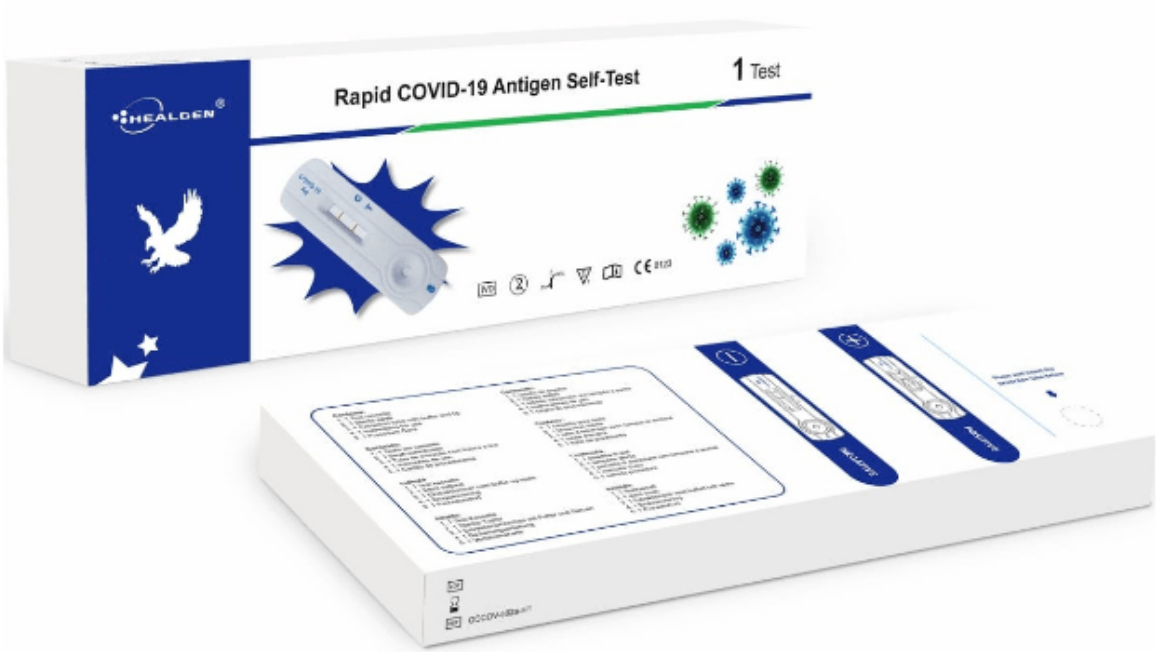
HEALGEN®

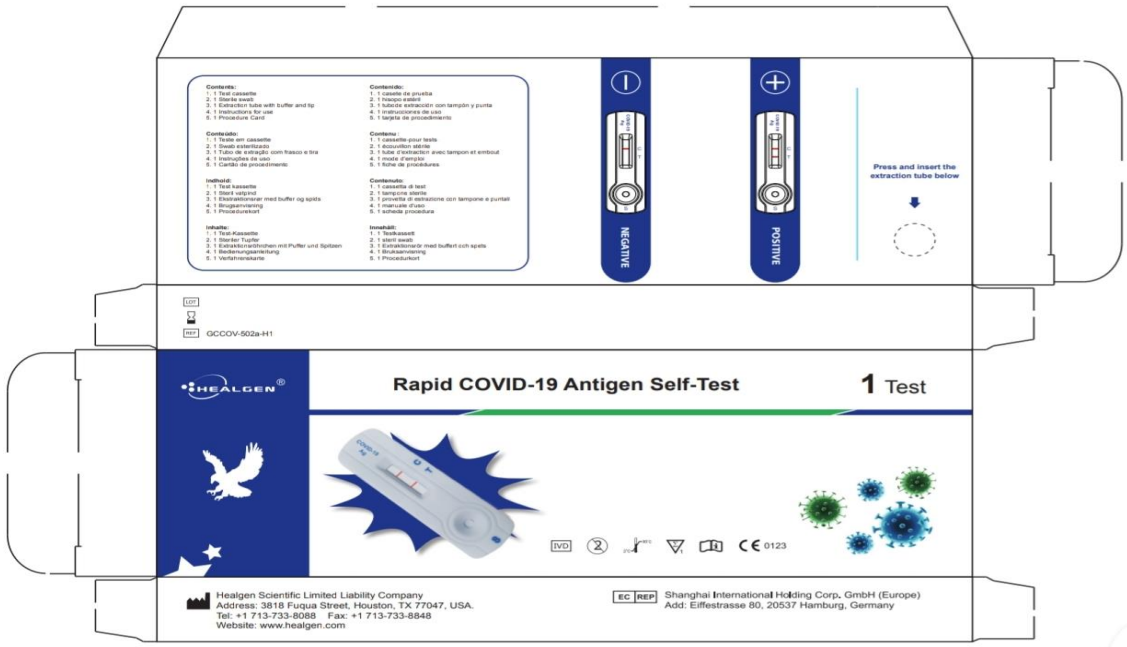
CE

Rapid COVID-19 Antigen Self-Test



For Rapid Detection of SARS-CoV-2

CE | Public Health England | ISO | NHS


Contents:
1. 1 Test cassette
2. 1 Sterile swab
3. 1 Extraction tube with buffer and tip
4. 1 Instructions for use
5. 1 Procedure Card
Contenido:
1. 1 casete de prueba
2. 1 hisopo estéril
3. 1 tubo de extracción con tampón y punta
4. 1 instrucciones de uso
5. 1 tarjeta de procedimiento
Contenu :
1. 1 cassette-pour tests
2. 1 écouvillon stérile
3. 1 tube d'extraction avec tampon et embout
4. 1 mode d'emploi
5. 1 fiche de procédures
Conteúdo:
1. 1 cassette de test
2. 1 tampone sterile
3. 1 provetta di estrazione con tampone e puntali
4. 1 manuale d'uso
5. 1 scheda procedura
Innehåll:
1. 1 Testkassett
2. 1 steril svab
3. 1 Extraktionsrör med buffert och spets
4. 1 Bruksanvisning
5. 1 Proceduriort
Indhold:
1. 1 Test kassette
2. 1 Steril vatpind
3. 1 Ekstraktionsrør med buffer og spids
4. 1 Brugsanvisning
5. 1 Procedurekort
Inhalte:
1. 1 Test-Kassette
2. 1 Sterile Tupfer
3. 1 Extraktionsröhrchen mit Puffer und Spitzen
4. 1 Bedienungsanleitung
5. 1 Verfahrenskarte
NEGATIVE
POSITIVE
Press and insert the extraction tube below
LOT
REF
GCCOV-502a-H1
HEALGEN
Rapid COVID-19 Antigen Self-Test
1 Test
IVD
CE 0123
Healgen Scientific Limited Liability Company
Address: 3818 Fuqua Street, Houston, TX 77047, USA.
Tel: +1 713-733-8088 Fax: +1 713-733-8848
Website: www.healgen.com
EC REP
Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany


Rapid COVID-19 Antigen Self-Test
1 Test


Rapid COVID-19 Antigen Self-Test
1 Test


NEGATIVE
POSITIVE
Press and insert the extraction tube below


NEGATIVE
POSITIVE
Press and insert the extraction tube below


Rapid COVID-19 Antigen Self-Test
1 Test
Press and insert the extraction tube below

Rapid COVID-19 Antigen Self-Test

PROCEDURE CARD

IMPORTANT

- This test can be used within the first ten days that symptoms appear for COVID-19.
- This test is approved for use at home by individuals aged 12 years or older. Nasal swab samples from individuals aged below 12 years or above 70 years should be collected by or under supervision of adults.
- The test will take approximately 5 minutes to setup and the test results must be read at 15 minutes.
- It is important that you carefully follow the instructions to achieve the correct result.
- The test device and the buffer solution must be at room temperature (15-30°C) before starting the test.
- Please wash or sanitize your hands before and after the test.
- Please take required safety measures when testing other people (e.g. face mask, gloves).

If you have questions about using the test or reading the results, please call customer care.
Telephone: 0800-40 40 633 (free of charge)
Internet: www.healgen.com

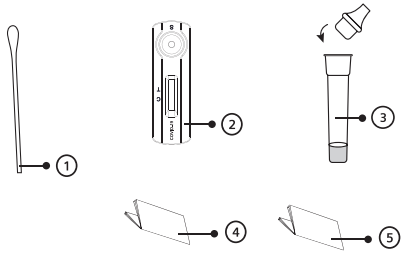
GETTING STARTED (GCCOV-502a-H1/H2/H3/H5)

Kit Contents

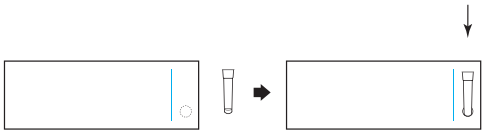
1/2/3/5	Test Device(s)
1/2/3/5	Sterile Swab(s)
1/2/3/5	Extraction Tube(s) with Buffer and Tip(s)
1	Instructions For Use
1	Procedure Card

ITEMS REQUIRED BUT NOT PROVIDED

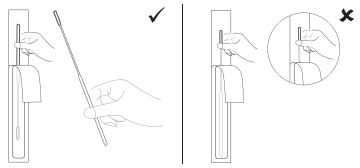
Clock, timer or stopwatch and plastic bag for waste.



TEST PROCEDURE

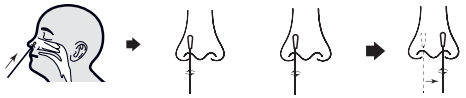


Step 1.
Insert the tube into the workstation. Remove the lid from the top of the tube.



Step 2
Open the swab package where indicated.
Pull the swab out by grasping the plastic end.
Do not touch the absorbent swab tip.

Step 3.
Carefully insert the absorbent tip of the swab into your left nostril. Ensure that the entire swab tip is inside your nostril (2–4 cm deep). Do not insert the swab further after you feel resistance.



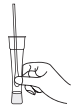
Step 4.
Roll the swab at least 5 times against the insides of your nostril. Ensure good contact between the swab and the insides of your nostril.

Step 5.
Remove the swab and insert into your right nostril.
Repeat Steps 3 and 4.

Step 6.
Remove the swab from your nostril and insert the swab into the prepared tube in the workstation.

Step 7.
Mix well by rolling the swab at least 6 times while pressing the head of the swab against the bottom and sides of the tube.

Step 8.
Start timer. Leave the swab in the tube for 1 minute.



Step 9.
Squeeze the tube several times from the outside. Try to dissolve as much solution from the swab as possible.

Step 10.
Remove the swab and discard in a plastic bag.

Step 11.
Push the tip provided in the kit into the tube and ensure it fits tightly.

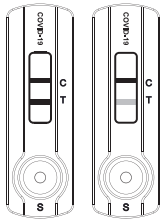
Step 12.
Remove the test device from the pouch and lay it on a flat clean surface.

Step 13.
Add 4 drops of the solution into the sample well of the test device by gently squeezing the tube.

Step 14.
Start timer and read results at 15 minutes. It is important to read the results at 15 minutes.

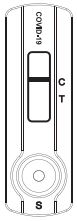
Step 15.
Read your results. There are three possible types of results.

Positive Test Result



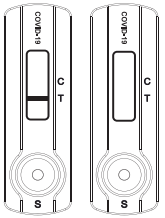
If the test device looks like either of the positive result windows as shown on the left, you have a current Covid-19 infection. Please call your doctor or your local health department and make sure you adhere to local guidelines for self-isolation. Re-testing with other test methods such as a PCR test may be required.

Negative Test Result



If the test device looks like the negative result window as shown on the left, no Covid-19 infection could be detected. In a suspected case, repeat the test after 1-2 days since the virus cannot be accurately detected in all phases of an infection. Despite a negative test result, you still have to comply with all applicable rules regarding contact with others and protective measures.

Invalid Test Result



If your test result looks different, meaning there is no line visible or only one line at T, the result is invalid. This may be a result of the test execution, and the test should be repeated. If invalid test results continue, please contact your doctor or a COVID test center.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
					Manufacturer

Healgen Scientific Limited Liability Company
Address: 3818 Fuqua Street, Houston, TX 77047, USA.
Tel: +1 713-733-8088 Fax: +1 713-733-8848
Website: www.healgen.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

CE 0123

REF GCCOV-502a-H1
GCCOV-502a-H2
GCCOV-502a-H3
GCCOV-502a-H5

Revision Date: 2021-04-17

CE-DOC-H091
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Healgen Scientific Limited Liability Company*

Legal Manufacturer Address: *3818 Fuqua Street, Houston, TX 77047, USA.*

Declares, that the products
Product Name and Model(s)

Coronavirus Ag Rapid Test Cassette (Swab)	GCCOV-502a-NN

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned,hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: Jan 26, 2021

Joyce Pang

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Healgen Scientific Limited Liability Company
3818 Fuqua Street
Houston, TX 77047
USA

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of In Vitro Diagnostic Reagents for Cardiac Diseases, Infectious Diseases, Oncology and for Biochemistry as well as Rapid Tests for Fertility and Drugs of Abuse

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-03-01
Certificate Registration No.:	SX 60135029 0001
An audit was performed. Report No.:	15090679 004
This Certificate is valid until:	2022-02-28

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-12-29

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 092378 0007 Rev. 00

Holder of Certificate: **Healgen Scientific Limited Liability Company**
3818 Fuqua Street
Houston TX 77047
USA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Cardiac Diseases, Infectious Diseases, Oncology and for Biochemistry as well as Rapid Tests for Fertility and Drugs of Abuse**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 092378 0007 Rev. 00

Report No.: SH21178301

Valid from: 2021-03-02
Valid until: 2022-02-28

Date, 2021-02-25

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 092378 0007 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Healgen Scientific Limited Liability Company
3818 Fuqua Street, Houston TX 77047, USA

Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Cardiac Diseases, Infectious Diseases, Oncology and for Biochemistry as well as Rapid Tests for Fertility and Drugs of Abuse

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Cardiac Diseases, Infectious Diseases, Oncology and for Biochemistry as well as Rapid Tests for Fertility and Drugs of Abuse

.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security and Vaccination

EU health preparedness:

A common list of COVID-19 rapid antigen tests, including those of which their test results are mutually recognised, and a common standardised set of data to be included in COVID-19 test result certificates

Agreed by the Health Security Committee

This document was agreed by the HSC on 17 February 2021

A first update to Annex II was agreed by the HSC on 19 March 2021

A first update to Annex I was agreed by the HSC on 10 May 2021

I. Introduction

Robust testing strategies are an essential aspect of preparedness and response to the COVID-19 pandemic, allowing for early detection of potentially infectious individuals and providing visibility on infection rates and transmission within communities. Moreover, they are a prerequisite to adequate contact tracing to limit the spread through prompt isolation. Also in the context of the circulation of SARS-CoV-2 variants of concern, surge testing in addition to existing testing deployment has proven to be key for controlling and suppressing further spread of the virus.

While the reverse transcription real-time polymerase chain reaction (RT-PCR) assay, which is a nucleic acid amplification test (NAAT) remains the 'gold standard' for COVID-19 diagnosis, new tests are rapidly entering the market, allowing faster and cheaper ways to detect ongoing infection. Rapid antigen tests, which detect the presence of viral proteins (antigens), are increasingly being used by Member States as a way of further strengthening countries' overall testing capacity, particularly in case of limited NAAT capacities or where prolonged testing turnaround times results in no clinical utility.

