

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0987858	<b>(X3) Date Survey Completed</b>  11/02/2023
<b>Name of Provider or Supplier</b>  Kansas Medical Clinic Pa - Dermatology	<b>Street Address, City, State</b>  2921 Sw Wanamaker Drive, Topeka, 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 current pipette function check records, certificates of accuracy, protocols and lack of accuracy checks for calibrated pipettes and interview with technical consultant #2 (TC #2), the laboratory failed to perform a function check protocol for two of two pipettes. Findings: 1. No documentation was available for function checks on two of two pipettes for 2023 at the time of survey. 2. Documentation available for pipette SN: 104686Z and pipette SN: 106073Z accuracy checks were performed January 4, 2022. 3. Interview with TC #2 on 11/2/23 at 11:55 a.m. confirmed, the laboratory failed to perform a function check protocol for two of two pipettes.</p>