Public Health England

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Rapid assessment of Liferiver Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 Genes)

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Introduction

The emergence of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in humans and spread of the associated disease, COVID-19, has been declared a Public Health Emergency of International Concern by the World Health Organization (WHO). In the UK, the deployment of a PHE in-house real-time PCR assay in PHE, PHE collaborating laboratories as well as in Devolved Administrations is being followed up with assessments of commercially developed and provided diagnostic tests for SARS-CoV-2 detection.

This assessment examined the Liferiver Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 Genes) Product REF: RR-0479-02 (Revision No. ZJ0010).

The assessment panel

The assessment sample-panel totalled 195 specimens, including respiratory clinical specimens negative for SARS-CoV-2 as determined by the validated in-house PHE PCR assay and 3 dilutions of material positive for SARS-CoV-2. Statistical assessment of panel sizes determined that when the measured specificity for 195 samples is 100% that the true specificity of the test is at least 98.1%.

Performing and analysing the assay

The RR-0479-02 assay is used for the *in vitro* qualitative detection of 2019 novel coronavirus (2019-nCoV) RNA in upper respiratory tract specimens (nasopharyngeal and oropharyngeal extracts) and lower respiratory tract specimens (bronchoalveolar lavage fluid (BALF) and deep cough sputum) by real time PCR systems. It measures simultaneously 3 target genes in a single tube: SARS-CoV-2 gene E, gene N, gene orf1ab, the assay includes a positive control and an internal control and quotes an analytical sensitivity of 1×10^3 copies/mL. The probes specific for SARS-CoV-2 RNA are

labelled with the fluorophore FAM (orf1ab), HEX/VIC/JOE (gene N), and Cal Red 610/ROX/TEXAS RED (gene E). The probe specific for IC is labelled with the fluorophore Cy5.

The assessment was carried out following the instructions for use (IFU) for RR-0479-02 (Revision No. ZJ0010), with one exception; the IFU for RR-0479-02 requires the internal control (IC) to be added into the extraction mixture to monitor the whole process. However, as the assessment sample-panel consists of extracted nucleic acid, 1µL/test of the IC was added into the PCR master mix with 4µL of RNA extracts from clinical samples added to the reaction (a final reaction volume of 25 µL). Samples were processed in batches of 64 or 88 with appropriate; negative, internal and positive controls.

Real time PCR was performed upon an Applied Biosystems™ 7500 Fast Real-Time PCR System following the cycling and fluorescence acquisition parameters detailed in the LifeRiver Novel Coronavirus (2019-nCoV) Real Time Multiplex (RR-0479-02).

Results of real time PCR testing were verified as valid if the designated control wells achieved the defined criteria in the LifeRiver Novel Coronavirus (2019-nCoV) Real Time Multiplex (RR-0479-02) IFU. Samples and controls were assigned a cycle threshold value at which signal was detected above the background fluorescence in any of the FAM, Cy5, Texas Red or JOE channels, following the data analysis methodology detailed in the IFU. The samples were then interpreted as either ‘COVID-19 Positive’, ‘COVID-19 Negative’ or ‘Potential positive’ (to retest), or ‘result invalid’ (to retest) dependent upon the presence.

Results

Compared with results from the PHE COVID-19 in-house real-time PCR assay, the following was found:

	Samples (n)	**True positive**	**False positive**	**True negative**	**False negative**	**Negative percentage agreement**
Liferiver Novel Coronavirus Real Time Multiplex RT-PCR Kit (3 Genes) (RR-0479-02)	195	0	0	195	0	100% (195/195)

Report date

A version of the report was distributed by PHE's COVID-19 Incident Virology Cell on 16/04/2020.

Disclaimer

PHE's assessments of commercial products for diagnosing COVID-19 infection have been carried out primarily for PHE's own use and under agreement; the reports of such assessments are shared solely for the readers' information; PHE does not in any way recommend any particular COVID-19 diagnostic assay or extraction platform; PHE shall not be responsible for any choice of COVID-19 diagnostic assay or extraction platform, and it is the testing laboratory's responsibility to ensure that any such assay or platform implemented has undergone the necessary verification and validation; and PHE shall not be liable, to the greatest extent possible under any applicable law, for any claim, loss or damage arising out of or connected with the use of this and related reports and any choice of COVID-19 diagnostic assay products or extraction platforms.

A position statement regarding COVID-19 tests evaluated by PHE is available at: https://www.gov.uk/government/publications/position-statement-regarding-covid-19-tests-evaluated-by-phe

Further information

Queries about our assessments of SARS-CoV-2 (COVID-19) diagnostics should be sent to labvalidation.cov@phe.gov.uk

Table of changes

Date	New version no.	Details of changes
27/04/2020	1.2	Changes to disclaimer
27/04/2020	1.2	Consistency for use of the term "assessment"
27/04/2020	1.2	Tables of changes added
12/05/2020	1.2	Change of template
12/05/2020	1.2	Version number and website added (footer)
12/05/2020	1.2	Addition of date reported by Virology Cell
26/05/2020	1.2	Minor changes for consistency with other reports