The Health Security Committee agreed on 17 September 2020 on Recommendations for a common EU testing approach for COVID-19[1], setting out various actions for consideration by countries when updating or adapting their testing strategies. The Recommendations included Member States' first experiences with rapid antigen tests and their deliberations concerning the settings and situations in which these tests should be used. Since then, the Committee has been discussing the use and application of rapid antigen tests in great depth, and has brought together a wealth of (technical) information on the types of tests used in European countries and the conditions applied.

On 21 January 2021, Member States unanimously agreed on a Council Recommendation setting a common framework for the use of rapid antigen tests and the mutual recognition of COVID-19 test results across the EU[2]. The Council Recommendation called on Member States to agree on three concrete deliverables:

1. **A common list of COVID-19 rapid antigen tests** that are considered appropriate for use in the context of the situations described in the Council Recommendation, that are in line with countries' testing strategies and that:
    a. carry CE marking;
    b. meet the minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity; and
    c. have been validated by at least one Member State as being appropriate for their use in the context of COVID-19, providing details on the methodology and results of such studies, such as the sample type used for validation, the setting

[1] https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/common_testingapproach_covid-19_en.pdf
[2] https://data.consilium.europa.eu/doc/document/ST-5451-2021-INIT/en/pdf

in which the use of the test was assessed, and whether any difficulties occurred as regards the required sensitivity criteria or other performance elements.

2. A selection of rapid antigen tests of which Member States will **mutually recognise the test results for public health measures**.
3. **A common standardised set of data to be included in COVID-19 test result certificates**, further facilitating the mutual recognition of COVID-19 test results.

Based on the information collected by the Health Security Committee, and taking into consideration the current epidemiological situation and the testing strategies and approaches that have been put in place across the EU, this document sets out the three deliverables as agreed by Member States. Its content is prepared based on the criteria set out in the Council Recommendation and considers the relevant recommendations published by the Commission[3] and technical guidance issued the European Centre for Disease Prevention and Control (ECDC)[4] and the World Health Organization (WHO)[5].

II. Common list of rapid antigen tests

Point 11 of the Council Recommendation of 21 January 2021, calls on Member States to, without prejudice to Directive 98/79/EC, agree on and maintain a common and updated list of COVID-19 rapid antigen tests that are considered appropriate for use in the context of the situations described under point 6 and are in line with countries' testing strategies. Moreover, the antigen tests included in the list should:

(a) Carry CE marking;

(b) Meet the minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity; and

(c) Have been validated by at least one Member State as being appropriate for their use in the context of COVID-19, providing details on the methodology and results of such studies, such as the sample type used for validation, the setting in which the use of the test was assessed, and whether any difficulties occurred as regards the required sensitivity criteria or other performance elements.

This list should be shared with ECDC and the Commission to prevent duplication of work and to feed into ongoing initiatives, particularly the "COVID-19 In Vitro Diagnostic Devices and Test Methods Database[6], hosted by the Joint Research Centre (JRC). Annex I to this document sets out a common list of rapid antigen tests that meet the criteria as specified above. This list has been incorporated by the JRC in its COVID-19 In Vitro Diagnostic Devices and Test Methods Database. An update to Annex I was agreed by the Health Security Committee on 10 May 2021.

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020H1595 and https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020H1743&from=EN
[4] https://www.ecdc.europa.eu/en/publications-data/options-use-rapid-antigen-tests-covid-19-eueea-and-uk
[5] https://www.who.int/publications/i/item/9789240017740
[6] https://covid-19-diagnostics.jrc.ec.europa.eu/devices

The common list of rapid antigen tests is regularly being reviewed by Member States in the context of Health Security Committee meetings, and, if necessary, be updated in line with new results from independent validation studies becoming available and new tests entering the markets. These updates are also taking into account how mutations of the SARS-CoV-2 virus may affect the efficacy of any particular rapid antigen tests, allowing for the removal of tests no longer deemed effective. The effect of mutations of the SARS-CoV-2 virus on the efficacy of NAAT, in particular RT-PCR assays, will also be kept under review.

III. Rapid antigen tests of which the test results are mutually recognised

As stipulated in point 15 of the Council Recommendation of 21 January 2021, Member States will agree on a selection of rapid antigen tests of which they will **mutually recognise the test results for public health measures**, based on the information included in the common list (see Annex I).

The Health Security Committee agrees that, for rapid antigen test results to be mutually recognised, at least three Member States should be using a rapid antigen tests in practice. Based on this criterion, those rapid antigen tests for which Member States agree that their results will be mutually recognised for public health measures, are highlighted in yellow in Annex I[7]. An update to Annex I, including the selection of tests of which their results are mutually recognised, was agreed by the Health Security Committee on 10 May 2021.

Whenever Member States will review the common list of rapid antigen tests and consider whether any tests should be added or deleted, they will also take into account – also based on new results from independent national validation studies - whether any rapid antigen tests should be removed from or added to the selection of rapid antigen tests of which their results are being mutually recognised. This information will be provided to the JRC, who will update its database accordingly.

IV. Common standardised set of data for COVID-19 test certificates

In order to facilitate in practice the mutual recognition of results of rapid antigen tests as well as NAAT, including RT-PCR assays, point 18 of Council Recommendation 2020/1475 defines that Member States should agree on a common standardised set of data to be included in the form for test result certificates.

Based on information that was submitted by members of the Health Security Committee in response to a survey on mutual recognition on COVID-19 test results and further discussions that took place in the context of the Health Security Committee, Member States agree on the common standardised set of data for COVID-19 test result certificates as presented in Annex II. An update to this Annex was agreed by the Health Security Committee on 19 March 2021, addressing input received from the eHealth Network and in particular the Semantic Subgroup

[7] This list has been incorporated by the JRC in its COVID-19 In Vitro Diagnostic Devices and Test Methods Database.

and based on discussions that took place in the context of the EU Digital Green Certificate. Member States agree that COVID-19 test results should be made available in the national language(s) of the country where the test was taken, as well as English.

The Health Security Committee will discuss, whenever relevant, possible updates to the agreed common standardised set of data for COVID-19 test certificates, and publish, if necessary, an updated agreed document.

V. Continuous discussions and further work on the common rapid antigen tests list and common dataset for COVID-19 test result certificates

As described in the sections above, the content of this document, as agreed by the Health Security Committee on 17 February 2021, will continue to be discussed by Member States and updated whenever deemed relevant. Whenever updates are required, these will be published as an update to this current document and/or as an update to the JRC COVID-19 In Vitro Diagnostic Devices and Test Methods Database, depending on scope of the update.

Based on the increasing political and commercial interest in the HSC agreed common rapid antigen test list, including those of which their results are mutually recognised by EU Member States, on 21 April 2021, the Commission and JRC presented to the HSC a new procedure for updating the lists. This includes setting up a HSC Technical Working Group on rapid antigen tests, who will play a key role in reviewing the information submitted by EU countries (as well as manufactures) on the use and performance of rapid antigen tests that are available on the market. Once established, the HSC Technical Working Group will, in particular, address the following points:

Common RAT list

- **Sampling methods to be used**

The current HSC agreed common list of rapid antigen tests includes tests for which their clinical performance was measured based on samples collected from nasal, oropharyngeal or nasopharyngeal specimens. Other rapid antigen tests exist that have been validated in EU Member States based on alternative samples, such as saliva, sputum and/or faeces. Further discussions are required to reach consensus on whether these tests should also be included in the HSC agreed common RAT list.

- **Harmonised methodology for national validation studies on the clinical performance of rapid antigen tests**

This will be addressed by future guidelines to be developed by the JRC and the ECDC, also taking into consideration the implementation guide published by WHO on 21 December 2020 on SARS-CoV-2 antigen-detecting rapid diagnostic tests[8] as well as the guidance that is being developed by the MDCG-IVD Working Group.

[8] https://www.who.int/publications/i/item/9789240017740

Moreover, Member States will continue sharing details via the HSC on the implementation of national validation studies, particularly concerning the validation methodologies and protocols applied.

- **Quality of data produced through independent validation studies**

It is key that the sensitivity levels of the rapid antigen tests, as reported by independent national validation studies, reflect clinical performance as measures in practice, rather than the sensitivity reported by the manufacturer. In this context, the JRC is planning to verify the science behind the validation data that has been made available from the Member States through the Health Security Committee, and to verify the findings (eventually in laboratory settings). For the validation of rapid antigen tests, the JRC plans to use the "gold standard" method of NAAT, in particular RT-PCR, by benchmarking the antigen test samples against qPCR and digital PCR.

Moreover, Member States will continue sharing details via the HSC on the results produced by national validation studies, particularly concerning the sample type used for validation, the setting in which the use of the test was assessed, and whether any difficulties occurred as regards the required sensitivity criteria or other performance elements.

- **Occurrence of SARS-CoV-2 variants of concern**

Future updates to the common rapid antigen tests list should also take into account how mutations of the SARS-CoV-2 virus may affect the efficacy of any particular rapid antigen tests, allowing for the removal of tests no longer deemed effective. The effect of mutations of the SARS-CoV-2 virus on the efficacy of RT-PCR tests should also be kept under review. In particular, in the current context of circulation of variants of concern, the use of rapid antigen tests does not allow samples to be used for subsequent detection of new variants (by NAAT and/or sequencing).

Mutual recognition of COVID-19 test results

- **Criteria to be used for the mutual recognition of rapid antigen test results**

At the moment, the extent to which rapid antigen tests are being used in practice by Member States differs greatly. In this context, Member States have agreed that, for now, the criterion that at least 3 Member States should be using a specific type of rapid antigen test in practice for it to be mutually recognised, applies. Member States will further discuss and explore whether other criteria should be used in the future. It is key that such discussions are held in the context of quality assurance measures.

- **Context in which mutual recognition should be applied**

Member States should further discuss the situation in which there is a need for mutual recognition of rapid antigen test results (as well as other COVID-19 test results). In addition to the context of travel, it is relevant to further discuss between countries when the list of rapid antigen tests of which their results will be mutually recognised should be applied.

ANNEX I: Common list of rapid antigen tests[9]

As agreed by Member States on 17 February 2021 and updated on 10 May 2021

The entries highlighted in yellow are the RATs of which Member States have agreed to mutually recognise their test results for public health measures

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
AAZ-LMB	COVID-VIRO® Rapid antigen test COVID-19	Yes	96.1% sensitivity 100% specificity	**BE**: 96.6% sensitivity, 100% specificity, NP swab **FR:** >95%% sensitivity, 100% specificity **SI**: 96.6% sensitivity, 100% specificity, NP swab		BE, FR, SI	CH	FR CH		Yes (1833)	Yes
Abbott Rapid Diagnostics	Panbio™ COVID-19 Ag Rapid Test	Yes	91.4% sensitivity 99.8% specificity Nasal/NP swab	**BE**: 93.3% sensitivity, 99.4% specificity, NP Swab 98.1% sensitivity, 99.8% specificity, Nasal swab **DE**: 91.4% sensitivity 99.8% specificity, NP swab 98.1% sensitivity, 99,8 specificity, Nasal swab	FIND Evaluation - Studies in DE and CH, NP swab, 10 Dec 2020	AT, BE, BG, CY, CZ, DE[2], DK, EE, EL, ES, FR[1], HR, IT, LT, LV, MT, NL[5], PL, PT, RO, SE, SK	CH, ME, MK, NO, UK, UA	DE[2], ES, NL[5] CH, NO	CY, ES, HR, HU, IE, LU, PT, SE	Yes (1232)	Yes
Acon Biotech (Hangzhou) Co., Ltd	Flowflex SARS-CoV-2 Antigen Rapid Test	Yes	97.1% sensitivity 99.6% specificity Nasal swab	**BE:** 96.9% sensitivity, 99.5% specificity, NP swab **DE**: 97.1% sensitivity, 99.5% specificity, NP/Nasal swab	Ongoing	AT, BE, LT, LV, SI		DE[2]		Yes (1468)	Yes
AESKU.DIAGNOSTICS GmbH & Co, KG	AESKU.RAPID SARS-CoV-2	Yes		**DE**: 96% sensitivity, 98% specificity **SI**: 96% sensitivity, 98% specificity, Nasal swab		AT, DE[2], SI		DE[2]		No	No

[9] This is the list of RATs as referred to by the Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate), COM/2021/130 final, of 17 March 2021, which is currently being negotiated in the European Parliament and the Council. Member States shall issue and accept Digital Green Certificates based on this list (and subsequent updates).

[10] In case rapid antigen tests are not included in the JRC Database, manufacturers are invited to submit this information here: https://covid-19-diagnostics.jrc.ec.europa.eu/contact/feedback_ant.

