

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2214802	(X3) Date Survey Completed 04/26/2023
Name of Provider or Supplier Grand River Medical Group Urgent Care Warren Plaza	Street Address, City, State 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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test reports, hematology instrument printouts, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:40 am on 04/26/2023, the laboratory failed to include all units of measure for three out of three patient test reports (patient identifiers A, B, and C) reviewed from February 2023. The findings include: 1. Patient A had a complete blood count (CBC) with automated differential performed on 02/15/2023. 2. Patient B had a CBC with automated differential performed on 02/16/2023. 3. Patient C had a CBC with automated differential performed on 02/20/2023. 4. The electronic health record (EHR) test reports 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, hemoglobin, hematocrit, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelets, red blood cell distribution width (RDW-CV), absolute neutrophil count, neutrophil percentage, absolute lymphocyte count, lymphocyte percentage, absolute monocyte</p>

count, monocyte percentage, absolute eosinophil count, eosinophil percentage, absolute basophil count, basophil percentage, absolute immature granulocyte count, and immature granulocyte percentage.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedure manual and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 04/26/2023, the laboratory director failed to ensure the laboratory established and maintained a quality assessment program which covered the four quality systems: general, pre-analytic, analytic, and post-analytic. At the time of the survey the laboratory did not have a written quality assessment policy/procedure which covered the four quality systems.