

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0442057	(X3) Date Survey Completed 02/18/2020
Name of Provider or Supplier Heartland Laboratory	Street Address, City, State 221 S Main St, Chaffee, MO	
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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on the centrifuge function checks and interview with the laboratory director, the laboratory failed to define a function check protocol to verify the accuracy of the timer and speed mechanisms on the laboratory centrifuge. Findings: 1. No documentation was found to show the laboratory defined a function check protocol to verify the accuracy of the timer and speed mechanisms on the laboratory centrifuge. 2. Review of the direct smear preparation of urine specimens procedure revealed centrifuge for 10-15 minutes at 1500 rpm. 3. Interview with the laboratory director on February 18, 2020 at 11:30 AM confirmed, the laboratory failed to to have a protocol to verify the accuracy of time and speed on the laboratory centrifuge.</p>