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Affimedix	TestNOW® - COVID-19 Antigen	Yes		**DE**: 93.7% sensitivity, 99.2% specificity		DE[2]		DE[2]		No	No
AMEDA Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	Yes	97.3% sensitivity 100% specificity NP swab 97.3% sensitivity 98.8% specificity Nasal swab	**BE**: 97.3% sensitivity, 100% specificity, NP swab **DE**: 97.3% sensitivity, 100% specificity **SI**: 97.3% sensitivity, 100% specificity, NP swab		AT, BE, BG, DE[2] HR, PT, SI	CH, UA	DE[2] CH	HR	Yes (1304)	Yes
AmonMed Xiamen Biotechnology Co., Ltd.	COVID-19 Antigen Rapid Test Kit (Collodial Gold)	Yes	95.05% sensitivity Nasal swab	**DE**: 98.02% sensitivity , 99.6% specificity		DE[2]		DE[2]		Yes (1763)	Yes
Anbio (Xiamen) Biotechnology Co., Ltd.	Rapid COVID-19 Antigen-Test (colloidal Gold)	Yes	99.2% sensitivity 100% specificity	**DE**: 99.27% sensitivity, 100% specificity		AT, DE[2]		DE[2]		Yes (1822)	No
Anhui DeepBlue Medical Technology Co. Ltd	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)	Yes		**BE**: 95% sensitivity, 99% specificity, NP/OP swab **DE**: 97.1% sensitivity, 99.8% specificity		BE, DE[2]	UK	DE[2]		Yes (1589 or 1736)	Yes
ArcDia International Ltd	mariPOC SARS-CoV-2	Yes	92.3% sensitivity 100% specificity	**FI:** Meets the minimum performance requirements – see the report for details.		FI		FI		No	Yes
Asan Pharmaceutical CO., LTD	Asan Easy Test COVID-19 Ag	Yes	94.7% sensitivity 97.7% specificity	**DE**: 94.67% sensitivity, 97.71% specificity		DE[2]		DE[2]		Yes (1654)	Yes
Atlas-Link (Beijing) Technology Co. Ltd	NOVA Test ® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	Yes		**DE**: 97.6% sensitivity, 99.2% specificity		AT, DE[2]	CH	DE[2] CH		Yes (2010)	Yes
AXIOM Gesellschaft für Diagnostica und Biochemica mbH	COVID-19 Antigen Rapid Test	Yes		**DE**: 98.1% sensitivity, 100% specificity		DE[2]		DE[2]		No	No
Azure Biotech, Inc.	Dia Sure COVID-19 Antigen Rapid Test Device	Yes		**DE**: 94.3% sensitivity, 99.1% specificity		DE[2]		DE[2]		No	No
Beijing Hotgen Biotech Co., Ltd.	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Yes	97.1% sensitivity 99.76% specificity	**BE**: 98.6% sensitivity, 100% specificity, NP Swab 97.3% sensitivity, 99.2% specificity. OP swab **DE**: 95.37% sensitivity, 99.13% specificity **SI**: 96.6% sensitivity, 99.8% specificity, NP swab	Validation study to start	AT, BE, DE[2], RO, SI		DE[2]		Yes (1870)	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Beijing Lepu Medical Technology	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)	Yes	92% sensitivity unknown specificity Nasal swab	**BE**: 92% sensitivity, 99.3% specificity, Nasal **DE**: 92.0% sensitivity, 99.26% specificity **SI**: 92% sensitivity, 99.2% specificity, NP swab		AT, BE, DE[2], SI, RO	UA	DE[2]		Yes (1331)	Yes
Beijing Wantai Biological Pharmacy Enterprise Co Ltd	WANTAI SARS-CoV-2 Ag Rapid Test (FIA)	Yes	96.6% sensitivity, unknown specificity Nasal swab	**DE**: 96.6% sensitivity, 96.9% specificity		DE[2]		DE[2]		Yes (1484)	Yes
BIOSYNEX SWISS SA	BIOSYNEX COVID-19 Ag BSS	Yes		**BE**: 96% sensitivity, 100% specificity, NP swab **DE**: 96% sensitivity, 100% specificity		AT, BE, DE[2], DK,FR, NL[5], PT	CH	DE, NL[5], CH		Yes (1223)	Yes
BTNX Inc.	Rapid Response COVID-19 Antigen Rapid Test Device	Yes	94.55% sensitivity 100% specificity	**DE**: 94.55% sensitivity, 100% specificity		AT, DE[2]		DE[2]		Yes (1236)	No
CerTest Biotect S.L.	CerTest SARS-CoV-2 CARD TEST	Yes	92.9% sensitivity 99.6% specificity NP swab	**BE**: 92.9% sensitivity, 99.6% specificity, NP swab **SI**: 92.9% sensitivity, 98.4% specificity, NP/OP swab		ES, PT, SI		ES		Yes (1173)	Yes
Core Technology Co., ltd	Canea Covid-19 Antigen Rapid Test	Yes		**DE**: 97.5% sensitivity, 100% specificity		DE[2]		DE[2]		No	No
Core Technology Co., ltd	Coretests COVID-19 Ag Test	Yes	98.1% sensitivity	**DE**: 98.1% sensitivity, 99.6% specificity		AT, DE[2], RO		DE[2]		Yes (1919)	No
Dialab	DIAQUICK COVID -19 Ag Cassette	Yes		**BE**: Z20401CE: 93.2% sensitivity, 100% specificity, NP swab Z20601CE: 96.4% sensitivity, 99.2% specificity, NP swab **DE**: 97.3% sensitivity, 100% specificity		AT, BE, DE[2]		DE[2]		Yes (1375)	Yes
DDS DIAGNOSTIC	Test Rapid Covid-19 Antigen (tampon nazofaringian)	Yes	98.77% sensitivity 99.03% specificity	**RO:** Meets the minimum performance requirements.		RO		RO China	RO	Yes (1225)	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
GenBody Inc	GenBody COVID-19 Ag Test	Yes	90% sensitivity 98% specificity NP/OP swab	**DE**: 90% sensitivity 98% specificity	Withdrawn	DE[2]	UA	DE[2]		Yes (1244)	Yes
GenSure Biotech Inc	Gensure COVID-19 Antigen Rapid Test Kit (REF: P2004) (DIA-COVID - 19 Ag Rapid Test)	Yes		**DE**: 96.86% sensitivity, 100% specificity		DE[2]		DE[2]		Yes (1253)	Yes
Green Cross Medical Science Corp.	GENEDIA W COVID-19 Ag	Yes		**BE**: 90.2% sensitivity, 100% specificity, NP swab **DE**: 90.1% sensitivity, 100% specificity		AT, BE, DE[2]		DE[2]		Yes (1144)	Yes
Guangdong Hecin Scientific, Inc.	2019-nCoV Antigen Test Kit (colloidal gold method)	Yes	96.23% sensitivity 98.51% specificity Nasal swab	**DE**: 96.6% sensitivity, 99.07% specificity		AT, DE[2]		DE[2]		Yes (1747)	No
Guangdong Wesail Biotech Co. Ltd	COVID-19 AG Test Kit	Yes	90% sensitivity 98% specificity NP/Nasal swab	**DE**: 90% sensitivity, 99.2% specificity **SI**: 90% sensitivity, 98% specificity, NP/Nasal swab		DE[2], SI		DE[2]		Yes (1360)	No
Guangzhou Wondfo Biotech Co., Ltd	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	Yes		**BE**: 96.2% sensitivity, 99.7% specificity, NP/OP swab **DE**: 96.18 % sensitivity, 99.72% specificity		AT, BE, BG, DE[2], FR	CH	DE[2]		Yes (1437)	Yes
Hangzhou AllTest Biotech Co., Ltd	ALL TEST Covid 19 Antigen- Rapidtest (Swab)	Yes		**AT:** 96,4% sensitivity, 99,0% specificity, specimen type: NP; if N sens reduced to: 92,9%		AT		AT	AT	Yes (1256)	Yes
Hangzhou Clongene Biotech Co., Ltd.	COVID-19 Antigen Rapid Test Kit	Yes	98.5% sensitivity unknown specificity Nasal swab	**BE**: 91.4% sensitivity, 100% specificity, NP/OP swab **DE**: 91.4% sensitivity, 99.4% specificity **SI**: 91.4% sensitivity, 100% specificity, NP/OP swab		AT,BE, DE[2], FR, SI	CH	DE[2] CH	HR	Yes (1363)	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Hangzhou Clongene Biotech Co., Ltd.	COVID-19/Influenza A+B Antigen Combo Rapid Test	Yes	91% sensitivity 100% specificity NP swab	**DE**: 97.7% sensitivity, 99.8% specificity		DE[2]		DE[2]		Yes (1365)	Yes
Hangzhou Laihe Biotech Co.	LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Yes		**DE**: 96.29% sensitivity, 100% specificity		AT	CH	DE[2]		Yes (1215)	No
Hangzhou Lysun Biotechnology Co., Ltd.	COVID-19 antigen Rapid Test Device (Colloidal Gold)	Yes		**DE**: 96.29% sensitivity, 100% specificity		DE[2]	CH	DE[2]		No	No
Hangzhou Testsea Biotechnology Co., Ltd.	Testsealabs Covid-19 Antigen Rapid Test Cassette	Yes	92.1% sensitivity 98.1% specificity Nasal swab	**DE**: 97.6% sensitivity 98.4% specificity		DE[2]		DE[2]		Yes (1392)	No
Hangzhou Immuno BiotechCo., Ltd	SARS-CoV2 Antigen Rapid Test	Yes		**DE**: 95.6% sensitivity, 100% specificity		AT, DE[2]		DE[2]		No	No
Hangzhou Immuno BiotechCo., Ltd	Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasiv)	Yes	94% sensitivity 100% specificity Nasal swab, NP	**DE**: 94.39% sensitivity 97.67% specificity		DE[2]		DE[2]		Yes (1844)	No
Healgen Scientific Limited	Coronavirus Ag Rapid Test Cassette (Swab)	Yes		**DE**: 97.25% sensitivity, 100% specificity **SI**: 96.7% sensitivity, 99.2% specificity, NP/Nasal swab		AT, DE[2], NL[5], SE, SI	CH	DE[2], NL[5]	SE[3]	Yes (1767)	No
Humasis Co. Ltd	HUMASIS COVID-19 Ag test	Yes		**BE**: 95.5% sensitivity, 100% specificity, NP swab **DE**: 95.5% sensitivity, 100% specificity **SI**: 95.5% sensitivity, 100% specificity, NP swab		AT, BE, BG, DE[2], FR, HR, SE, SI		DE[2]	HR, SE	Yes (1263)	Yes
Joinstar Biomedical Technology	COVID-19 Antigen Rapid Test (Colloidal Gold)	Yes	96.1% sensitivity 98.1% specificity Nasal swab	**DE**: 96.1% sensitivity, 98.1% specificity **SI**: 96.1% sensitivity, 98.1% specificity, NP swab		AT, DE[2], PT, SI		DE[2]		Yes (1333)	Yes
JOYSBIO (Tianjin) Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)	Yes	98.13% sensitivity	**SI:** Meets the minimum performance requirements – see the report for details.	FIND evaluation studies in CH 11 Feb 2021	CZ, SI		SI CH		Yes (1764)	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Labnovation Technologies Inc.	SARS-CoV-2 Antigen Rapid Test Kit	Yes		**DE**: 96.3% sensitivity, 97.3% specificity **SI**: 96.3% sensitivity, 97.3% specificity, NP/OP swab		DE[2], SI		DE[2]		Yes (1266)	Yes
Lumigenex (Suzhou) Co., Ltd	PocRoc SARS-Cov-2 Antigen Schnellnachweiskit (Gold kolloidal)	Yes		**DE**: 93.33% sensitivity , 99.16% specificity		DE[2]		DE[2]		No	No
LumiQuick Diagnostics Inc.	QuickProfile™ COVID-19 ANTIGEN Test	Yes		**BE**: 94% sensitivity, 99% specificity, NP swab **DE**: 93.7% sensitivity, 98.8% specificity **SI**: 93.7% sensitivity, 98.8% specificity, NP swab		BE, DE[2] ,FR, SI,		DE[2]		Yes (1267)	Yes
LumiraDX UK LTd	LumiraDx SARS-CoV-2 Ag Test	Yes	97.6% sensitivity 96.7% specificity Nasal swab	**DE**: 93.8% sensitivity, 98.8% specificity **SI**: 97.6% sensitivity, 97.7% specificity, NP/Nasal swab		DE[2], ES, SI	CH	DE[2], ES CH		Yes (1268)	No
MEDsan GmbH	MEDsan® SARS-CoV-2 Antigen Rapid Test	Yes	92.5% sensitivity 99.8% specificity NP/OP swab	**BE**: 92.5% sensitivity, 99.8% specificity, Nasal/OP swab **DE**: 92.5% sensitivity, 99.8% specificity		AT, BE, DE[2]	CH	DE[2] CH		Yes (1180)	No
MöLab	COVID-19 Rapid Antigen Test	Yes		**DE**: 97.25% sensitivity , 99.99% specificity		DE[2]		DE[2]		Yes (1190)	No
MP Biomedicals Germany	Rapid SARS-CoV-2 Antigen Test Card	Yes	96.39% sensitivity 99.03% specificity Nasal swab	**BE**: 96.4% sensitivity, 99% specificity, NP/OP swab **DE:** 96.39 % sensitivity, 99.03% specificity		AT, BE, DE[2]	CH	DE[2] CH		Yes (1481)	Yes
nal von minden GmbH	NADAL COVID -19 Ag +Influenza A/B Test	Yes		**DE**: 97.6% sensitivity, 99.9% specificity		DE[2]		DE[2]		No	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
nal von minden GmbH	NADAL COVID -19 Ag Test	Yes	97.6% sensitivity 99.9% specificity Nasal swab	**BE**: 97.6% sensitivity, 99.9% specificity, NP/OP swab **DE**:97.6% sensitivity, 99.9% specificity **SI**: 97.6% sensitivity, 99.9% specificity, NP/OP swab	FIND Evaluation studies 26 April 21	AT, BE, DE[2], PT, SI		DE[2], FR China	HR	Yes (1162)	No
NanoEntek	FREND Covid-19 Ag	Yes	94.12% sensitivity 100% specificity NP swab	**DE**: 94.12% sensitivity , 100% specificity		DE[2]		DE[2]		Yes (1420)	Yes
Oncosem Onkolojik Sistemler San. ve Tic. A.S.	CAT	Yes	93.75% sensitivity 98.04% specificity Nasal swab	**DE**: 96.36% sensitivity, 98.04% specificity		DE[2]		DE[2]		Yes (1199)	No
PCL Inc	PCL COVID19 Ag Rapid FIA	Yes		**DE**: 94,92 % sensitivity, 99,99 % specificity **SI**: 95.5% sensitivity, 98.6% specificity, NP/OP swab, sputum		FR, DE, RO, SI		DE[2]		Yes (308)	No
PerGrande Biotech Development Co., Ltd.	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic assay)	Yes		**DE**: 94.28% sensitivity, 99.11% specificity		AT, DE[2]		DE[2]		No	No
Precision Biosensor Inc (Axon Lab SG)	Exdia COVI-19 Ag Test	Yes	93.9% sensitivity 98% specificity NP swab	**DE**: 93.88% sensitivity , 98% specificity **SI**:93.9% sensitivity, 98% specificity, NP swab		SI, DE[2]	CH	DE[2] CH		Yes (1271)	Yes
Qingdao Hightop Biotech Co Ltd	SARS-CoV-2 Antigen Rapid Test	Yes	95% sensitivity unknown specificity Nasal swab	**DE**: 95% sensitivity 99.75% specificity		AT, DE[2]		DE[2]		Yes (1341)	No
Quidel Corporation	Sofia 2 SARS Antigen FIA	Yes	96.7% sensitivity 100% specificity NP/Nasal swab	**BE**: 96.7% sensitivity, 100% specificity, NP/nasal swab **DE**: 96.7% sensitivity , 100% specificity **SI**: 96.7% sensitivity, 100% specificity, NP/Nasal swab		AT, BE, DE[2], FI, NL[5], PT, SI	CH	DE[2], NL[5] CH	SI	Yes (1097)	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Rapigen Inc.	BIOCREDIT COVID-19 Ag - SARS-CoV 2 Antigen test	Yes	90.2% sensitivity 100% specificity NP swab	**SI**: 90.2% sensitivity, 100% specificity, NP swab		AT, RO, SK, FR, SI		HU	PT	Yes (1606)	Yes
Roche (SD BIOSENSOR)	SARS-CoV-2 Antigen Rapid Test	Yes	96.52% sensitivity 99.2% specificity NP	**DE**: 96.52% sensitivity, 99.68% specificity		AT, DE[2], NL, RO	CH, NO	DE[2]		Yes (1604)	Yes
Safecare Biotech Hangzhou Co	COVID-19 Antigen Rapid Test Kit (Swab)	Yes	97.04% sensitivity unknown specificity Nasal swab	**DE**: 97.27 % sensitivity , 99.42% specificity		AT, DE[2], FR	CH	DE[2]		Yes (1489)	No
Safecare Biotech Hangzhou Co	Multi-Respiratory Virus Antigen Test Kit (Swab) (Influenza A+B/COVID-19)	Yes	Sensitivity: 97.04%	**DE**: 97.04% sensitivity , 99.44% specificity		DE[2]		DE[2]		Yes (1490)	No
SD BIOSENSOR, Inc.; Roche	STANDARD F COVID-19 Ag FIA	Yes	94,09% sensitivity 98.52% specificity	**BE**: 96.5% sensitivity, 99.7% specificity, NP swab **DE**: 94% sensitivity 97% specificity	FIND Evaluation - Studies in DE and Brazil, 10 Dec 2020	AT, BE, BG, DE[2], IT , LU, LV, NL[5], PT, RO, SK	CH	DE[2], IT, NL[5], DK CH, UK, BR	LU, PT	Yes (344)	Yes
SD BIOSENSOR, Inc.; Roche	STANDARD Q COVID-19 Ag Test	Yes	96.52% sensitivity 99.68% specificity NP swab	**BE**: 96.5% sensitivity, 99.7% specificity, NP swab **DE**: 96.52% sensitivity, 99.68% specificity **SI**: 96.5% sensitivity, 99.7% specificity, NP swab	FIND Evaluation - Studies in DE, CH and Brazil, 10 Dec 2020	AT, BE, BG, CY, DE[2], DK, EE, ES, FI, FR, HR, IT, LU, LV, MT, NL[5], RO, SE, SK, SI	ME, NO, CH	DE[2], ES, IT, NL[5], DK CH, UA, UK, BR	HR, IE, LU, SI, SE	Yes (345)	Yes
SGA MÜHENDİSLİK DANIŞMANLIK EĞİTİM İÇ VE DIŞ TİC. A.Ş.	V-Chek SARS-CoV2- Rapid Ag Tets (Coloidal Gold)	Yes	96.6% sensitivity, Nasal swab	**DE**: 96.6% sensitivity, 99% specificity		DE[2]		DE[2]		Yes (1319)	No
Shenzen Ultra-Diagnostics Biotec Co.	SARS-COV-2 Antigen test Kit (colloidal gold)	Yes		**BE**: 92% sensitivity, 100% specificity, NP swab 100% sensitivity, 100% specificity, OP swab 96% sensitivity, 100% specificity, Saliva **SI**: 95.9% sensitivity, 99.9% specificity, NP/OP/Nasal swab, saliva		AT, BE, ES, SI		BE, SI		No	No
Shenzhen Lvshiyuan Biotechnology Co., Ltd.	Green Spring SARS-CoV-2-Antigen-Schnelltests-Set	Yes		**DE**: 98% sensitivity , 100% specificity		DE[2]		DE[2]		No	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Shenzhen Watmind Medical Co., Ltd	SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	Yes	95.15% Sensitivity Nasal swab, Salvia	**DE**: 95.15% sensitivity , 99.12% specificity		AT, DE[2], FR		DE[2]		Yes (1769)	No
Shenzhen Zhenrui Biotech Co., Ltd	Zhenrui ®COVID-19 Antigen Test Cassette	Yes	96% sensitivity Nasal swab, Salvia	**DE**: 96% sensitivity 97% specificity		DE[2]		DE[2]		Yes (1574)	No
Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Test	Yes	96.72% sensitivity 96.72% specificity Nasal swab	**BE**: 98.32% sensitivity, 99.6% specificity, NP swab 97.25% sensitivity, 100% specificity, Nasal swab **SI**: 96.7% sensitivity, 99.2% specificity, NP/Nasal swab		AT, BE, DE[2], FR, HR, NL[5], PT, SE, SI	CH	DE[2], ES, NL[5]	HR, PT, SE[3]	Yes (1218)	Yes
Sugentech, Inc.	SGTi-flex COVID-19 Ag	Yes		**DE**: 95.1% sensitivity, 99% specificity		AT, DE[2]		DE[2]		Yes (1114)	No
TODA Pharma	TODA CORONADIAG Ag®	Yes	98.6% sensitivity unknown specificity Nasal swab	**BE**: 96.6% sensitivity, 100% specificity, NP/OP swab **DE**: 96.6% sensitivity, 100 specificity **SI**: 96.6% sensitivity, 100% specificity, NP/OP swab		BE, DE[2], SI		DE[2]		Yes (1466)	No
Tody Laboratories Int.	Coronavirus (SARS-CoV 2) Antigen - Oral Fluid	Yes	90.1% sensitivity 99.3% specificity	**RO**: Meets the minimum performance requirements.		RO		ES UA, China	RO	No	Yes
Vitrosens Biyoteknoloji Ltd. Şti.	RapidFor SARS-CoV-2 Ag Test Kit	Yes	97.3% sensitivity unknown specificity Nasal swab, saliva	**DE**: 97.3% sensitivity, 99% specificity **SI**: 97.3% sensitivity, 99% specificity, NP/OP/Nasal swab		DE[2], SI		DE[2]		Yes (1443)	Yes
VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiagTM Pro SARS-CoV-2 Ag Rapid Test	Yes		**AT**: 97,06% sensitivity, 100% specificity, all specimen types, i.e. N&OP&NP swab		AT		AT	AT	Yes (1246)	Yes
Wuhan EasyDiagnosis Biomedicine Co., Ltd.	Antigen-Testkit für COVID-19 (SARS-Cov-2)	Yes		**DE**: 96.15% sensitivity , 99.26% specificity		DE[2]		DE[2]		No	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[10]	In FIND database
Xiamen Boson Biotech Co	Rapid SARS-CoV-2 Antigen Test card	Yes	Not specified	**BE**: 93.8% sensitivity, 100% specificity, NP swab **DE**: 96.49% sensitivity, 99.03% specificity		AT, BE, BG, DE[2], FR, RO	CH	DE[2] CH		Yes (1278)	Yes
Xiamen Wiz Biotech Co., Ltd.	SARS-CoV-2 Antigen Rapid Test	Yes		**DE**: 96.3% sensitivity, 100% specificity		AT, DE[2]		DE[2]		No	Yes
Xiamen Wiz Biotech Co., Ltd.	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	Yes		**DE**: 95.91% sensitivity , 100% specificity		AT, DE[2]		DE[2]		No	No
Zhejiang Anji Saianfu Biotech Co.., Ltd.	AndLucky COVID-19 Antigen Rapid Test	Yes	95.8% sensitivity, Nasal swab, Saliva	**DE**: 97.5% sensitivity, 99.1% specificity		AT, DE[2]		DE[2]		Yes (1296)	No
Zhejiang Anji Saianfu Biotech Co.., Ltd.	reOpenTest COVID-19 Antigen Rapid Test	Yes	95.8% sensitivity, Nasal swab, Saliva, Plasma	**DE**: 95.8% sensitivity, 99% specificity		DE[2]		DE[2]		Yes (1295)	No
Zhejiang Orient Gene Biotech Co., Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	Yes	96.72% sensitivity unknown specificity Nasal swab	**BE**: 98.32% sensitivity, 99.6% specificity, NP swab 97.25% sensitivity, 100% specificity, Nasal swab **DE**: 96.72% sensitivity, 99.22% specificity		AT, BE, BG, DE[2], PT	CH, UK	DE[2]	SE[3]	Yes (1343)	No

