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Rapid assessment of the Randox Extended Coronavirus Multiplex Array 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 Randox Extended Coronavirus Multiplex Array assay (REF: EV4418), following the manufacturers IFU (200302 Randox Extended Coronavirus Multiplex Array EV4418 IFU) as supplied (02/03/2020).

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

The assay tests extracted RNA, and utilises 2 main laboratory processes in order to determine a result. Firstly, reverse transcription combined with PCR amplification from labelled oligonucleotides is performed. Secondly a DNA-DNA hybridisation, washing and signal detection process for the detection of target nucleic acids (i.e. SARS-CoV-2) within the specimen. The signal is detected via imaging of the chip surface using the Randox Evidence Investigator™ where on-board software identifies the presence of the pathogen within the sample.

Reverse transcription and DNA amplification was performed upon an Applied Biosystems™ Veriti PCR System following the instructions for use. Nucleic acids extracted from clinical samples were aliquoted and 5 µL used in each reverse-transcriptase / DNA amplification PCR reaction, with a final volume for 20 µL as per the IFU.

For the DNA-DNA hybridisation step, labelled amplicons were added to an array chip for hybridisation with DNA probes spotted onto the surface of the Randox Biochip in (up to) 6 multiples of 9 samples, with appropriate; negative, internal and positive controls. The labelled amplified DNA that has been hybridised to corresponding DNA probes on the surface of the chip was detected via conjugation with horseradish peroxidase-labelled streptavidin and development of signal.

Conventional formats for molecular diagnostics are multiples of 8, typically as 96 or 384 well plate formats. The Biochips of Randox Extended Coronavirus Multiplex Array assay (REF: EV4418), can process 9 samples and each run can process a maximum of 6 biochips, assuming one negative and positive control per run a total of 52 unknown samples can be processed. For this assay it was necessary to re-order the samples in batches of 9 prior to PCR amplification. Issues with chips falling from holders during wash steps and failed signal development prompted repeat assays.

Results of the tests were verified as acceptable if the designated control wells achieved the defined criteria in the manufacturer's instructions for use. Samples and controls were assigned a positive or negative for SARS-CoV-2 result by the software following the data analysis methodology detailed in the IFU, results were also checked manually. Per sample, the results for each of the NCOVA and NCOVB (COVID-19) targets were then interpreted as either 'Positive', 'Negative' or 'Borderline' (to retest), with samples considered positive when both targets had corresponding results. Samples with one positive target are considered positive pending repeat testing.

Results

Compared to 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**
Randox Extended Coronavirus Multiplex Array assay	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