Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2214802	11/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Grand River Medical Group Urgent Care Warren Plaza	3500 Dodge Street, Suite 135, Dubuque, IA	

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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of hematology instrument maintenance records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 11/03/2021, the laboratory failed to document weekly maintenance for 14 out of 22 weeks and monthly maintenance for five out of five months of patient testing on the Sysmex KX-21N hematology instrument from 06/01 /2021- 10/31/2021. The findings include: 1. According to the Sysmex K-Series Maintenance Log, the manufacturer requires the laboratory to perform and document cleaning of the SRV tray weekly. 2. The Sysmex K-Series Maintenance Logs from June- October 2021 indicated that the laboratory did not document weekly maintenance during the following weeks: 06/01/2021, 06/06/2021, 06/13/2021, 06/20 /2021, 06/27/2021, 07/04/2021, 07/11/2021, 07/18/2021, 07/25/2021, 08/01/2021, 09 /26/2021, 10/03/2021, 10/10/2021, and 10/24/2021. 3. The Sysmex K-Series Maintenance Log also indicated that the manufacturer requires the laboratory to perform and document the following monthly maintenance: clean transducer and clean waste chamber. 4. The Sysmex K-Series Maintenance Logs indicated that the laboratory did not document monthly maintenance from June 2021- October 2021. 5. At the time of the survey, personnel identifier #1 confirmed that the laboratory failed to document weekly and monthly maintenance on the The Sysmex KX-21N hematology instrument as required by the manufacturer.
D5805	TEST REPORT

	CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports, instrument printouts, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 11/03/2021, the laboratory failed to include all units of measure for three out of three patient test reports reviewed (patient identifiers A, B, and C). The findings include: 1. Patient A had complete blood count (CBC) testing performed on 08/05/2021. 2. Patient B had complete blood count (CBC) testing performed on 08/12/2021. 3. Patient C had complete blood count (CBC) testing performed on 08/23/2021. 4. The electronic health record (EHR) test report for patients A, B, and C did not include units of measure for the following CBC parameters: white blood cell count, red blood cell count, hematocrit, hemoglobin, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, mean corpuscular volume, red cell distribution width, lymphocyte percentage, absolute lymphocyte count, neutrophil percentage, and absolute neutrophil count. 5. At the time of the survey, personnel identifier #1 confirmed that the EHR test reports for patients A, B, and C did not include the units of measure listed above.