

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1015844	(X3) Date Survey Completed 10/11/2019
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 10/11/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory supervisor and office manager at the conclusion of the survey.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, and interview with the laboratory supervisor and office manager, the laboratory failed to have written policies and procedures that included reportable ranges. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor the laboratory</p>

purchased a new Beckman Coulter AcT Diff2 analyzer, which was put into use to perform patient CBC (Complete Blood Count) testing on 10/29/18; (2) The surveyor reviewed written policies and procedures. The following could not be located: (a) Reportable ranges for each analyte as established or verified in 493.1253. (3) The surveyor reviewed the findings with the office manager, who stated the reportable ranges, as established or verified by the laboratory, were not included in the procedure manual. NOTE: Reportable ranges must be demonstrated by the laboratory (e.g., validation studies, calibration verification performance). The ranges cannot be obtained from the manufacturer.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the office manager, the technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of testing. Findings include: (1) During the survey, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #3 - The initial training for this person was completed on 12/01/17. There was no evidence that a semiannual evaluation had been performed (the next competency evaluation had been performed on 10/09/18); (2) The surveyor reviewed the records with the office manager, who stated there were no records to prove the above person had been evaluated semiannually.