

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0958089	(X3) Date Survey Completed 03/02/2021
Name of Provider or Supplier Randy D Roberts, Md	Street Address, City, State 1000 East Matthews, Jonesboro, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Through a review of manufacturer's instructions for the Medonic M Series hematology analyzer, a review of the laboratory policy and procedure manual, a review of four patient complete blood count reports which were flagged by the instrument, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to follow manufacturer's instructions, and laboratory policies for Medonic analyzer flags on complete blood count (CBC) results. Survey findings include: A. Manufacturer's instructions for the Medonic M Series hematology analyzer state that if the WBC differential is flagged with "OM" or "TM" the action required is to follow the laboratory's protocol for verification of results. B. The laboratory protocol for verifying differential results flagged by the Medonic analyzer, as listed in the policy and procedure manual, is as follows: 1. Check the specimen for clots or agglutination. Recollect if clots are found; 2. If no clots are detected, the specimen will be re-mixed and re-tested; 3. If flags persist, at the discretion of the physician, send the specimen to the reference lab. C. In a review of four patient complete blood count reports which were flagged by the instrument, it was determined that three of the four reports included OM flags present on the WBC differential and one of the reports included TM flags on the WBC differential. It was further determined that there was no documentation that the laboratory protocol had been followed on four of four CBC reports with flags. D. In an interview, at 11:25 a. m. on 3/2/2021, lab employee #2 (as listed on the form CMS-209) confirmed the lack of documented actions for the flagged CBC results.</p>