Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0904604	11/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Woods Medical Clinic	250 South Hickman Street, Puxico, MO	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the office manager, the laboratory failed to include reference intervals(normal values). Findings: 1. Review of the procedure manual revealed a lack of normal values for urine microscopic. 2. Interview with the office manager on November 6, 2019 at 10:00 AM confirmed the laboratory failed to include normal values for urine microscopic.
D5807	TEST REPORT CFR(s): 493.1291(d)

	Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of reference ranges approved by the laboratory director, patient test report and interview with the office manager the laboratory failed to ensure the test report included pertinent normal ranges as determined by the laboratory. Eleven of eleven complete blood count (CBC) parameters differed from those in the approved procedure manual. Findings: 1. Review of reference ranges for the CBC test in the procedure manual revealed: WBC: 4.8-10.8 RBC: male 4.7-6.1, female 4.2-5.4 HGB: male 14-18, female 12-16 HCT: male 42-52, female 37-47 MCV: male 80-94, female 81-99 MCH: 27-31 MCHC: 33-37 PLT: 130-400 Lymph: 26.0-41.0 Neutrophil: 48.0-65.0 Mid-Range: 7.0-15.0 2. Review of reference ranges for the CBC test on the patient test report revealed: WBC: 4.5-10.5 RBC: male 4.2-5.5, female 3.6-5.5 HGB: male 13.3-17.6, female 11.4-15.6 HCT: 38.0-52.0 MCV: 89.0-100.0 MCH: 29.0-34.0 MCHC: 32.4-35.5 PLT: 150-350 Lymph: 19.0-44.0 Neutrophil: 45.0-70.0 MXD: 4.5-14.0 3. Interview with the office manager on November 6, 2019 at 10:00 AM confirmed the laboratory failed to ensure correct reference ranges approved in the procedure manual were included on the LIS patient report.
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 review of competencies and interview with the office manager, the technical consultant failed to evaluate and document performance for one of one testing personnel for moderate complexity testing at least semiannually during the first year. Findings: 1. Review of competencies showed no documentation of competency for testing personnel #2 semiannually during the first year. 2. Interview with the office manager on November 6, 2019 at 10:00 AM confirmed the technical consultant failed to evaluate and document semiannual competency for testing personnel #2.