

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D2190563	(X3) Date Survey Completed 12/03/2020
Name of Provider or Supplier University Of New Hampshire	Street Address, City, State Gregg Hall Room 337, Durham, NH	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform maintenance specified in the operator's manual for the instrumentation used for virology testing in August, September, October, and November 2020. Findings include: 1) Review on 12/3/2020 of the operator's manual for "Applied Biosystems 7500 Dx Real-Time PCR Instrument" (ABI 7500) revealed on page 26 a background calibration is required monthly and after replacing the lamp. 2) The laboratory could not provide documentation at the time of survey on 12/3/2020 that the background calibration had occurred in August (month of verification of performance specifications), September (beginning of patient testing), October and November 2020. 3) Interview on 12/3/2020 at 12:30 p.m. with the Technical Supervisor revealed the background calibration for the ABI 7500 had not been performed by the laboratory from August through November. 4) The laboratory performed 231 Sars-CoV-2 RT-PCR tests in September and 431 tests in October. Test volume for November was unknown at the time of the survey.</p>