Notes:

[1] FR: Reference to validation study (not specifying which specific RAT is being recommended or was tested in practice): https://www.has-sante.fr/upload/docs/application/pdf/2020-10/synthese_tests_antigeniques_vd.pdf

[2] DE: Rapid antigen tests that have completed practical validation studies in Germany: See: https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/evaluierung-sensitivitaet-sars-cov-2-antigentests-04-12-2020.pdf?__blob=publicationFile&v=43

[3] SE: Smaller evaluations ongoing in some of the regions.

[4] BE: In the clinical performance study performed in three different clinical laboratories during the ascendant phase of the epidemiological curve, we found an overall sensitivity and specificity of 57.6 and 99.5%, respectively with an accuracy of 82.6%.

[5] NL: Collected validation data from accredited laboratories in the Netherlands. The report includes evaluations of various RAT that labs performed at their own initiative. https://lci.rivm.nl/antigeensneltesten

ANNEX II: Common standardised set of data to be included in COVID-19 test result certificates, as agreed by Member States on 17 February 2021 and updated on 19 March 2021

Section	Data element	Description	Preferred Code System
Person identification	Person name	The legal name of the tested person. Surname(s) and forename(s), in that order.	
	Person identifier *(optional)*	An identifier of the tested person, according to the policies applicable in each country. Examples: citizen ID and/or document number (ID-card/passport).	
	Person date of birth *(optional)*	Tested person's date of birth. Mandatory if no Person identifier is provided.	Complete date, without time, following the ISO 8601.
Test information	Disease or agent targeted	Specification that it concerns the detection of SARS-CoV-2 infection.	ICD-10, SNOMED CT
	Type of test	Description of the type of test that was conducted, e.g. NAAT or rapid antigen test.	LOINC, NPU
	Test name *(optional for NAAT)*	Commercial or brand name of the test.	
	Test Manufacturer *(optional for NAAT)*	Legal manufacturer of the test.	
	Sample origin *(optional)*	The type of sample that was taken (e.g. nasopharyngeal swab, oropharyngeal swab, nasal swab, saliva).	SNOMED CT
	Date and time of the test sample collection	Date and time when the sample was collected.	Complete date, with time and time zone, following ISO 8601
	Date and time of the test result production *(optional)*	Date and time when the test result was produced.	Complete date, with time and time zone, following ISO 8601
	Result of the test	For example, negative, positive, inconclusive or void.	SNOMED CT
	Testing centre or facility *(mandatory for NAAT)*	Name/code of testing centre, facility or a health authority responsible for the testing event. *Optional*: address of the testing facility.	
	Health Professional identification *(optional)*	Name or health professional code responsible for conducting (and validating) the test. Surname(s) and forename(s), in that order.	
	Country where the test was taken	The country in which the individual was tested.	ISO 3166 Country Codes
Test certificate metadata	Test result certificate issuer	Entity that issued the COVID-19 test result certificate (allowing to check the certificate).	
	Certificate identifier	Reference of the COVID-19 test result certificate (unique identifier).	

Manufacturer's Statement Letter

To whom it may concern,

RE: Healgen Brand COVID-19 Rapid Antigen Test Kit

The nucleocapsid phosphoprotein of SARS-CoV-2 was used as the main detected target in this COVID-19 antigen test cassette (Orient Gene). This antigen test can be used to detect both wild and mutant SARS-CoV-2 variants, including UK B.1.1.7, South Africa B.1.351 and Brazil P.1, however, this test reagent cannot distinguish these different strains.

Zhejiang Orient Gene Biotech Co., Ltd.

January 17th, 2021

Public Health England

Protecting and improving the nation's health

Public Accountability Unit
Wellington House
133-155 Waterloo Road
London SE1 8UG

T 020 8327 6920

www.gov.uk/phe

By email
request-718423-251b54fd@whatdotheyknow.com

Our ref: 14/01/hf/2448

9 February 2021

Dear Pierre Perrott

Re: Which Lateral Flow tests have passed phase 3A testing at Porton Down

Thank you for your request received on 14 January 2021 addressed to Public Health England (PHE). In accordance with Section 1(1)(a) of the Freedom of Information Act 2000 (the Act), I can confirm that PHE does hold the information you have specified.

Request

Please can you supply a list of all Lateral Flow Covid-19 Antigen tests that have passed Phase 3A assessment at PHE Porton Down. The list should contain Manufacturers name and date Phase 3A assessment was passed. The timeframe can be limited from March 1st 2020 to present.

Response

PHE can confirm it does hold the information you have requested. As of the date of your request, the following Lateral Flow Devices (LFDs) had passed Phase 3A testing at PHE Porton Down:

Date	LFD
11 September 2020	SD Biosensor saliva
11 September 2020	Innova
29 September	Abbott Panbio
2 October 2020	Healgen / Orient Gene
23 October 2020	Deep Blue
13 November 2020	Fortress
2 December 2020	Surescreen
2 December 2020	Roche SD Biosensor swab

If you have any queries regarding the information that has been supplied to you, please refer your query to me in writing in the first instance. If you remain dissatisfied and would like to request an internal review, then please contact us at the address above or by emailing foi@phe.gov.uk.

Please note that you have the right to an independent review by the Information Commissioner's Office if a complaint cannot be resolved through the PHE complaints procedure. The Information Commissioner's Office can be contacted by calling the ICO's helpline on 0303 123 1113, visiting the ICO's website at www.ico.org.uk or writing to the ICO at Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Yours sincerely
FOI Team

Preliminary report from the Joint PHE Porton Down & University of Oxford SARS-CoV-2 test development and validation cell: *Rapid evaluation of Lateral Flow Viral Antigen detection devices (LFDs) for mass community testing:*

Executive summary

- At the request of Ministers in the UK Department of Health and Social Care, Public Health England Porton Down and the University of Oxford developed and delivered the infrastructure required to identify the most promising LFDs with the best performance characteristics

- Extensive pre-clinical and clinical evaluation of LFDs has been completed both in the laboratory and in the field

- LFDs show acceptable viral antigen detection with high specificity, sufficient sensitivity and low kit failure rates

- One LFD, the *Innova SARS-CoV-2 Antigen Rapid Qualitative Test,* is nearing completion of the four-phase evaluation and the performance characteristics are summarised in this report.

1. Background

National governments and international organisations including the World Health Organisation (WHO) have highlighted the importance of testing and subsequent contact tracing to halt the chain of transmission of SARS-CoV-2, the virus responsible for COVID-19. The current 'gold standard' diagnostic procedure involves reverse-transcription polymerase chain reaction (RT-PCR) testing in specialised laboratories. However, there are significant challenges in expanding these testing facilities to increase capacity to identify those with asymptomatic infections or to test contacts with individuals with COVID-19, and turnaround time is typically >24 hours depending on testing location. It is widely accepted that PCR alone will not provide sufficient volumes of tests to enable mass testing at a scale that can help to identify infectious people - whether symptomatic or asymptomatic - and help break chains of transmission fast.

The development of point of care diagnostic devices for COVID-19 has formed an important part of the WHO's *"Co-ordinated global research roadmap"* since March 2020. As such, manufacturers across the world have responded to this call to align investment into this global research priority with the leading candidate being the development of Lateral Flow Devices (LFD) for COVID-19. In the summer of 2020, the NHS Test and Trace Innovation Team identified a pipeline of new products that could enable saturation testing through comprehensive and repeated testing. They concluded that these tests would need to perform with sufficient sensitivity and very high specificity so that they could be used to detect and direct responses to emerging outbreaks. This could also provide national population surveillance. In order to do so, a need was identified for evaluation of devices to be completed at pace, reliably and to a high standard so that any orders could be made with sufficient confidence. DHSC Ministers therefore commissioned PHE Porton Down to establish a time-limited SARS-CoV-2 LFD test development and validation cell in collaboration with the University of Oxford. In this document, we report on the systematic and rapid evaluation of LFDs over the past three months, which have been used by HM Government to inform decisions on increasing rapid COVID-19 testing capability in the United Kingdom.

2. Scientific Background

LFDs can be designed to test for different protein targets and are routinely used in healthcare settings as a result of their affordability, ease of use, short time to deliver a result, and high-test accuracy, e.g. pregnancy tests that detect human Chorionic Gonadotropin (hCG). In brief, a liquid sample is placed on a conjugation pad where the analyte (or antigen) of interest is bound by conjugated antibodies. The analyte-antibody mix subsequently migrates along a membrane (e.g. nitrocellulose) by capillary flow across both 'test' and 'control' strips. These strips are coated with antibodies detecting the analyte of interest and a positive test are confirmed by appearance of a coloured line; denoting successful detection of the analyte or antigen of interest.

SARS-CoV-2 antigen LFDs identify the presence of SARS-CoV-2 proteins, using conjugated antibodies to the spike, envelope, membrane or nucleocapsid proteins. As such, these tests differ from existing SARS-CoV-2 tests, that includes the first-generation LFDs that test for human antibody (IgM/IgG) against SARS-CoV-2, and RT-PCR tests that detect the presence of viral RNA. In contrast to the IgM/IgG "antibody tests", the test directly identifies

SARS-CoV-2 viral proteins and is not reliant on the host's immune response. In contrast to RT-PCR, LFDs detect viral protein rather than RNA. Results for LFDs are observed in 8-30 minutes, depending on the device, providing potential benefit through early interventions to halt the chain of transmission earlier in the disease course when individuals are most infectious

3. Aims & Objectives

The aim of the SARS-CoV-2 LFD test development and validation cell has been to design and deliver rapid systematic scientific and clinical evaluation for LFDs. Specifically, the objectives of the cell were to

- develop a high throughput pre-clinical evaluation platform focussing on:
  - Viral antigen detection
  - Specificity of the test
  - Cross-reactivity of the test to seasonal coronaviruses
  - Test kit failure rates
- establish a research and clinical trials infrastructure to establish the use of LFDs with regards to:
  - Specificity and viral antigen detection
  - Evaluation in the community and hospital
  - Pilot implementation of point of care testing in community and institutional settings

4. Methodology

Department of Health and Social Care evaluation (phase 1 evaluation)

The role of the DHSC was to identify a pipeline of manufacturers and products which had developed viral antigen LFD that could enable mass testing for SARS-CoV-2. A desktop review was performed of manufacturers' claimed performance and instructions for use to identify tests which, prima facie, may perform with high specificity and sufficient sensitivity to enable them to be used to detect SARS-CoV-2. As set out above, the DHSC were also responsible for commissioning work with Public Health England (PHE) Porton Down and the University of Oxford (https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/protocol-for-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices).

