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Rapid assessment of the Roche Ltd Coronavirus LightMix® Modular SARS and Wuhan CoV E-gene assay

V01.20. Uncontrolled when printed or downloaded
Current version available at: https://www.gov.uk/government/publications/covid-19-phe-laboratory-assessments-of-molecular-tests

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Published June 2020
PHE publications
gateway number: GW-1316

PHE supports the UN
Sustainable Development Goals

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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 Roche Ltd Coronavirus LightMix® Modular SARS and Wuhan CoV E-gene assay (Roche material no: 09155368001). Following the instructions for use V200112.

The assay utilises a real-time technology to amplify and detect 76 bp long fragment from a conserved region in the E gene is detected with FAM-labelled hydrolysis probes (530 channel). This assay will detect SARS and Wuhan 2019 CoV pneumonia virus as well as other members of the Sarbecovirus sub-genus. The assay is designed not to cross-react with common human respiratory Coronaviruses; NL63, 229E, HKU, OC43 or MERS.

The assessment panel

The assessment sample-panel totalled 165 specimens (162 combined nose & throat swabs, 3 sputum samples). All samples included in the assessment were also tested using Public Health England's in-house PHE PCR assay, that had been previously verified on the Roche MP96 and LightCycler® 480 II system.

Prior to commencing the assessment, a statistical assessment determined that a sample size of 165 specimens would be necessary for measured specificity for samples is 100% that the true specificity of the test is at least 97.8%.

Performing and analysing the assay

All samples were processed using the Roche Flow system. Briefly, 500 µL of residual clinical was combined with 500 µL of Qiagen AL Buffer under Biosafety level 3 conditions as per locally validated protocols.

Samples were then processed on the on the Primary Sample Handling unit, then extracted using a Magna Pure 96 using the Pathogen Universal protocol 200 v4.0. PCR reactions were setup using the Roche PCR setup unit using 5 µL of extracted nucleic acid, to a final reaction volume of 20 µL. Real- time PCR performed upon the LightCycler® 480 II system, with appropriate controls.

Results of real-time PCR testing was verified as acceptable if the designated control wells achieved in the manufacturer's instructions for use. The samples were then interpreted as either 'SarbecoV Positive', 'Not detectable' or 'PCR failure Repeat' dependent upon the real-time PCR data analysis as per the instructions for use.

Results

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

	Samples (n)	True positive	False positive	True negative	False negative	Negative percentage agreement	Positive percentage agreement
Roche Ltd Coronavirus LightMix® E-gene assay	165	15	0	150	0	100% (150/150)	100% (15/15)

The specificity of the assay was confirmed by processing a panel of 26 pathogens commonly detected in respiratory pathogens. No cross reactivity was observed.

A serial dilution of Severe acute respiratory syndrome coronavirus was performed and the Roche Ltd Coronavirus LightMix® Modular SARS and Wuhan CoV E-gene assay demonstrated a comparable limit of detection to the PHE assay.

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