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Rapid assessment of the GenMark ePlex SARS-CoV-2 test

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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 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 GenMark ePlex SARS-CoV-2 test, which is intended for the qualitative detection of SARS-CoV-2 nucleic acid in nasopharyngeal swab specimens (NPS) eluted in viral transport media (VTM). The test targets the N gene. Product Code EA008222 – SARS-CoV-2 Test Kit – (12 tests/kit). The ePlex SARS-CoV-2 Test has been approved for use in the USA under the Food and Drug Administration's Emergency Use Authorisation.

The assessment panel

The evaluation sample panel totalled 230 specimens, including respiratory clinical specimens negative (n= 120) and positive (n=93) for SARS-CoV-2 as determined by the in-house PHE PCR assay. In addition, samples distributed as the QCMD 2020 Coronavirus Outbreak Preparedness (CVOP) EQA Pilot Scheme (n=8), and a 10-fold dilution series (down to 10^{-9} dilution; n=9) of positive control material (RNA) from virus isolate BetaCoV/England/02/2020, were also included to evaluate performance. Positive control material was provided as a 10^{-4} dilution stock, equivalent to 7.39×10^3 TCID₅₀/mL.

Performing and analysing the assay

The ePlex SARS-CoV-2 test is an automated, qualitative nucleic acid *in vitro* diagnostic test that aids in the detection of SARS-CoV-2 and diagnosis of COVID-19 infection using *The True Sample-to-Answer Solution*® ePlex instrument. The test is based on nucleic acid amplification technology and each test cartridge includes all reagents needed to extract, amplify and detect SARS-CoV-2 RNA in nasopharyngeal swab samples.

The ePlex instrument automates all aspects of nucleic acid testing including extraction, amplification, and detection, combining electrowetting and GenMark's eSensor® technology in a single-use cartridge. The eSensor® technology is based on the principles of competitive DNA hybridization and electrochemical detection.

Samples were loaded into each ePlex SARS-CoV-2 cartridge as per the instructions for use. This entails adding 200uL of a respiratory specimen (in viral transport medium) into the supplied lysis buffer tube, a pulse vortex followed by direct addition of the entire contents into the port on the cartridge and closure of the lid.

Each cartridge includes internal controls that monitor performance of each step of the testing process. A DNA control verifies extraction, amplification, and detection of DNA targets, and RNA controls verify amplification and detection of RNA targets. For a test to be valid, either the internal control or target must generate signal above a defined threshold in the amplification reaction.

Internal control results are interpreted by the ePlex software and displayed on ePlex SARS-CoV-2 Test Reports as Internal Control (IC) with a result of PASS, FAIL, N/A or INVALID.

The results from the ePlex test are qualitative for SARS-CoV-2 so the results are displayed by means of the SARS-CoV-2 Test Detection Report which includes the results for each individual sample run on the ePlex instrument. Results are either 'Detected', 'Not Detected' or 'Invalid' based on pre-defined parameters. (ePlex SARS-CoV-2 Test Assay Manual – EUA).

Results

Of the 230 specimens processed on the ePlex instrument, 5 specimens (2 known positives & 3 known negatives) gave invalid results (IC failure) and were removed from the comparison. In triplicate testing of the SARS-CoV-2 RNA (BetaCoV/England/02/2020) dilution series, the ePlex SARS-CoV-2 test detected down to the -7 dilution (all 3 detected) where the in-house PHE PCR assay only detected 2/3 of the triplicates at the same dilution.

The comparator in-house PHE PCR assay gave 100% concordance with the expected results of the QCMD 2020 CVOP EQA pilot Scheme, but the ePlex SARS-CoV-2 test missed a borderline positive sample at ~200 copies/mL. The QCMD panel was processed on the ePlex instrument without addition of the lysis buffer, as was recommended by the manufacturer.

All discrepant findings were repeated by both tests in duplicate.

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

	Samples (n)	True positive	False positive	True negative	False negative
ePlex SARS-CoV-2 Test	225	101	2*	124	1**

The ePlex SARS-CoV-2 test demonstrated the following assay performance:

Sensitivity 99.02% (94.66 – 99.98%; 95% CI)

Specificity 98.41% (94.38 – 99.81%; 95% CI)

* Both false-positive samples were negative when repeated by the ePlex SARS-CoV-2 test and by the in-house PHE assay.

** Corresponds to a borderline-positive EQA specimen.

Report date

A version of the report was distributed by PHE’s COVID 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