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Rapid assessment of the GeneFirst Novel Coronavirus (COVID-19) Real-Time PCR assay

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Introduction

The emergence of the 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 GeneFirst Novel Coronavirus (COVID-19) Real-Time PCR assay (REF: COVID-19), following the manufacturer's Instructions for Use, IFU (GeneFirst_COVID-19 Protocol.pdf) as supplied (17/03/2020). The assay utilises a real time technology targeting orf1ab, using the FAM channel as well as the N gene using the ROX channel. The assay also includes an internal control which signals the presence of human genetic material, using the Cy5 channel.

The assessment panel

The assessment sample panel totalled 195 specimens, including upper or lower respiratory clinical specimens negative for SARS-CoV-2 as determined by the validated in-house PHE PCR assay and dilutions of SARS-CoV-2. Statistical assessment of the panel size 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 parameter detailed in the GeneFirst Novel Coronavirus (COVID-19) Real-Time PCR assay IFU.

Nucleic acids extracted from clinical samples were aliquoted and 5 µL used in each real-time PCR reaction, with a final volume of 20 µL as per the IFU. Samples were processed in batches of 90 with appropriate negative, internal and positive controls.

Results of real time PCR testing were verified as acceptable if the designated control wells achieved the defined criteria in the GeneFirst Novel Coronavirus (COVID-19) IFU. Samples and controls were assigned a cycle threshold value at which signal was detected above the background fluorescence in any of the FAM, ROX or Cy5 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 and value of a Ct in either/or the Cy5, FAM or ROX channels.

Results

Compared to the 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**
GeneFirst Novel Coronavirus (COVID-19) Real-Time PCR	195	0	0	195	0	100% (195/195)

From a challenge with positive material, all samples for a 3-step dilution series were found positive for SARS-CoV-2.

Report date

A version of the report was distributed by PHE's COVID-19 Incident Virology Cell on 25/03/2020.

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