

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0448255	(X3) Date Survey Completed 10/29/2020
Name of Provider or Supplier Watkins Health Services	Street Address, City, State 1200 Schwegler Drive, Room 1710, Lawrence, KS	
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 an absence of thermometer and hygrometer function check protocols, records or certificates of accuracy and interview, the laboratory failed to define and perform a function check protocol for the thermometers and hygrometer. Findings: 1. No documentation of a function check protocol for the thermometers and hygrometer was available at the time of survey. 1. No documentation was available for performance of function checks on 13 of 13 thermometers and 1 of 1 hygrometers for a 2 year period. 2. No documentation was available for the certification of accuracy (NIST traceable) on 13 of 13 thermometers and 1 of 1 hygrometers for a 2 year period. 2. Interview with the General Supervisor on 10/29/2020 at 11:15 a.m. confirmed, the laboratory failed to define and perform a function check protocol for the thermometers and hygrometer.</p>