The work has been overseen by an LFD Oversight Group.

Pre-clinical evaluation (phase 2 evaluation)

Pre-clinical evaluation of potential LFDs was performed by PHE Porton Down with a team comprising staff from the Rare and Imported Pathogens Laboratory and the Virology and Pathogenesis Research Group. LFDs were evaluated against known PCR-negative controls consisting of saliva collected from healthy adult staff volunteers. The virus positive dilution series consisted of saliva from SARS-CoV-2- negative individuals that had been spiked with SARS-CoV-2 virus stock to give dilutions of 10^5, 10^4, 10^3 and 10^2 plaque-forming-units (pfu)/mL (n=60). An *a priori* "prioritisation" criteria was defined to evaluate LFDs and consisted of a kit failure rate of <10%, a specificity of ≥99% and a sensitivity of ≥50% at 10^2 pfu/mL, which corresponds to a PCR cycle threshold (Ct) value of approximately 25. LFDs that passed evaluation against the positive dilution series and negative controls were then evaluated against seasonal coronaviruses (229E, NL63 and OC43).

Secondary Care evaluation (phase 3a evaluation)

Evaluation against clinical samples was performed at PHE Porton Down with samples from a secondary healthcare setting. All LFDs were assessed against 1,000 known negative samples in viral transport medium (VTM) and 200 banked known positive VTM samples that had previously been frozen. These were diluted in saliva, aliquoted and frozen for later use. Analyses were performed to identify kit failure rates, specificity and viral antigen detection by LFDs in relation to viral load determined through PCR.

Community research evaluation (phase 3b evaluation)

Further evaluation against clinical samples was performed using volunteer samples from staff and patient volunteers. The clinical study of positive cases was conducted in collaboration with the UK Condor Programme "COVID-19 National Diagnostic Research and Evaluation Platform", specifically within the Falcon-C19 study (IRAS 284229). For the positive panel, this study involved the recruitment of adult individuals in the community with a known diagnosis of COVID-19 from 14 research sites around England. Participants were required to provide a paired swab sample (1 dry swab and 1 swab in VTM) and complete a study questionnaire. LFDs were evaluated according to the manufacturer's instruction using "dry swabs". For the negative panel, volunteers from PHE Porton Down and an acute hospital were recruited.

Community pilot field service evaluation (phase 4 evaluation)

Wider field service evaluation was performed within a number of institutions and settings. These institutions included secondary healthcare settings, PHE Porton Down, military establishments, schools and universities. Further evaluation was also performed at regional COVID-19 testing centres. Analyses were performed to identify kit failure rate, specificity and viral antigen detection by LFDs as a function of CT values. Further analyses were also performed in terms of assessing LFDs in relation to usability in the field, as well as uptake and feedback in terms of training.

5. Results

Over 130 suppliers of COVID-19 LFDs were identified by the DHSC for desktop review, 40 of which were sufficiently promising to be referred to PHE Porton Down for evaluation. To date, across phases 2-4 LFD of evaluations, a total of 20,545 LFD tests have been performed either directly or indirectly by the SARS-CoV-2 LFD test development and validation cell.

As part of phase 2 evaluations, 5,802 LFD tests were performed at PHE Porton Down across the 40 candidate devices (as of 31 October 2020). To date, only 9 kits (24.3%) have performed at a level in accordance with the UK lateral flow oversight group's *a priori* "proceed criteria" as published on the government website. All nine kits also passed cross-reactivity analyses against seasonal human coronaviruses. The remainder failed either due to false negative rates that did not pass the sensitivity threshold and/or false positives which did not pass the pre-defined specificity rate, and, in some cases, due to kit failures which exceeded the pre-defined rate.

A total of 7,185 tests with 6 LFDs had been completed at PHE Porton Down as part of the ongoing phase 3a evaluation. Similar to the pre-clinical testing phase, using these VTM samples, all kits significantly outperformed the pre-defined detection rate of 50% at the viral cycle threshold of 25, with an observed viral antigen detection of 83 to 97%. A total of 878 individuals with COVID-19 in the community were enrolled into the Falcon-C19 study to take part in Phase 3b evaluations. 5 kits are being evaluated and 2,678 tests have been performed to date. Taking a viral load of a cycle threshold of 25, the observed viral antigen detection of kits ranged from 95.2-100%. When all individuals in the analyses were analysed, irrespective of viral load, the viral antigen detection in the whole cohort was 77.8-93.9%.

The LFD that is currently in most advanced stages of validation is the *Innova SARS-CoV-2 Antigen Rapid Qualitative Test*, which reflects the fact that it was one of the first tests to be evaluated and successfully pass Phase 2. In total, across Phase 2-4 evaluation stages, 8,774 Innova LFD tests have been performed in the UK, including a diverse cohort of populations as part of the Phase 3b and Phase 4 testing: out-patient SARS-CoV-2 cases; healthcare staff; armed forces personnel; and school students aged 11-18 (Table 1). Due to the rapid implementation of Innova for mass testing in the United Kingdom, the purchasing and roll-out decisions which have been made by DHSC, we have focussed on the performance characteristics (kit failure rate, specificity and viral antigen detection) of the *Innova SARS-CoV-2 Antigen Rapid Qualitative Test.*

Innova LFD evaluation phase	LFD failures		LFD successes				
	fail//total	%	PCR+	PCR-	PCR-void	PCR-not done	TOTAL
Phase 2 negatives	0/72	0.0	0	72	0	0	72
Phase 2 positive dilution series	0/215	0.0	215	0	0	0	215
Phase 3a positives	12/212	6.0	199	0	1	0	200
Phase 3a negatives	50/1040	5.1	0	990	0	0	990
Phase 3b FALCON (Dry swabs-field)	28/296	10.4	252	15	1	0	268
Phase 3b FALCON (Dry swabs-lab)	9/221	4.2	204	8	0	0	212
Phase 3b FALCON (VTM swabs)	9/166	5.7	142	14	1	0	157
Phase 4 hospital staff	17/375	4.7	2	346	10	0	358
Phase 4 armed forces	6/163	3.8	46	111	0	0	157
Phase 4 PHE staff	19/231	8.9	0	212	0	0	212
Phase 4 school 1	311/2166	16.8	0	0	0	1855	1855
Phase 4 school 2 + 3 + 4	14/2146	0.65	0	0	0	2132	2132
Phase 4 COVID-19 testing centre	27/1973	1.4	139	1789	18	0	1946
TOTAL	502/9276	5.4	1199	3557	31	3987	8774

Table 1. Table illustrating the number of evaluations performed in the Innova LFD across phases 2-4 of the evaluations). The table demonstrates the kit failure rate and the where PCR results are available.

Kit Failure Rates

Table 1 show the Kit Failure Rates. There were marked differences in the kit failure rates ranging from 0.65% to 16.8% (P<0.00001; chi2(12)=530) suggesting that there might be differences between batches.

Limit of Detection

We measured the limit of detection of the antigen test with reference to plaque forming units and with RNA copies. Table shows the association between viral antigen detection and viral load as part of Phase 2 evaluations. Under these ideal concentrations, at a PFU of 100/mL, which corresponds to Ct of 25.5, the LFD identified >95% at this viral load.

PFU/ml	Ct equivalent	Positive LFD tests/total LFD tests	% positive
100000	16	20/20	100.0
10000	19	25/25	100.0
1000	23.7	65/65	100.0
390	25.2	5/5	100.0
100	25.5	63/65	95.5
40	28.5	3/5	60.0
20	29.3	0/5	0.0
10	30.2	0/5	0.0
5	31	0/5	0.0
2.5	31.7	0/5	0.0
1.2	32.5	0/5	0.0

Table 2. Table illustrating the limit of sensitivity for SARS-CoV-2 detection by the LFD for antigen detection using spiked saliva samples. Ct - cycle threshold. PFU - plaque forming units.

We also analysed the association between viral antigen detection and viral load as part of Phase 3a evaluations with clinical samples which were placed in viral transport medium allowing direct comparison of viral load and antigen tests (Fig1). This shows that samples with a CT<25.5 (calculated as a viral load >100,000 RNA copies/ml) had a 90% or greater chance of being detected.

Fig 1a

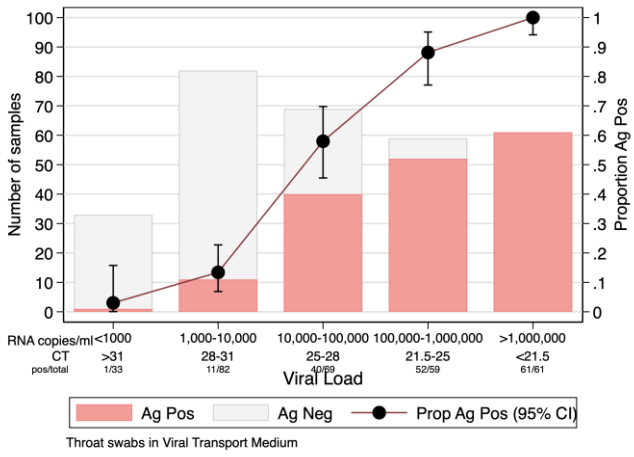


Fig 1b

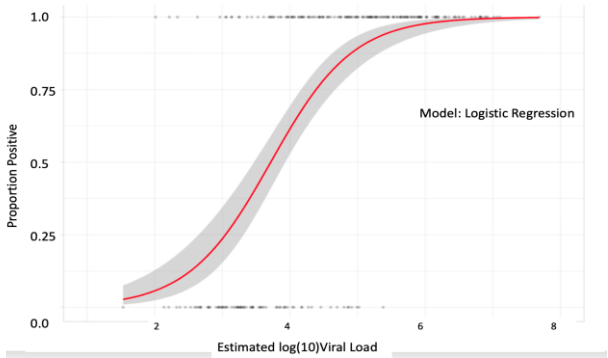


Figure 1 Proportion of Samples antigen positive according to Viral Load in Samples placed in Viral Transport Medium. 1a) Actual Numbers 1b) Proportion (with SE) estimated using logistic regression model

Specificity

Device specificity was determined through an analysis of 6,967 tests from evaluation phases 2-4. There was an overall false positive rate of 0.32% (specificity 99.68%). However, there was some indication that there was a difference in the false positive rates between laboratory-based testing (0.06%) compared to field testing (0.39%) (P=0.041 Fishers Exact Test). Our evaluations noted that where there were challenges in interpreting the results when the test result was "weak", these tests were often negative on re-testing. (Table 2).

Evaluation Phase	Testing Centre	False positives/total number	False positives and 95% CI
Phase 2 evaluation	Porton	0/72	0.00% (0.00-5.07)
Phase 3a evaluation- negative samples	Porton	0/940	0.00% (0.00-0.41)
Phase 4 evaluation- armed forces	Porton	0/105	0.00% (0.00-3.53)
Phase 4 evaluation- PHE staff	Porton	0/209	0.00% (0.00-1.80)
Phase 4 evaluation- hospital staff	Oxford	1/329*	0.30% (0.05-1.70)
Subtotal (Experienced laboratory workers)		*1/1655*	*0.06% (0.02-0.3)*
Phase 4 evaluation- school 1	Local	9/1855**	0.49% (0.26-0.92)
Phase 4 evaluation- school 2 + 3 + 4	Local	7/2130**	0.33% (0.16-0.68)
Phase 4 evaluation- COVID-19 testing centre	Local	5/1327***	0.38% (0.16-0.88)
Subtotal (Locally trained)		21/5312	0.39% (0.24-0.60)
TOTAL		22/6967	0.32% (0.21-0.47)

*This was 1 weak positive result that was also a weak positive on repeating** Weak positives result were negative on re-testing with Innova.,
*** Not photographed or repeated. Taken in setting of prevalence of 14% LFD positive results.

Table 2. Table illustrates the number of false positives in each evaluation stage and associated 95% confidence interval.

Antigen Detection in Field Studies;

Community research evaluation (phase 3b evaluation)

Viral antigen detection in individuals with confirmed SARS-CoV-2 infection was assessed in the Phase 3b evaluation as part of the FALCON-C19 research study. In particular, throat swabs were placed directly into the kit buffer solution (without using viral transport medium). Tests were performed either by laboratory scientists at PHE Porton Down or by fully trained research health care workers at the testing site. Overall 248/323 (76.8%) of the PCR positives were antigen positive. Figure 2 shows the relationship between viral load and antigen detection. There were no discernible differences in viral antigen detection in asymptomatic vs. symptomatic individuals (33/43 76.7% vs. 100/127 78.7%, p=0.78).

Phase 4 evaluation

A further series of individuals were recruited from consecutive cases from COVID19 Testing centres with tests performed by self-trained individuals and the results were compared to the Phase 3b shown above. Performance was optimal when the LFD was used by laboratory scientists (156/197 LFDs positive [79.2%, 95% CI: 72.8-84.6%])] versus trained healthcare-workers (92/126 LFDs positive [73.0%, 95% CI: 64.3-80.5%]) and self-trained members of the public given a protocol (214/372 LFDs positive [57.5%, 95% CI:52.3-62.6%]; p<0.0001 chi2(2)=30.1) (Figure 3).

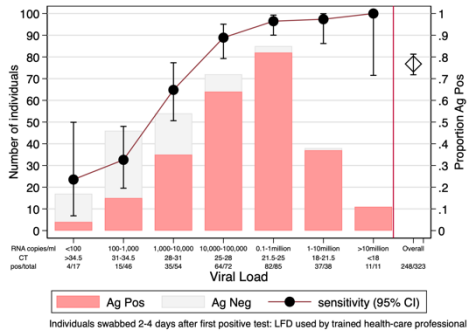


Figure 2 illustrates the association between viral antigen detection and viral load (RNA copies/ml) in phase 3b evaluation

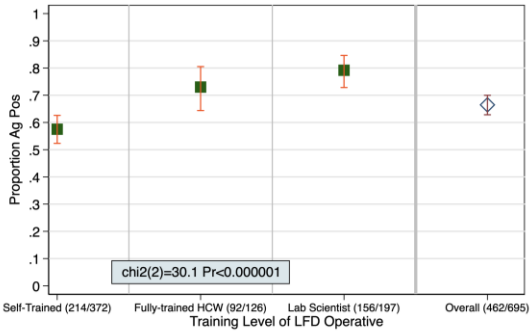


Figure 3 illustrates effect of operator and training on viral antigen detection

6. Conclusions

Enhanced identification of individuals with COVID-19 through increased availability of testing potentially offers an avenue to stop the chain of transmission for SARS-COV-2. Rapid, point of care devices for COVID-19 viral antigens offer several potential advantages over existing testing strategies.

