Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2035986	05/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Sherwood Urgent Care-Lonoke	1306 N Center Street, Lonoke, 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 laboratory policy titled, "Error Flags for the Sysmex XP 300", instrument data logs for January through April 2022, and through interviews with laboratory staff, it was determined the laboratory failed to follow manufacturer's instructions for error flags generated by the complete blood count (CBC) instrumentation. Survey findings include: A. A review of the policy "Error Flags for the Sysmex XP 300" revealed that an AG flag is caused by "Presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, presence of proteins or lipids, etc." and the manufacturer correction is listed as "Warm the Sample and repeat analysis". Other instructions listed in this policy state, "Above are the common flags and their causes generated by the Sysmex XP 300. When these flags are generated by the instrument: 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 flag persists, at the discretion of the physician, send the sample to the reference laboratory for a manual differential." B. The surveyor reviewed ten randomly selected patient test results listed on the instrument data logs for January through April 2022. Nine of ten patients selected had AG flags documented on the platelet portion of the CBC. Six of the nine flagged results had no documentation that the sample had been repeated or sent to the reference laboratory for a manual differential. C. In an interview, at 11:17 on 5/12 /2022 the laboratory director (as listed on the form CMS-209) confirmed the laboratory did not repeat the CBC testing on six of nine samples with flagged results.