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Rapid assessment of the Altona RealStar SARS-CoV-2 RT-PCR Kit 1.0. assay for the detection of SARS-CoV-2 (COVID-19)

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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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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 RealStar SARS-CoV-2 RT-PCR Kit 1.0. (Altona Diagnostics), detecting and delineating members of the Sarbecovirus sub-genus.

The assessment panel

The assessment 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 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 were aliquoted and added to aliquoted RT-PCR mastermix according to the manufacturer’s instructions in batches of up to 94 samples, plus a positive and negative control. Amplification was performed using the ABI 7500 Fast instrument according to the manufacturer’s instructions. Data analysis was performed using the ABI 7500 software as well as visual inspection of amplification plots. The presence / absence calls were confirmed visually and agreed between 2 Clinical Scientists.

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**
RealStar SARS-CoV-2 RT-PCR Kit 1.0.	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