Analyses of LFDs are at an advanced stage of evaluation in the United Kingdom. A comprehensive, systematic national pipeline has been established to rapidly evaluate the performance characteristics of LFD in laboratory and a multitude of community settings (hospitals, military establishments, schools, universities and COVID-19 testing centres). Many of the LFDs tested to date have not performed to levels established by the test and validation cell and confirmed by the LFD Oversight Group to proceed to community field service evaluations. However, a small number of LFDs have the desired performance characteristics and phase 4 evaluations have been completed for the *Innova SARS-CoV-2 Antigen rapid qualitative test.*

To date, the performance characteristics of the *Innova* LFD in the evaluations performed to date are good with a low failure rate, high specificity 99.6% and high viral antigen detection. Furthermore, issues need to be addressed to understand batch to batch variation, acceptance of the tests by the general public and the effect of operator/training effects upon performance characteristics. The delivery of appropriate training appears important to test performance. It is important to note the possibility that performance of these tests may improve with time as more research is performed within phase 4 evaluations. LFD implementation may offer advantages in national testing strategies focusing on risk reduction and warrant further testing in mass-testing scenarios. It also promises a massive increase in testing by enabling a distributed community-based use separate from the overburdened national and NHS testing laboratories.

James McGuire, Consul of British Consulate General in Shanghai, Healgen Scientific

2020-09-21

On September 18, Mr. James McGuire, Consul Life Sciences and Assistant Director, Life Sciences, Health and Social Care, British Consulate General in Shanghai, visited Healgen Scientific and made in-depth communication with Mr. Fang Xiaoliang, Chairman of the Company, about the R&D and production of COVID-19 detection reagent and visited the production line of COVID-19 antigen reagent.

Healgen Scientific is one of the first companies in China to research and develop COVID-19 antigen reagents. It is the first company to obtain CE certification in China on April 14, and was officially approved to export to the EU in August.

Compared with COVID-19 nucleic acid and antibody reagents, antigen reagent has the advantages of rapid, simple and easy extraction, which can be detected by simple

nasopharyngeal swab sample extraction on the first day after infection with COVID-19. In addition, during the research and development process, the Company found the most suitable antibody fragments and developed antigens, which were tested in France and the UK and received favorable evaluations. Therefore, since late August, the Company started batch exporting the COVID-19 antigen reagents to countries such as Germany, France, Britain, Italy and Austria.

Recently, the Company is expanding its production capacity for COVID-19 antigen reagents to satisfy the demands in Europe and other parts of the world.

European Commission

Live, work, travel in the EU

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

COVID-19 In Vitro Diagnostic Medical Devices

CE Marking

Yes

Detection Principle

ImmunoAssay-Antigen

Format

Rapid diagnostic test

Manufacturer

Healgen / Zhejiang Orient Gene Biotech

Commercial Name

Healgen / Zhejiang Orient Gene Biotech

Clear filters Search

Download as CSV

CE Marking	Detection Principle	Manufacturer	Commercial Name	Target	Format	Commercial Status
yes	ImmunoAssay-Antigen	Zhejiang Orient Gene Biotech	Coronavirus Ag Rapid Test Cassette (Swab)	Antigen	Rapid diagnostic test	Commercialised
Yes	ImmunoAssay-Antigen	Zhezhiang Orient Gene Biotech Co Ltd	RAPID TEST AntigenE GCCOV-502a	Antigen	Rapid diagnostic test	Commercialised

The database contains publicly available In Vitro Diagnostic Medical Devices for COVID-19 and it is being updated periodically. Please note that additional performance (as retrieved from manufacturers web pages) is provided only for devices commercially available with CE-IVD mark.
Acknowledgements

GOV.UK

Guidance

SARS-CoV-2 lateral flow antigen tests: evaluation of VOC1 (Kent, UK) and VOC2 (South Africa)

Published 12 February 2021

This publication is available at https://www.gov.uk/government/publications/sars-cov-2-lateral-flow-antigen-tests-evaluation-of-voc1-and-voc2/sars-cov-2-lateral-flow-antigen-tests-evaluation-of-voc1-kent-uk-and-voc2-south-africa

1. Working with academic collaborators at the University of Oxford, Public Health England (PHE) Porton Down has been evaluating the performance of lateral flow devices (LFDs) since mid-August 2020. Over 80 have been considered to date, approximately 30% of which have progressed to extended evaluation on clinical samples at Phase 3.

2. In December 2020, the leading LFDs were tested against a large batch of clinical VTM swab samples from the Lighthouse Laboratory at Milton Keynes. These samples contained a significant number representative of the new variant strain VOC-202012/01 (VOC1 Kent, UK, B.1.1.7) and all were detected where the viral titre was above LOD for the LFD, as previously reported on GOV.UK on 23 December 2020 (https://www.gov.uk/government/publications/sars-cov-2-lateral-flow-antigen-tests-evaluation-of-vui-20201201).

3. Subsequently, these LFDs and the Orient Gene LFD have also been successfully evaluated using characterised cultured virus VOC-202012/01 (VOC1 Kent, UK) from material provided by colleagues at PHE Colindale, and also cultured virus for the VOC-202012/02 (VOC2 South Africa, B.1.351 variant). Stocks of cultured virus were diluted down in synthetic mucus and replicates tested at each dilution following manufacturers instructions. The LFDs, including those currently in use, successfully detected samples containing the new variants.

Variant of concern, virus titre and detection level				
	VOC1	**Kent, UK**	**VOC2**	**South Africa**
Lateral Flow Device	**10^4 pfu/ml**	**10^3 pfu/ml**	**10^4 pfu/ml**	**10^3 pfu/ml**
Fortress	Detected	Detected	Detected	Detected
Roche SD Biosensor swab	Detected	Detected	Detected	Detected
Abbott Panbio	Detected	Detected	Detected	Detected
Innova	Detected	Detected	Detected	Detected
Surescreen	Detected	Detected	Detected	Detected
Orient Gene	Detected	Detected	Detected	Detected

4. The VOC1 (Kent, UK) and VOC2 (South Africa) both contain multiple nucleotide changes across the genome which result in amino acid substitutions and other changes in different proteins. These include a large number of changes in the spike protein and a lesser number in the nucleocapsid protein. Whilst some lateral flow tests in development are using the spike protein, the majority of those tested use the nucleocapsid protein as the antigen target; these include the current lateral flow tests in use. The changes in both variants for these antigen targets are listed in the table below.

Variant	VOC 1 (Kent, UK)	VOC2 (South Africa)
Spike protein	N501Y; A570D; D614G; P681H; T716I; S982A; D1118H; 69/70 HV deletion; 144Y deletion	D80A, D215G, K417N, E484K, N501Y, D614G, A701V
Nucleocapsid protein	D3L; R203K; G204R; S235F	T205I

5. In summary, the LFDs listed above, all of which target the nucleocapsid protein, have detected the new variants that contain a limited number of amino acid changes from the original viral sequence in the target antigen. This does not affect their performance and we will monitor further variant changes as they arise as part of our ongoing evaluation programme.

Print this page

Clinical Report

Coronavirus Ag Rapid Test Cassette (Swab)

Manufacturer: Zhejiang Orient Gene Biotech Co., LTD
Address: 3787#, East Yangguang Avenue, Dipu Street, Anji 313300,Huzhou,Zhejiang,China.

Product Name
Coronavirus Ag Rapid Test Cassette (Swab)

Manufacturer
Zhejiang Orient Gene Biotech Co., LTD

Clinical Site
Clinical Performance of the Coronavirus Ag Rapid Test Cassette (Swab) was evaluated by being involved in 7 Point of Care sites within the US, where patients were enrolled and tested. Testing was performed by Health Care Workers.

Test Interval

September,2020-December,2020

Introduction
Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses (229E, OC43, NL63, and HKU1) are prevalent and typically cause common cold symptoms in immunocompetent individuals. The three other strains (SARS-CoV, MERS-CoV, SARS-CoV-2) are zoonotic in origin and have sometimes been linked to fatalities.

The Coronavirus Ag Rapid Test Cassette (Swab) is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. The Rapid COVID-19 Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2.

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases.

This test is for detection of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

Principle

The Coronavirus Ag Rapid Test Cassette (Swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in swab. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

Purpose

The primary objective is to determine the sensitivity and specificity of the Coronavirus Ag Rapid Test Cassette when testing intended use populations who meet the criteria of having COVID-19 infection by Centers for Disease Control and Prevention (CDC). The test is to be performed by healthcare professionals at clinical settings.

Design

Sample population and size

The clinical evaluation will be conducted at the actual user site and the study population will be"real-world"patients. To support the test performance, clinical specimens will be tested with the goal of testing a minimum of 40 positive specimens and 200 negative specimens in a randomized, blinded fashion.

The testing to be conducted will include the following:

A. Enroll 40 subjects known to be positive for COVID-19 by a RT-PCR assay within 14 days. These would be the patients that are already under the PI's care.

B. Enroll 250 subjects where the healthcare provider suspects the individual may have COVID-19 infection based on the CDC description of COVID-19 symptoms.

C. All the subjects will agree to be simultaneously sampled for a COVID-19 RT-PCR test and sampled for an antigen test at the clinical site.

D. If a subject has a known RT-PCR result less than 14 days ago, the RT-PCR test can be waived.

Inclusion and Exclusion Criteria

Inclusion Criteria

1. Must be 21 years old or older.
2. Has symptoms that lead the healthcare provider to suspect the individual of possibly having SARS-CoV-2 infection.
3. Was exposed to a COVID-19 patient within 14 days that leads the healthcare provider to suspect the individual of possibly having SARS-CoV-2 infection
4. Has an immediate need to determine COVID-19 status for occupational purposes.

5. Must be willing to provide a sample for COVID-19 RT-PCR testing if the subject has not been previous tested for COVID-19 RT-PCR within 14 days.
6. Must be willing to provide a sample for additional tests required by the study site.
(antigen test or RT-PCR).
7. Must be able to sign a consent form.
8. Must be able to provide swab samples.

Exclusion Criteria

1. Is receiving treatment with infusion of convalescent plasma or other antibody therapy related to SARS-CoV-2 infections.
2. Is participating in a SARS-CoV-2 vaccine study.
3. Tested positive for COVID-19 positive more than 14 days ago.

Candidate Test

Coronavirus Ag Rapid Test Cassette (Swab)

Lot: 2008139

Comparator Test

The comparator tests included high sensitivity Emergency Use Authorized RT-PCR tests used at each testing site as the routine testing method for COVID-19 diagnostics. The EUA RT-PCR tests use a chemical lysis step followed by solid phase extraction of nucleic acid. The patient specimens were all prospective collected and immediately tested by operators.

FDA Emergency Use Authorized RT-PCR tests routinely are used as the testing method for COVID-19 diagnostics. Multiple RT-PCR tests were used as the comparator assay because Manufacturer had no control of which assay the test site used for patient testing. Sometimes, a testing site used multiple RT-PCR assays due to test supply constraints. In addition, it is very burdensome to collect multiple samples from one subject to accommodate an additional, separate RT-PCR test because the subject was already sampled twice (once for the clinical testing and once for the investigational testing).

Test Procedure

Perform the Test according to the Instructions for Use (IFU)package insert.

The technique is described and illustrated in the Quick Reference Instruction (QRI)

The test device and swab is provided with the test kit. The fresh specimens were tested immediately, and no transport media was used for shipping the samples to a different location for testing. All clinical specimens tested in this submission were tested and evaluated in accordance with the proposed diagnostic algorithm.

Results, Data process and Analysis

Clinical Performance of the Coronavirus Ag Rapid Test Cassette (Swab) was evaluated by being involved in 7 sites within the US where patients were enrolled and tested. Testing was performed by Healthcare Workers that were not familiar with the testing procedure. A total of 865 fresh nasopharyngeal swab samples was collected and tested, which includes 119 positive samples and 746 negative samples. The Coronavirus Ag Rapid Test Cassette (Swab) results were compared to USFDA Emergency Use Authorized RT-PCR assays for SARS-CoV-2 in nasopharyngeal swab specimens.

Overall study results are shown in **Table 1**.

Table 1: Summary Results of nasopharyngeal swab

Method		**PCR**		**Total Results**
Coronavirus Ag Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	117	3	120
	Negative	2	743	745
Total		119	746	865

Relative Sensitivity: 98.32% (95% Cl* 94.06% to 99.80%)
Relative Specificity: 99.60% (95% CI* 98.83.% to 99.92%)
Accuracy: 99.42% (95%CI* 98.66% to 99.81%)

Conclusion: From the results above, the relative sensitivity is 98.32% (95% Cl* 94.06% to 99.80%) , the relative specificity: 99.60% (95% CI* 98.83.03% to 99.92%) and the accuracy: 99.42% (95%CI* 98.66% to 99.81%)

A total of 237 fresh nasal swab samples was collected and tested, which includes 109 positive samples and 128 negative samples. The Coronavirus Ag Rapid Test Cassette (Swab) results were compared to results of USFDA Emergency Use Authorized RT-PCR assays for SARS-CoV-2 in Nasopharyngeal swab specimens. Overall study results are shown in **Table 2**.

Table 2: Summary Results of Nasal Swab

Method		**PCR**		**Total Results**
Rapid COVID-19 Antigen Test (Nasal Swab)	Results	Positive	Negative	
	Positive	106	0	106
	Negative	3	128	131
Total		109	128	237

Relative Sensitivity: 97.25% (95% Cl*: 92.17% to 99.43%)
Relative Specificity: 100% (95% CI*: 97.69% to 100%)
Accuracy: 98.73% (95%CI*: 96.35% to 99.74%)

Conclusion: From the results above, the relative sensitivity is 97.25% (95% Cl*: 92.17% to 99.43%) , the relative specificity: 99.60% 100% (95% CI*: 97.16% to 100%) and the accuracy: 98.73% (95%CI*: 96.35% to 99.74%).

COVID-19: Rapid Antigen detection for SARS-CoV-2 by lateral flow assay: a national systematic evaluation for mass-testing

UK COVID-19 Lateral Flow Oversight Team

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Running Title: Clinical utility of lateral flow SARS-CoV-2 antigen detection

Keywords: coronavirus, COVID-19, SARS-CoV-2, United Kingdom, Public Health, lateral flow, viral antigen detection, testing, national evaluation, LFD, lateral flow tests, lateral flow devices.

Abstract

Background: New lateral flow device (LFD) viral antigen immunoassays have been developed by commercial and research organisations around the world as diagnostic tests for SARS-CoV-2 infection. To support decisions by the UK Government on potential scale-up of mass population testing, we have at their request evaluated the diagnostic performance of a significant number of point-of-care rapid SARS-CoV-2 LFDs.

Methods: 132 LFDs were initially reviewed by a Department of Health and Social Care team, part of the UK government, from which 64 were selected for further evaluation. Standardised laboratory evaluations, and for those that met the published criteria, field testing in the Falcon-C19 research study and UK pilots were performed (UK COVID-19 testing centres, hospital, schools, armed forces).

Results: 4/64 LFDs so far have desirable performance characteristics from independent laboratory studies and early preliminary field evaluations (Orient Gene, Deepblue and *Innova SARS-CoV-2 Antigen Rapid Qualitative Test*), of which one underwent extended clinical assessment in field studies (*Innova*). 8951 Innova LFD tests were performed with a kit failure rate of 5.6% (502/8951, 95% CI: 5.1-6.1), false positive rate of 0.32% (22/6954, 95% CI: 0.20-0.48) and a viral antigen detection/sensitivity (using RNA RT-PCR as a proxy for the presence of antigen) of 78.8% when performed by laboratory scientists (156/198, 95% CI 72.4-84.3). Sensitivity was significantly lower when testing was undertaken by non-experts with limited initial training

Interpretation: Several LFDs have promising performance characteristics for mass population testing and can be used to identify infectious positive individuals. The Innova LFD shows good viral antigen detection/sensitivity with excellent specificity, although kit failure rates and the impact of training are potential issues. These results support the expanded evaluation of LFDs, and assessment of greater access to testing on COVID-19 transmission.

