

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2183478	(X3) Date Survey Completed 04/30/2021
Name of Provider or Supplier National Veterinary Services Laboratories	Street Address, City, State 1920 Dayton Avenue, Ames, IA	
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 review of centrifuge function check records and the Qiagen QIAamp manufacturer's instructions and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 4/30/2021, the laboratory failed to define the frequency for performing centrifuge speed and timer function checks. Additionally, the laboratory failed to perform centrifuge speed and timer function checks on one out of one centrifuge from 5/6/2020 - 4/30/2021. The findings include: 1. The laboratory used centrifuge 5674 to perform SARS-CoV-2 testing. 2. The Qiagen QIAamp manufacturer's instructions for the extraction step of the SARS-CoV-2 testing did not state the frequency of performing centrifuge speed and timer checks. 2. At the time of the survey, the laboratory had not performed speed and timer checks on centrifuge 5674 since 3/4/2016.</p>