Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2032677	11/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pocahontas Medical Clinic East	1601 Market Dr, Pocahontas, AR	

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: Through a review of laboratory procedure titled "Diagnostic Urinalysis", a review of "Clinical Diagnosis and Management by Laboratory Methods", a review of the technical consultant's centrifuge speed documentation dated 7/22/2020, and through interviews with laboratory staff, it was determined the laboratory procedure was not accurate and the procedure did not follow the literature referenced. Survey findings include: A. The laboratory procedure titled "Diagnostic Urinalysis" states, "centrifuge the 12 mL urine sample for 2 minutes at a speed of between 2900 and 3500 RPMs. (Averages 400 G on sample) B. Through review of Clinical Diagnosis and

	Management by Laboratory Methods (listed as a reference for the urinalysis procedure) it was determined the reference stated that the urine sample should be centrifuged at an RCF of 400 G (400 times gravity). C. A review of the technical consultant's centrifuge speed documentation dated 7/22/2020 determined the urine centrifuge speed was 3374 RPM on that date. D. In an interview at 11:07 on 11/19 /2020 the technical consultant (as listed on the form CMS-209) stated that she believed the centrifuge head radius was around 13 centimeters. E. Calculation of relative centrifugal force (RCF) is as follows: RCF =(RPM)squared x 1.118 x .00001 x r (where r is the radius of centrifuge head). F. Based on the RPM of the urine centrifuge measured on 7/22/2020 and the approximate radius of the centrifuge, the laboratory is centrifuging urines at an RCF of 1659 G instead of the 400 G listed in the reference material and the written procedure. G. In an interview at 11:15 on 11/19 /2020, the technical consultant (as listed on the form CMS-209) confirmed the laboratory is centrifuging urines for microscopic analysis at a higher centrifugal force than stated in the written procedure.