Funding: Department of Health and Social Care. University of Oxford. Public Health England Porton Down, Manchester University NHS Foundation Trust, National Institute of Health Research.

Introduction

National governments and international organisations including the World Health Organisation (WHO) and European Commission have highlighted the importance of individual testing, mass population testing and subsequent contact tracing to halt the chain of transmission of SARS-CoV-2, the virus responsible for COVID-19.[1,2,3] The current diagnostic test involves reverse-transcription polymerase chain reaction (RT-PCR) testing of nose/throat swabs in specialised laboratories. Such capacity in the UK is currently estimated at ~500,000 tests/day[4–7] and this is used with contact tracing procedures and mobile applications to identify close symptomatic contacts of infected symptomatic individuals.[8–10] However, there are significant challenges in creating testing capacity to identify those with asymptomatic infections or to test contacts of individuals with COVID-19. To date, turnaround time for RT-PCR has been typically slow (>24 hours).

To better understand and control SARS-CoV-2 transmission, there is an urgent need for large-scale, accurate, affordable and rapid diagnostic testing assays, with the ability to detect infectious individuals. Lateral flow device (LFD) immunoassays can be designed to test for different protein targets and are routinely used in healthcare settings principally as a result of their affordability, ease of use, short turnaround time, and high-test accuracy. In brief, a sample is placed on a conjugation pad where the analyte (or antigen) of interest is bound by conjugated antibodies. The analyte-antibody mix subsequently migrates along a membrane by capillary flow across both 'test' and 'control' strips. These strips are coated with antibodies detecting the analyte of interest and a positive test is confirmed by the appearance of coloured control and test lines.[11]

Newly developed SARS-CoV-2 antigen LFDs identify the presence of specific viral proteins, using conjugated antibodies to bind spike, envelope, membrane or nucleocapsid proteins. In contrast to the IgM/IgG "antibody tests", these antigen tests directly identify viral proteins, and are not reliant on the host's immune response. In contrast to RT-PCR, results for LFDs are observed in 10-30 minutes depending on the device, providing a window for early interventions to halt the chain of transmission earlier in the disease course when individuals are most infectious.[12]

To date, many manufacturers have developed first-generation rapid SARS-CoV-2 antigen-detecting LFDs. However, many of these tests have not been independently validated. There is evidence of variable performance when assessing test sensitivity and specificity, although several candidates looked promising on the basis of early data.[13–15] An independent national evaluation of these devices is important to facilitate population-level or mass testing initiatives globally.

Here, we report the diagnostic performance of first-generation SARS-CoV-2 antigen-detecting LFD for rapid point-of-care (POC) testing in work that was commissioned by the UK's Department of Health and Social Care (DHSC) from PHE Porton Down and the University of Oxford.

Methods

A phased evaluation of available SARS-CoV-2 antigen LFDs was undertaken.

Department of Health and Social Care evaluation (Phase 1 evaluation)

The DHSC identified manufacturers supplying SARS-CoV-2 antigen LFDs that could enable mass testing at a population level. A desktop review was performed to ensure there were appropriate instructions for use and to assess manufacturers' claimed performance and manufacturing capabilities.[16]

Pre-clinical evaluation (Phase 2 evaluation)

Pre-clinical evaluation of candidate LFDs was performed by trained laboratory scientists at Public Health England (PHE) Porton Down. LFDs were evaluated against SARS-CoV-2 spiked positive controls and known negative controls, consisting of saliva collected from healthy adult staff volunteers.

Pre-defined and publically available "prioritisation" criteria to pass on to the next evaluation phase had to be met for LFDs, consisting of (i) a kit failure rate of <10%; (ii) an analytical specificity of ≥97%, and (iii) an analytical LOD of $\geq$9 of 15 (60%) at 10^2 pfu/mL, corresponding to a RT-PCR cycle threshold (Ct) of approximately 25 (~100,000 RNA copies/ml); and (iv) lack of cross-reactivity with seasonal coronaviruses to further test analytical specificity.

Retrospective secondary care evaluation (Phase 3a evaluation)

Evaluation using patient samples retrospectively was started in August 2020 at PHE Porton Down. Samples were obtained from a secondary healthcare setting (Oxford University Hospitals NHS Foundation Trust).

- 1,000 SARS-CoV-2 negative samples: fresh samples held refrigerated were supplied the day after they were tested negative by RT-PCR by the laboratory service at the John Radcliffe Hospital, Oxford, UK.
- 200 SARS-CoV-2 positive samples: swabs collected in VTM from patients admitted to hospital during the first wave of the UK pandemic (March-June 2020).[17] These were diluted 1:4 SARS-CoV-2 RT-PCR negative saliva, aliquoted and frozen at -20°C for later use. For each positive sample, in addition to the original diagnostic RT-PCR Ct value, a confirmatory RT-PCR was performed at PHE Porton Down on the diluted sample to determine the new Ct value.

Community research evaluation (Phase 3b evaluation)

We undertook a field evaluation using samples from volunteers in the community in collaboration with the National Institute for Health Research (NIHR) funded CONDOR Platform "COVID-19 National Diagnostic Research and Evaluation Platform". This was performed within the FALCON-C19 study (Facilitating Accelerated Clinical validation Of Novel diagnostics for COVID-19, 20/WA/0169, IRAS 284229), between 17th September and 23rd October 2020. This involved the recruitment and re-testing of consenting adults with a RT-PCR-confirmed diagnosis of SARS-CoV-2 infection within 5 days of the original PCR result.

For the *Innova SARS-CoV-2 Antigen Rapid Qualitative Test*, testing was additionally performed for a subset of samples on-site at four COVID-19 testing centres by trained research staff using the "dry swabs" to evaluate "real-life"/diagnostic performance. Dry swabs are those that are not placed into viral transport medium prior to performing the LFD test.

Community field service evaluation (Phase 4 evaluation)

Wider field service evaluations were performed within a number of UK institutions and settings. These evaluations utilised the *Innova SARS-CoV-2 Antigen Rapid Qualitative Test*. These institutions included a secondary healthcare setting (John Radcliffe Hospital, Oxford), PHE Porton Down, armed forces members (following an outbreak) and in secondary schools (pupils aged 11-18). Evaluations were also undertaken at regional COVID-19 testing centres as part of an NHS Test and Trace service evaluation involving the general public. The John Radcliffe Hospital, Oxford performed an evaluation as part of their asymptomatic staff screening service using the Respiratory Diagnostic Kit Evaluation ('Red Kite') study (Research Ethics Committee reference: 19/NW/0730; North West-Greater Manchester South Research Ethics Committee).

Statistical analyses

Fisher's exact and chi-squared tests were used to determine non-random associations between categorical variables. Statistical analyses and data visualisation were performed using R version 4.0.3. Sensitivity and specificity and 95% confidence intervals were calculated using the exact Clopper-Pearson method.

Results

Phase 1

A total of 132 suppliers of SARS-CoV-2 antigen detection LFDs were identified and referred to the DHSC for initial Phase 1 review. Among these, at the time of publication, 64 were selected by the DHSC for further evaluation by the UK lateral flow oversight group.

Phase 2

As part of Phase 2 evaluations, 9,692 LFD tests were performed at PHE Porton Down across the 64 candidate devices as of the 3rd December 2020. 5 LFDs had a kit failure rate above the pre-specified threshold for exclusion (>10%), 17 kits had a false-positive rate below the pre-defined specificity threshold (<97%) and 28 kits a false-negative rate below the LOD threshold (<60% at 10^2 pfu/m). In total, across all three criteria, nineteen kits performed at a level in accordance with the UK Lateral Flow Oversight Group's *a priori* "prioritisation criteria". All nineteen kits also passed cross-reactivity analyses against seasonal human coronaviruses.

Phase 3

To date, eight LFDs have passed Phase 3a evaluation, namely: *Innova SARS-CoV-2 Antigen Rapid Qualitative Test* (Innova)*, Zhejiang Orient Gene Biotech Co. Coronavirus Ag Rapid Test Cassette* (Swab) (Orient Gene)*, Anhui Deepblue Medical Technology COVID-19 (Sars-CoV-2) Antigen Test kit (Colloidal Gold) (*Deepblue)*, Fortress Diagnostics Coronavirus Ag Rapid Test (Fortress), Roche SD Biosensor Standard Q COVID-19 Ag Test (SD Bio swab), Surescreen Diagnostics SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal swab (Surescreen) and LFD x (the manufacturer had not given consent to be named).* (Supplementary Table 1). Three LFDs did not pass 3a evaluation and the remaining LFDs are currently undergoing evaluation. Four LFDs (Deepblue, Innova, Orientgene, LFD x) have passed Phase 3b evaluation (Table 1, Supp Figure 1), one LFD did not pass and the remainder have not been evaluated.

Viral Load	Average Ct	Innova Number tested/number positive (%)	LFD x Number tested/number positive (%)	Orient Gene Number tested/number positive (%)	Deepblue Number tested/number positive (%)
>10million	<18	5/5 (100)	1/1 (100)	-	3/3 (100)
1-10 million	18-21.5	23/23 (100)	12/13 (92)	17/17 (100)	19/19 (100)
0.1-1 million	21.5-25	52/54 (96)	19/21 (91)	18/18 (100)	43/44 (98)
10,000-100,000	25-28	37/42 (88)	13/13 (100)	18/19 (95)	38/38 (100)
1,000-10,000	28-31	25/33 (76)	17/19 (90)	14/18 (78)	18/29 (62)
100-1,000	31-34.5	11/33 (33)	10/26 (39)	11/19 (58)	8/36 (22)
<100	>34.5	2/7 (29)	1/6 (17)	0/4 (0)	0/8 (0)
Overall	na	155/197 (79)	73/99 (74)	78/95 (82)	129/177(73)

Table 1. Results of the Phase 3b evaluations showing viral antigen detection/sensitivity of four LFD tests using dry-swab samples from community sampling. Tests were performed by laboratory scientists. Ct – cycle threshold on RT-PCR.

Extended Innova LFD evaluation (Phases 2-4)

The limit of detection of the Innova LFD (Table 2) was determined as part of Phase 2 evaluations for the Innova test. This analysis consisted of saliva spiked with SARS-CoV-2 with stock of SARS-CoV-2 with a standardised PFU. Under these ideal concentrations, at an estimated PFU of 390/mL, which corresponds to a Ct of ~25, the LFD identified all samples.

PFU/ml	Ct equivalent	Positive LFD tests/total LFD tests	% positive
100000	16	20/20	100
10000	19	25/25	100
1000	23.7	65/65	100
390	25.2	5/5	100
100	25.5	63/65	96
40	28.5	3/5	60
20	29.3	0/5	0
10	30.2	0/5	0
5	31	0/5	0
2.5	31.7	0/5	0
1.2	32.5	0/5	0

Table 2. Limit of sensitivity for SARS-CoV-2 detection by the Innova LFD for antigen detection using saliva sample spiked with SARS-CoV-2. Ct - cycle threshold. PFU - plaque forming units.

Our phase 4 evaluation focused on field testing of the Innova LFD, for which we had a sufficient supply of kits available for wider testing at the time. Device specificity was determined through an analysis of 6954 tests from evaluation phases 2-4. The percentage of false-positives ranged from 0.00-0.49%, with an overall specificity of 99.68%. The false-positive rate was centre-dependent (p=0.014, Fisher's exact test). These evaluations noted that where there were challenges in interpreting the results when the test result was "weak" (i.e. the test line was very faint) (Table 3).

Evaluation Phase	False positives/total number	False positives and 95% confidence interval
Phase 2 evaluation	0/72	0.0% (0.0-5.0)
Phase 3a evaluation- negative samples	0/940	0.0% (0.0-0.4)
Phase 4 evaluation- hospital staff	1/329*	0.3% (0.01-1.7)
Phase 4 evaluation- armed forces	0/105	0.0% (0.0-3.5)
Phase 4 evaluation- PHE staff	0/209	0.0% (0.0-1.8)
Phase 4 evaluation- school 1	9/1855**	0.5% (0.2-0.9)
Phase 4 evaluation- school 2 + 3 + 4	7/2130**	0.3% (0.1-0.7)
Phase 4 evaluation- COVID-19 testing centre	5/1314***	0.4% (0.1-0.9)
TOTAL	22/6954	0.3% (0.2-0.5)

*This was 1 weak positive result that was also a weak positive on repeating; ** Weak positives result were negative on retesting with Innova; *** Not photographed or repeated. Taken in a setting of prevalence of 14% LFD positive results.

Table 3. Number of false positives in negative samples in each evaluation stage for the Innova LFD. 95% confidence intervals presented in each case.

Across Phase 2-4 evaluation stages, 8,951 Innova LFD tests were performed, including a diverse cohort of populations as part of Phase 3b and Phase 4 testing, namely out-patient SARS-CoV-2 cases, healthcare staff, armed forces personnel and secondary school children. The overall kit failure rate for the Innova LFD was 5.6% (502/8951, 95% CI: 5.1-6.1) (Table 4). The most common reason for kit failure was poor transfer of the liquid within the device from the reservoir onto the test strip.

Innova LFD evaluation phase	LFD failures (%)
Phase 2 negatives	0/72 (0.0%)
Phase 2 positive dilution series	0/60 (0.0%)
Phase 2 positive extended dilution series	0/155 (0.0%)
Phase 2 Swab comparison	0/187 (0.0%)
Phase 3a positives	13/191 (6.8%)
Phase 3a negatives	50/990 (5.1%)
Phase 3b FALCON (Dry swabs- field)	27/267 (10.1%)
Phase 3b FALCON (Dry swabs- lab)	9/212 (4.2%)
Phase 3b FALCON (VTM swabs)	9/157 (5.7%)
Phase 4 hospital staff	17/358 (4.7%)
Phase 4 armed forces	6/157 (3.8%)
Phase 4 PHE staff	19/212 (8.9%)
Phase 4 school 1	311/1855 (16.8%)
Phase 4 school 2 + 3 + 4	14/2132 (0.7%)
Phase 4 COVID-19 testing centre	27/1946 (1.4%)
	502/8951 (5.6%)

Table 4. Evaluations of the Innova LFD across Phases 2-4. The table demonstrates the kit failure rate.

Viral antigen detection/sensitivity in individuals with confirmed SARS-CoV-2 infection using the Innova LFD was assessed in the Phase 3b evaluation as part of the FALCON-C19 research study. Optimal viral antigen detection/sensitivity when performed by laboratory scientists, was 78.8% (95% CI 72.4-84.3%; 156/198 cases where a paired PCR was performed; see below for differing performance by test operator category). Subgroup analyses showed there were no discernible differences in viral antigen detection/sensitivity in those without symptoms vs. symptomatic individuals (27/41 [65.9%] vs. 95/344 [72.4%], p=0.38). We did not find any evidence of associations between LFD positivity and symptoms or past medical history, with the exception of presence of headache (Supplementary Table 2).

The association between Innova LFD viral antigen detection/sensitivity and estimated viral load/Ct value was explored using the paired RT-PCR VTM swab sample taken at the same time as the swab used for LFD. There was a strong association between viral load detection (RNA copies/mL) determined through RT-PCR and viral antigen detection by LFD (Figure 1). Confirming earlier analyses, sensitivity of LFDs is highest in samples with higher viral loads.[18 19]

Within the 3b FALCON-C19 study, LFDs were also assessed by sampling 150uL of viral transport medium (VTM) solution instead of using dry swabs; this was associated with poorer performance rate (Supp Figure 2). The use of dry swabs forms the basis of the manufacturer's instructions for use. This was likely due to a dilution factor involved in placing the swab first into VTM and then analysing the VTM sample, and highlights potential issues in generating direct comparisons between LFDs and VTM samples (Supp Figure 2).

