

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0876227	(X3) Date Survey Completed 02/13/2019
Name of Provider or Supplier Wrmc Internal Medicine Clinic	Street Address, City, State 3443 Harrison Street, Batesville, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: . Through a review of manufacturer's instruction, observations made during a tour of laboratory, as well as interviews with staff, it was determined the laboratory failed to store quality control material consistent with manufacturer's recommendations to achieve accurate and reliable test results as evidenced by: A. The laboratory utilizes the Alere triage instrument to perform the waived B-type natriuretic peptide (BNP) test. B. A review of Alere Triage Quality Control for BNP package inserts revealed the storage requirement: "store frozen at -20 degrees Celsius or colder in a non-defrosting freezer." C. During a tour of the laboratory on 2/13/2019 at 1030, the surveyor observed three of three boxes of Alere BNP Quality Control stored in one of one Maytag defrosting freezer. (BNP Control Level 1 lot #C3490AN expires 6/25/19) (BNP Control Level 1 lot #C3411A expires 8/5/19) (BNP Control Level 2 Lot #C3413AN expires 9/19/19). D. In an interview on 02/13/2019, technical consultant (as listed on form CMS 209) confirmed the control materials were stored in a defrosting freezer.</p>