magnetiC

Viral RNA Purification

Magnetic Bead-Based RNA Isolation of SARS-CoV-2

Validation of Galenvs Viral RNA Extraction Kit for COVID-19 RNA Isolation

Purpose

To evaluate the extraction of Galenvs Viral RNA Extraction Kit for isolation and recovery of SARS-CoV-2 RNA. Validation was performed by the National Research Council of Canada (CNRC-NRC) – Medical Devices (MD-DM).

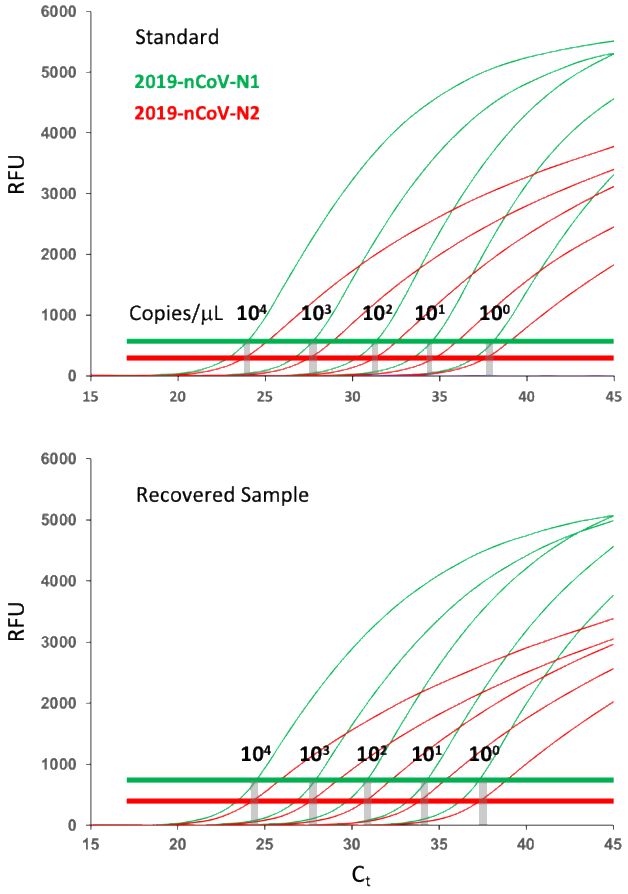
Method

Current sample collection is performed using swab that is inserted in a standard swab preservation solution. Synthetic SARS-CoV-2 RNA (Twist Bioscience) was spiked in standard preservation solution at varying dilutions between 10^4 and 1 copy/µL. Sample solutions were prepared at a volume of 100 µL, and the Galenvs protocol was followed for RNA capture and elution at 50 µL. The capture and extraction efficiency was then evaluated using RT-qPCR and compared against a standard curve for calibration purposes. A dual-plex assay – based on the CDC 2019-nCoV panel – was employed wherein primers and hydrolysis probes for N1 and N2 genes, supplied by Integrated DNA Technologies (IDT), are included for detection in FAM and HEX, respectively.

Results

It is critical for RNA extraction to be efficient at low copy concentrations in order to achieve early viral detection. In addition, the eluted samples should possess high purity to allow for routine RT-qPCR analysis. A commercial RT-qPCR mix from ThermoFisher (TaqPath 1-Step Master Mix) was used according to manufacturer protocol. Thermocycling and analysis was performed using a Biorad CFX96 instrument and CFX Maestro software.

The Galenvs kit was evaluated according to the provided protocol. Following sample elution and RT-qPCR analysis, the performance of the Galenvs kit showed high extraction efficiencies of 99-100% recovery for low SARS-CoV-2 copy numbers ranging from 1-100 copies/µL. This is of significant importance for detection of viral loads commonly associated with early onset COVID-19 infections, which are reported to be between 1-10 copies/µL, as outlined by Health Canada, FDA, CDC and WHO.



	Threshold Cycle, C_t		
Concentration	Standard	Recovered Sample	Percent Recovery
100 copies/µL	30.98	30.99	99%
10 copies/µL	34.29	34.29	100%
1 copy/µL	37.52	37.46	100%

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