Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0466705	01/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Sherwood Family Medical Center	1308 E Kiehl Ave, Sherwood, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Through review of laboratory policy and procedure, observation and interview it was determined that the laboratory failed to label two of two specimen collection containers with patient name or unique patient identifier. Findings follow: A) During a tour of the laboratory on 1/21/21 at approximately 11:45 AM two urine specimens were observed in a sink in the testing area one with the label written on the specimen container lid but no label on the container and the other labeled with the patient's last name and first initial only. B) Review of the laboratory policy and procedure revealed that specimen containers are to be labeled with the patient's first and last names and the patient's date of birth. C) In an interview on 1/21/21 at approximately 12:00 , the laboratory staff member, identified as number one on the CMS 209 form, confirmed that the specimens identified above lacked proper patient identification on the containers as required by policy and procedure and the specimens should be discarded.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and

	when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Through observation and interview it was determined that the laboratory failed to label three of three secondary containers into which aliquots of manufacturer supplied reagents were poured over. Findings follow: A) During a tour of the laboratory on 1/21 /21 at approximately 11:45 AM three plastic containers filled with an unknown liquid were observed without any labels of content in a closed cabinet beneath the Medonic hematology analyzer. B) In an interview on 1/21/21 at approximately 11:45 AM the laboratory staff member identified as number one on the CMS 209 form stated that they were not sure of the contents. C) In an interview on 1/21/21 at approximately 12: 00 PM the laboratoy staff member identified as number two on the CMS 209 form stated the contents of the containers were cleaning solutions provided by the manfacturer and the containers were not labeled and the solutions were available for use.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Through a review of laboratory policies and procedures, review of the Medonic hematology analyzer's "All Samples" report, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to perform function checks as defined by the laboratory on two of three months reviewed. Survey findings follow: A) Review of the laboratory policy and procedure manual revealed that quality control samples are to be run and be acceptable after monthly cleaning procedures on the Medonic hematology analyzer prior to performing and reporting patient results. B) Review of the Medonic analyzer's "All Samples" report revealed that on 3/5/20 monthly cleaning was performed between 03:00 PM and 03:44 PM and a CBC was run and reported on patient 560808 at 03:58 PM without quality control being performed and that on 7/9/20 monthly cleaning was performed between 03:09 PM and 03:55 PM and CBC's were performed and reported on patients 741210 and 51844 at 03:58 PM and 04:01 PM, respectively, without quality control being performed. C) In an interview on 2/21/21 at approximately 12:15 PM the laboratory staff member, identified as number one on the CMS 209 form, confirmed that CBC's were performed and reported on patients during the instances identified above.