

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0904604	(X3) Date Survey Completed 01/18/2018
Name of Provider or Supplier Woods Medical Clinic	Street Address, City, State 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of unregulated test verification twice annually and interview with the office manager the laboratory failed to verify accuracy twice annually of microscopic urine sediment and failed to completely document microscopic urine sediment, KOH and wet mount verification. Findings: 1. Review of microscopic urine sediment showed urine sediment was verified once in 2016 and once in 2017. Microscopic urine sediment must be verified for accuracy twice annually. 2. Review of microscopic urine sediment verification of accuracy showed urine sediment was not completely documented. Verification included date and initials only, no results. 3. Review of KOH and wet mount verification of accuracy showed KOH and wet mount's were not completely documented. Verification included date and initials only, no results. 4. Interview with office manager on January 18, 2018 at 12:45 PM confirmed the laboratory failed to verify accuracy of Microscopic urine sediment twice annually and failed to completely document verification of KOH, Urine sediment and wet mount.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as</p>

acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on review of hematology calibration records and interview with the office manager the laboratory failed to complete a calibration on the Pochi 100i hematology analyzer every six months. Findings: 1. Review of hematology calibration records showed no six month calibration was completed on the Pochi 100i in June 2017. 2, Interview with the office manager on January 18, 2018 at 12:45 PM confirmed the laboratory failed to complete hematology calibrations on the Pochi 100i every six months in 2017.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on observation of centrifuge and interview with the office manager the laboratory director failed to ensure the laboratory procedure for centrifuging urine was followed. Findings: 1. Laboratory procedure states urine is centrifuged "at 1500 rpm for 5 minutes." Observation of centrifuge showed 3348 rpm's with no way of changing rpm's.. 2. Laboratory had a rheostat to decrease rpm's but it was removed from the centrifuge. 3. Interview with the office manger on January 18, 2018 at 12:45 PM confirmed the laboratory director failed to ensure the laboratory procedure for centrifuging urine was followed.