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Rapid assessment of the Novacyt Primerdesign Coronavirus (COVID-19) genesig® Real-Time PCR assay

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Introduction

The emergence of the SARS-CoV-2 virus 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 Primerdesign Ltd Coronavirus (COVID-19) genesig® Real-Time PCR assay (Cat: Z-Path-COVID-19-CE). Following the instructions for use issue 2.0, published Date: 26 Feb 2020. The assay utilises a real time technology targeting the RNA-dependent RNA polymerase (RdRp) of SARS-CoV-2, using the FAM channel. The assay also includes an internal control labelled with HEX fluorophore.

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 genesig® Coronavirus (COVID-19) instructions for use. Nucleic acids extracted from clinical samples were aliquoted and 8 µL used in each real time PCR reaction, with a final volume for 8 µL as per the genesig® COVID-19 instructions for use. 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 genesig® COVID-19 instructions for use. Samples and controls were assigned a quantitation cycle (Cq) value following the data analysis methodology detailed in the genesig® COVID-19 instructions for use. The samples were then interpreted as either 'COVID-19 Detected', 'COVID-19 Not detected' or 'Result invalid' dependent upon the presence of Cq in either/or the FAM or HEX channels.

Results

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

Compared with the results from the PHE COVID-19 assay the following was found:

	Samples (n)	**True positive**	**False positive**	**True negative**	**False negative**	**Negative percentage agreement**
PrimerDesign genesig® Real-Time COVID-19	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 13/03/2020.

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