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Rapid assessment of the Elitech GeneFinder

COVID-19 Plus RealAmp kit

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Public Health England
Wellington House
133-155 Waterloo Road
London SE1 8UG
Tel: 020 7654 8000
www.gov.uk/phe
Twitter: @PHE_uk
Facebook: www.facebook.com/PublicHealthEngland

Prepared by NIS Laboratories, National Infection Service, Public Health England

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Rapid assessment of the Elitech GeneFinder COVID 19 PLUS RealAmp kit

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 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 GeneFinder COVID 19 PLUS RealAmp Kit REF: IFMR-45 March-2020 (rev.1). The assessment was carried out following the instructions for use (IFU) for IFMR-45.

The IFMR-45 assay is used for the *in vitro* qualitative detection of 2019 novel coronavirus (2019-nCoV) in viral RNA samples extracted from human respiratory tract specimens such as alveolar lavage fluid, throat swab, and sputum samples by real time PCR systems. It simultaneously measures 3 target genes in a single tube: SARS-CoV-2 E gene, N gene and the RNA-dependent RNA polymerase (RdRp) gene, the assay includes a positive control and an internal control. The analytical sensitivity of the assay was quoted as 10 copies / reaction for all target genes (RdRp, E, N gene). The probes specific for SARS-CoV-2 RNA are labelled with the fluorophore FAM (RdRp gene), VIC or JOE (N gene), and TEXAS RED (E gene). The probe specific for IC is labelled with the fluorophore Cy5.

The assessment panel

The assessment sample-panel totalled 235 specimens, including 197 respiratory clinical specimens negative for SARS-CoV-2 and 38 samples positive for SARS-CoV-2 as determined by the validated in-house PHE PCR assay and 3 dilutions of material positive for SARS-CoV-2. The PHE in house assay targets ORF1ab of SARS-CoV-2. Statistical assessment of panel sizes determined that when the measured specificity for 197 samples is 100% that the true specificity of the test is at least 98.4%. Therefore, the true specificity of the GeneFinder COVID 19 PLUS RealAmp Kit (IFMR-45) is above 98.4%.

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 GeneFinder COVID 19 PLUS RealAmp Kit (IFMR-45).

Five microliters of nucleic extracts from clinical samples were used in each real-time PCR reaction, with a final volume for 20 µL. Samples were processed in batches of 88 with appropriate; negative, internal and positive controls.

Results of real-time PCR testing were verified as valid if the designated control wells achieved the defined criteria in the GeneFinder COVID 19 PLUS RealAmp Kit (IFMR-45) 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

The GeneFinder COVID 19 PLUS RealAmp Kit demonstrated the following results in comparison with the PHE COVID-19 in-house real-time PCR assay targeting ORF1ab:

	Samples (n=)	True positive	False positive	True negative	False negative
GeneFinder COVID 19 PLUS RealAmp Kit	235	37	0	197	1

The GeneFinder COVID 19 PLUS RealAmp Kit demonstrated the following assay performance:

Sensitivity: 97.4% (84.6 to 99.9%; 95% CI)
Specificity: 100% (97.6 to 100%; 95% CI)

A single discordant result was found; a sample which returned a negative result using the GeneFinder COVID 19 PLUS was positive in the PHE ORF-1ab real-time PCR assay with a Ct of 37.40.

From an additional challenge with positive material prepared from titrated virus, 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 8 July 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
8 July 2020	01.00	None – new document