



Evaluation of Genetic PCR solutions CoVID-19 dtec-RT-qPCR Test.

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 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 Genetic PCR solutions CoVID-19 dtec-RT-qPCR Test F100 format.

The assessment panel

The evaluation 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 three dilutions of material positive for SARS-CoV-2. The PHE in house assay targets the RNA-dependent RNA polymerase (RdRP) of 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.

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 CoVID-19 dtec-RT-qPCR F100 format Edition E01 (03/2020) IFU.

Five microliters of nucleic extracts from clinical samples were used in each real time PCR reaction, with a final volume for 20 µL as per the IFU. Samples were processed in batches of 24 or 90 with appropriate; negative, internal and positive controls.

The assessment was carried out following the instructions for use (IFU) for the F100 format Edition E01 (03/2020). The assay includes a positive control and an internal control and utilises a real-time technology targeting CoVID-19, using the FAM channel as well as an internal control, detected in HEX, VIC or JOE channel.

Results of real time PCR testing were verified as valid if the designated control wells achieved the defined criteria in the CoVID-19 dtec-RT-qPCR F100 IFU. Samples and controls were assigned a cycle threshold value at which signal was detected above the background fluorescence in any of the FAM, HEX, VIC 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).

Results.

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

	Samples (n)	True positive	False Positive	True negative	False negative	Negative percentage agreement
Genetic PCR solutions CoVID-19 dtec-RT-qPCR Test F100	195	0	0	195	0	100% (195/195)

From a challenge with positive material, all tests for a three-step dilution series were found positive for SARS-CoV-2.

DISCLAIMER

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Further information

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