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Rapid assessment of the Genetic Signatures EasyScreen™ SARS-CoV-2 Detection Kit

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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 Genetic Signatures EasyScreen™ SARS-CoV-2 Detection Kit (RP010-HT). The assessment was carried out following the instructions for use (IFU) for RP010 V1.2, the pre-launch Research Use Only version of the CE-IVD RP011 Kit.

The RP010-HT assay will detect SARS and Wuhan 2019 CoV pneumonia virus as well as other member of the Sarbecovirus sub-genus. The assay utilises bisulphite chemistry coupled to real time PCR to specifically detect the N-gene (Texas Red channel) for SARS-related viruses and E-gene (Cy5 channel) for SARS-CoV-2, alongside an Extraction process control (VIC). The RP010-HT assay, as evaluated, also detected the common human respiratory Coronaviruses; NL63, 229E, HKU, OC43 or MERS in the pan-coronavirus (FAM) channel, this target is no longer present in the CE marked RP011-HT version.

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 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

Nucleic acid extracts and control material were reprocessed using the EasyScreen™ Sample Processing Kit (REF SP008) which extracts viral nucleic acids and converts all Cytosine bases to Uracil. This was performed upon the automated Genetic Signatures GS1 instrument according to the manufacturer's instructions for use (IFU: SP008 v1.0).

Aliquots (7.5 µL) of extracted and bisulfite converted samples and controls, were then used as target for real time PCR using the EasyScreen™ Pan-Coronavirus/ SARS-CoV-2 Detection Kit (RP010-HT). Real-time PCR was performed as per the manufacturer's instructions in a final reaction volume of 20 µL on an Applied Biosystems Quant Studio 5 Fast instrument. Data analysis was performed as per the manufacturer's instructions using the Quant Studio 5 software and as well as visual inspection of amplification plots. The presence / absence calls were confirmed visually and agreed between 2 Clinical Scientists. Results were considered valid if the Extraction process control, Negative Process Control and Positive Control achieved the desired criteria as per the IFU.

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**
Genetic Signatures EasyScreen™ SARS-CoV-2 Detection Kit	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