Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468124	08/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Piggott Family Medical Clinic	425 W Jackson Street, Piggott, 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 review of the Medonic operators' manual, laboratory policies and procedures, and Medonic patient datalogs, as well as interviews with laboratory staff, the laboratory failed to follow manufacturer's instructions for evaluating patient test results when instrument flags are present. Survey findings include: A. Review of the operators' manual for the Medonic hematology analyzer revealed a list of causes for instrument flags and actions the lab must take to resolve the flags. In the section for WBC (White Blood Cell) Differential Abnormalities, it states, "follow laboratory's protocol for verification of results". B. The laboratory "Error Code Policy" states, "Shifts in WBC distribution due to EDTA anticoagulant equilibration will often result in "error" codes next to one of the automated differential values. 1. Check the specimen for clots or agglutination. Recollect if clots are found. 2. If no clots are detected, the specimen will be retested." C. Review of the Medonic CBC (complete blood count) datalog for June and July of 2024 revealed, one of three CBCs with WBC distribution flags failed to be recollected or retested. On 6/11/2024 at 15:16 a CBC was performed on specimen #268591. Flags were present on all differential parameters. The datalog failed to include documentation of retesting of the sample or of recollection and retesting of the patient. D. In an interview, at 1:20 p.m. on 8/13/2024, the laboratory director confirmed the flags were not addressed as required by the manufacturer and the laboratory policy.