Public Health England

Protecting and improving the nation's health

# Rapid assessment of the BGI Real-Time Fluorescent RT-PCR kit for detecting 2019-nCoV

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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 BGI Real-Time Fluorescent RT-PCR kit for detecting 2019-nCoV (Cat. MFG0300010) following the instruction for use (IFU) released with kits produced 26/02/20.

# The assessment panels

The assessment sample panel consisted of residual nucleic acids extracted from 105 specimens (39 SARS-CoV-2 detected and 66 SARS-CoV-2 not detected), tested as part of clinical service provision. The residual nucleic acids had previously been tested with validated commercial assays as part of the clinical service provided by the Rare and Imported Pathogens Laboratory (RIPL) at PHE Porton. These samples were initially tested using either the Roche Ltd cobas® SARS-CoV-2 Test (n=86) or the CerTest BIOTEC ViaSure SARS-CoV-2 assay (VS-NCO296T) (n=19).

Statistical assessment of panel sizes determined that when the measured specificity for 100 samples at 10% prevalence would yield a true specificity of the test is at least 96.4%.

# Performing and analysing the assay

Nucleic acid extracts were aliquoted and added to aliquoted RT-PCR mastermix according to the manufacturer's instructions, including the appropriate controls. Amplification was performed using the Applied Biosystems ViiA7 Fast instrument according to the manufacturer's instructions. The BGI Real-Time Fluorescent RT-PCR kit for detecting 2019-nCoV is a multiplex RT-qPCR detecting SARS-CoV-2 RNA in the

FAM channel and a human sample adequacy control in the VIC/HEX channel. The assay detects a region within the SARS-CoV-2 ORF1ab gene.

# Results

During an initial assessment of the BGI Real-Time Fluorescent RT-PCR kit for detecting 2019-nCoV (Cat. MFG0300010), evidence of repeated PCR contamination was observed. Positive RT-qPCR amplification signals occurred in known negative samples and no-template controls.

This contamination occurred despite using kits of different lot numbers and was not resolved either by using different equipment and laboratory facilities that had not been previously utilised in the assessment or when different laboratory personnel conducted the testing. The assessment at this site was therefore suspended.

The assessment was relocated to another PHE site and was undertaken using kits bearing a different lot number. The PCR contamination issue was not observed following these changes.

Compared with results obtained with either the Roche COBAS SARS-CoV-2 or the CerTest BIOTEC ViaSure SARS-CoV-2 assay (VS-NCO296T), the following was found:

| | Samples (n) | True positive | False positive | True negative | False negative |
|---|---|---|---|---|---|
| BGI Real-Time Fluorescent RT-PCR kit for detecting 2019-nCoV (Cat. MFG0300010) | 105≠ | 38 | 2Ω | 64 | 1 |

≠ The sample panel consisted of 19 nucleic acid extracts tested using CerTest BIOTEC ViaSure SARS-CoV-2 assay (19 SARS-CoV-2 not detected) and 86 (39 SARS-CoV-2 detected and 47 not detected) tested using the Roche Ltd cobas® SARS-CoV-2 Test

Ω SARS-CoV-2 RNA was detected in 2 samples when tested with the BGI Real-Time Fluorescent RT-PCR kit for detecting 2019-nCoV but not when tested with the Roche Ltd cobas® SARS-CoV-2 Test

The BGI Real-Time Fluorescent RT-PCR kit for detecting 2019-nCoV assay demonstrated assay performance of:

- sensitivity – 97.4% (86.5 to 99.9%; 95% CI)
- specificity – 96.9% (89.5 to 99.6%; 95% CI)

# Validation of protocol modifications

It was noted during the assessment that the BGI Real-Time Fluorescent RT-PCR kit for detecting 2019-nCoV assay includes a sample adequacy control, but not an extraction or inhibition control. Implementation of this test would require local validation of nucleic acid extraction procedures.

# 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 www.gov.uk/government/publications/position-statement-regarding-covid-19-tests-evaluated-by-phe

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