

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0982582	<b>(X3) Date Survey Completed</b>  10/13/2021
<b>Name of Provider or Supplier</b>  Sharon Mitchell Medical Clinic Llc	<b>Street Address, City, State</b>  13 Village Plaza, Liberal, KS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5435</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> 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 an absence of thermometer and centrifuge function check records or certificates of accuracy, protocols for thermometer and centrifuge function checks and interview with the laboratory director (LD), the laboratory failed to define and perform a function check protocol for three of three thermometers and one of one centrifuge. Findings: 1. No documentation was available for function checks on three of three thermometers and one of one centrifuge at the time of survey. 2. No documentation was available for the certification of accuracy (NIST traceable) on three of three thermometers at the time of survey. 3. Protocols for the function checks of thermometers and centrifuge were not made available at the time of survey. 4. Interview with the LD on October 13, 2021 at 8:55 a..m. confirmed, the laboratory failed to define and perform a function check protocol for three of three thermometers and one of one centrifuge.</p>