory performed the following: (a) Sodium, Potassium, Chloride, CO<sub>2</sub>, Glucose, BUN (Urea Nitrogen), and Creatinine testing using the Ortho Vitros 5600 analyzer as the primary method and the iSTAT 1 analyzer and Chem 8+ cartridge as the backup method; (b) Troponin I testing using the Ortho Vitros 5600 analyzer as the primary method and the iSTAT 1 analyzer and the cTnI cartridge as the backup method. (2) A review of records from June 2023 through the current date identified no evidence the relationship between the different test methods had been evaluated twice in 2024. It had not been evaluated as follows: (a) Between 12/8/2023 and 07/01/2024; (b) Between 07/01/2024 and 01/14/2025. (3) The records were reviewed with the laboratory director who stated on 04/09/2025 at 03:30 pm, the relationship between the above test methods had not been evaluated at least twice during 2024.