

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2139397	(X3) Date Survey Completed 07/10/2023
Name of Provider or Supplier Cvmc Santaquin Medical Clinic	Street Address, City, State 210 E Main Street, Santaquin, UT	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's Standard Operating Procedures (SOP), the Thermometer Worksheet, and an interview with the laboratory director (LD), the laboratory failed to perform and document the annual function check on the thermometers in the laboratory refrigerator and freezer during 2022. The refrigerator is used to store the Quality Control (QC) material used on the Sysmex XP-300 Hematology analyzer. The laboratory performs approximately 2040 Hematology tests annually. Findings include: 1. A review of the laboratory's SOP manual at approximately 10:15 AM on 7/10/23 revealed that the SOP titled, "Thermometer Verification," states: "Our thermometers are checked annually against our standard thermometer unless there is a certificate of certification." 2. A certificate of certification was not available for either thermometer in the laboratory refrigerator or freezer at the time of survey. 3. A review of the Thermometer Worksheet at approximately 10:20 AM on 7/10/23 revealed that the thermometers in the laboratory refrigerator and freezer had not been checked against the standard thermometer during 2022. 4. In an interview with the Laboratory Director at approximately 10:25 AM on 7/10/23, it was confirmed that the thermometers in the laboratory refrigerator and freezer had not been checked against the standard thermometer during 2022.</p>