

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1015844	(X3) Date Survey Completed 09/04/2025
Name of Provider or Supplier Fallingwater Medical Associates Pllc	Street Address, City, State 2434 Harville Rd, Ste 100, Duncan, OK	
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 recertification survey was performed on 09/04/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with testing persons #1 and #3 at the conclusion of the survey.
D5421	<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 testing person #3, the laboratory failed to utilize the demonstrated reportable ranges for one of one new test methods for complete blood count (CBC) testing. Findings include: (1) On 09/04/2025 at 10:00 am, testing person #3 stated the laboratory began performing CBC (Complete Blood Count) testing using the Beckman Coulter DXH 520 analyzer on 08/22/2024; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) Hemoglobin - 0.9 - 19.29 g/dL (3) Interview with testing person #3 and a review of the CBC- Complete Blood Count policy on 09/04/2025 at 10:24 am confirmed the laboratory was using the following manufacturer's reportable ranges: (a) Hemoglobin - 2.1 -20.25 g/dL</p>