Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2070026	03/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Narmc Internal Medicine	724 N Spring Street, Suite C, Harrison, 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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: Through a review of the "Coulter AcT Diff Operator's Manual", the laboratory's procedure manual, the instrument data log for February 2023, patient CBC reports, and the plan of correction signed 8/28/2014, and through interviews with staff, it was determined the laboratory failed to follow the manufacturer's instructions for flags on patient results. Findings follow: A. The "Coulter AcT Diff Operator's Manual" states that if the patient result has a 1, 2, 3, 4, or M flag the laboratory should "Verify results according to your laboratory's protocol." B. The laboratory protocol titled, "AcT Diff Parameter Codes and Sample Flags Policy" states "1, 2, 3, 4, M Differential parameters failed the internal regional size distribution criteria at one specific region (1, 2, 3, 4) or multiple regions (M). 1. Check the specimen for clots. Recollect if clots are found. 2. If no clots are found, the specimen will be thoroughly remixed and retested. 3. If flags persist, at the discretion of the physician, send the specimen to the reference lab for manual differential." C. A review of instrument data logs for February 2023 revealed that fifty-seven samples were run during the month of February. Fifteen samples tested during February 2023 included differential parameter flags on the results. One of fifteen flagged samples did not have evidence of following the laboratory protocol to repeat the sample the testing. F. In an interview at 11:13 a. m. on 3/7/2023, laboratory employee #2 (as listed on the form CMS-209) confirmed the laboratory failed to follow its policy for addressing flagged CBC reports from the AcT Diff hematology analyzer.