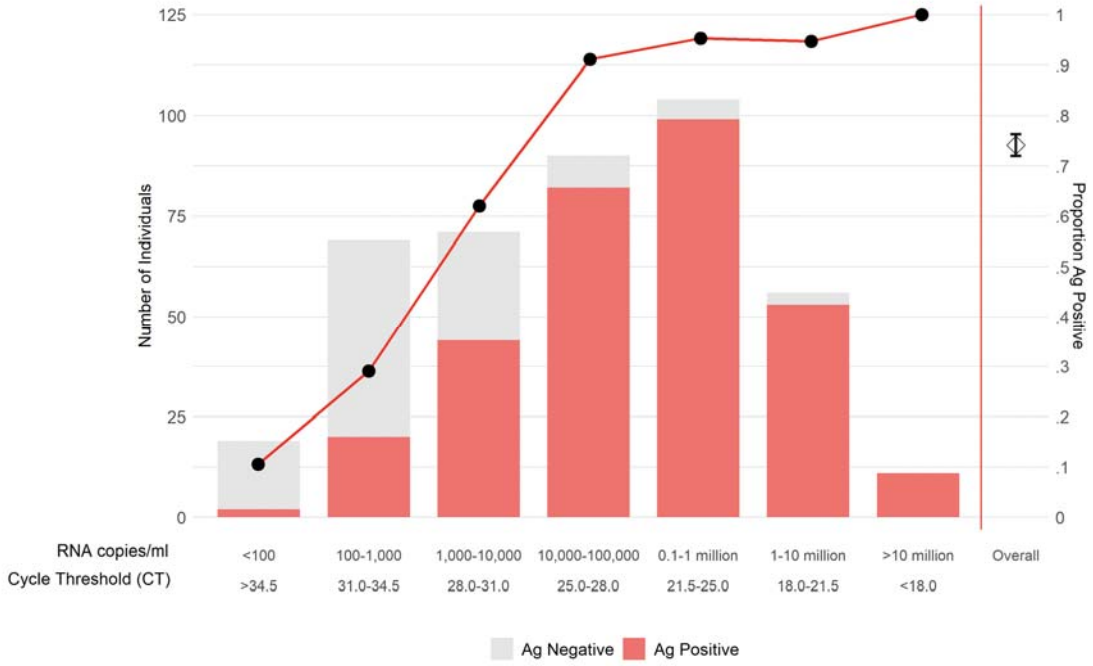
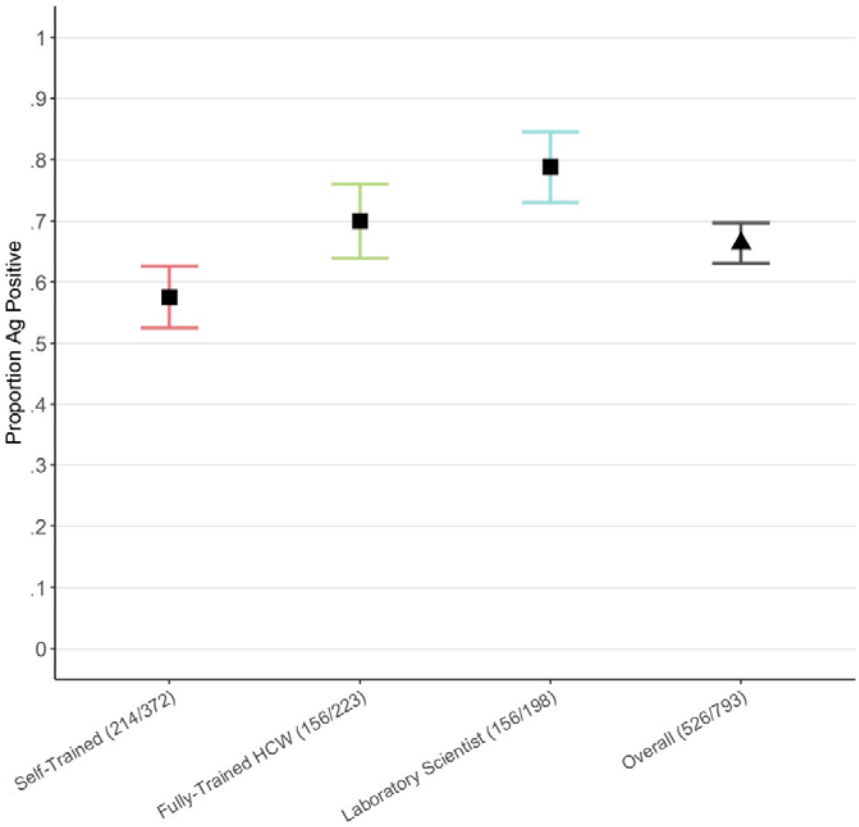


Figure 1. Association between viral antigen detection/sensitivity and viral load (RNA copies/mL and Ct) in Phase 3b Falcon-C19 study evaluation for dry swabs when performed by trained laboratory scientists and trained healthcare workers. Diamond shows point estimate, with 95% confidence intervals, pooling data from all other categories.

As part of Phase 3b-4 evaluations, work was performed to report on the effect of the operator on viral antigen detection/sensitivity in RT-PCR-positive cases using the Innova LFD. Tests were classified according to whether they were performed by a laboratory scientist, a fully trained research health care worker or by a self-trained lay individual working at a regional NHS Test and Trace centre. Performance was optimal when the LFD was used by laboratory scientists (156/198 LFDs positive [78.8%, 95% CI: 72.4-84.3%]) relative to trained healthcare-workers (156/223 LFDs positive [70.0%, 95% CI: 63.5-75.9%]) and self-trained members of the public given a protocol (214/372 LFDs positive [57.5%, 95% CI: 52.3-62.6%]; p<0.0001).



246
247 *Figure 2. Effect of training and operator on the viral detection/sensitivity of the Innova LFD in COVID-19 PCR-positive patients.*

Discussion

We report on our national evaluation of SARS-CoV-2 viral antigen-detecting LFDs, focussing on the *Innova SARS-CoV-2 Antigen Rapid Qualitative Test,* which has a viral antigen detection (sensitivity) of 78.8% when performed by laboratory scientists and a specificity of 99.7%, using RT-PCR as 'gold standard' for positive and negative status. In our evaluation, test performance was largely maintained across different settings and cohorts; however, performance was partly operator-dependent and kit failures are not infrequent.

Test performance to detect SARS-CoV-2-positive samples was improved at lower Ct values/higher viral loads, and were >90% at Ct values <25 equating to ~390 pfu/mL (Supplementary Table 3). There is an expanding body of evidence that suggests viral load/antigen is important as individuals with the highest viral loads are the most infectious, [20] and the presence/absence of viral antigens determined by LFDs is more strongly associated with a viral culture than RT-PCR positivity.[21]

Our experience is that many LFDs entering our national evaluation program do not perform at a level required for mass population deployment and this reflects the literature. To date, an increasing number of evaluations of SARS-CoV-2 antigen-detecting LFD have been published with variable results. A number of LFDs show good[24 25 13 19 26 27] or acceptable sensitivity and specificity[28 29], however, many studies have identified tests with poor sensitivities or specificities.[30 15]

A challenge for most countries during the SARS-CoV-2 pandemic has been the expansion of capacity for diagnostic testing to support the identification of symptomatic and asymptomatic cases. This would aid in offering testing to "contacts" of COVID-19 and enable targeted testing to better safeguard vulnerable populations e.g. care home residents. Reliance on RT-PCR involves significant infrastructural and specialist human resources to implement at increasing scale. Both the World Health Organisation and European commission have issued guidance supporting wider implementation of antigen-targeting LFDs, and in November, Slovakia became the first country in the world to implement entire population testing using LFDs. [1,3,31] The UK has similar aspirations to pursue a strategy of mass testing and has implemented a city wide mass testing in Liverpool using the Innova LFD in this study.[32]

It is important to note that there are some potential issues with considering RT-PCR as the gold standard test for COVID-19. Many individuals have persisting viral RNA fragments that can linger for weeks-months without any evidence of active viral replication; in this instance a PCR-positive is likely to overcall the "infectious" status of an individual [33] Indeed, when compared to the ability to perform viral culture, data suggest that RT-PCR tends to overestimate the presence of replicating or infectious virions.[34]

In field testing, performance of the Innova LFD was dependent on the test operator. Individuals who had read a protocol immediately prior to self-sampling did not perform as well as individuals with hands-on training, or clinical laboratory personnel who had performed several hundred LFD tests. Like other operator-dependent procedures, further work is required to determine the duration and content of "training" to derive optimal test performance. We also assume that the use of LFDs to successfully identify individuals with higher viral loads and enabling an earlier diagnosis will be of benefit in interrupting transmission, however, this remains to be proven.

SARS-CoV-2 control will benefit from a variety of testing strategies. This might include those optimised for determining past infection/exposure (e.g. serology), those that are of benefit in determining current/recent infection (e.g. RT-PCR), or those identifying potential infectivity. A combination of approaches incorporating the strengths of each of these tests can be effectively used for individuals and for population-level management of the pandemic. Approaches to testing will remain relevant even when effective vaccines become available as it may take several months for an appreciable effect on transmission to be fully realised.[35]

In conclusion, we completed late stage evaluations of seven LFDs. We report sensitivities of 70-80% and specificities ≥99.7% for each LFD evaluated in phase 3b, which involved testing by laboratory personnel or trained healthcare professionals. To identify patients with higher viral loads (Ct<25), each LFD had >90% sensitivity. Sensitivity was lower in phase 4 evaluations, while specificity was maintained. The simplicity of LFDs, without a requirement for specialist training or equipment, mean that they are an attractive option for mass testing. Future research should focus on post-implementation evaluation of diagnostic accuracy, including the potential benefit of regular serial sampling to improve accuracy and reduce transmission.

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Declaration of interest

DWE declares lecture fees from Gilead, outside the submitted work. LYWL has previously received speaker honorarium from the Merck group and Servier for unrelated work. The other authors have nothing to disclose.

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Research in Context

Evidence before the study:

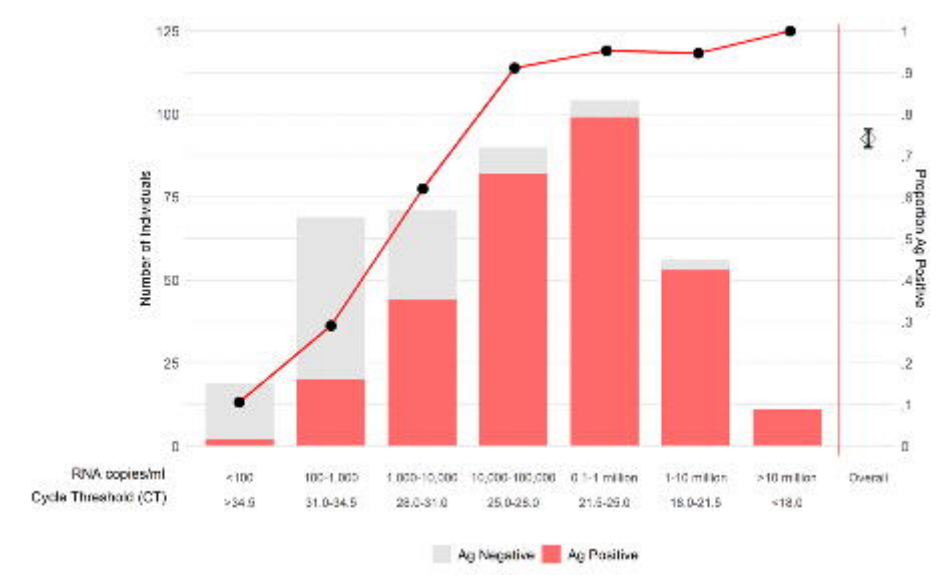
Lateral flow devices are a new form of testing for SARS-CoV-2. They differ from RT-PCR tests in that they rely on the detection of viral antigens by immunoassays and their utility has not yet been fully defined. A literature review was performed in PubMed and bioRxiv/medRxiv for all studies using lateral flow devices for the detection of SARS-CoV-2 viral antigen. This used the search terms “COVID-19”, “SARS-CoV-2”, “viral antigen” and “lateral flow devices” and was not limited to English language publications. To date, the majority of studies have been largely single centre studies analysing a single test and there are contrasting results with some LFDs showing good sensitivity and specificity[24 25 13 19 26 27 18], and others demonstrating poorer performance.[28 29]

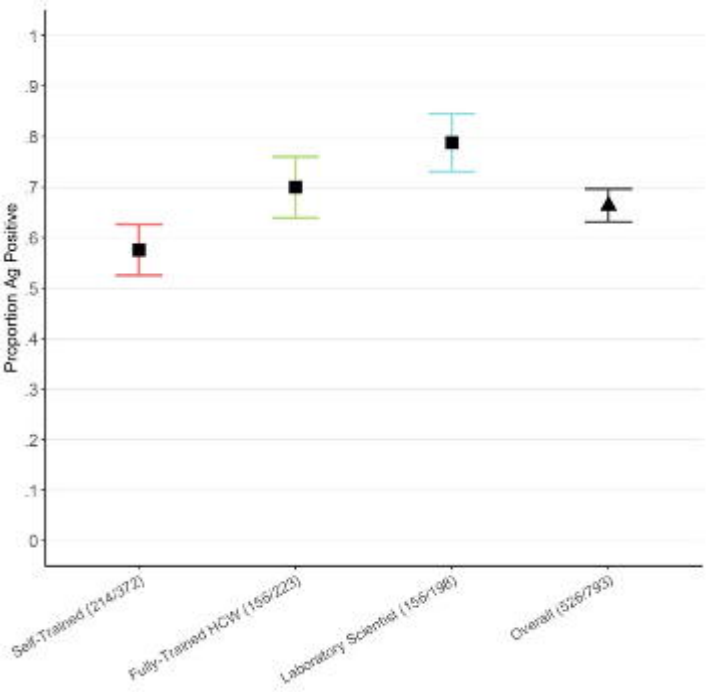
Added value of the study

This UK COVID-19 Lateral Flow Oversight group study is the largest national evaluation undertaken of viral antigen LFDs for COVID-19. We have flagged four LFDs with the best performance characteristics from our assessments. The Innova LFD has been tested the most extensively and has high specificity with acceptable sensitivity. Our data has also highlighted the critical importance of training. We also note the need for further clinical studies to demonstrate that the identification of individuals with higher viral loads will be of benefit in interrupting transmission.

Implications of all the available evidence

Our data indicates that LFDs for COVID-19 have performance characteristics attractive for the UK mass testing program. Ongoing iterative evaluation of the population-level roll-out of LFDs in reducing transmission of COVID-19, and the contribution of such tests to reducing the risk of morbidity and mortality for clinically vulnerable individuals, is desirable. Further work is required to determine the amount and content of “training” to derive optimal test performance.


125
100
75
50
25
0
Number of Individuals
1
.9
.8
.7
.6
.5
.4
.3
.2
.1
0
Proportion Ag Positive
RNA copies/ml
Cycle Threshold (CT)
<100
>34.0
100-1,000
31.0-34.5
1,000-10,000
28.0-31.0
10,000-100,000
25.0-28.0
0.1-1 million
21.5-25.0
1-10 million
18.0-21.5
>10 million
<18.0
Overall
Ag Negative
Ag Positive


Proportion Ag Positive
1
.9
.8
.7
.6
.5
.4
.3
.2
.1
0
Self-Trained (214/372)
Fully-Trained HCW (156/223)
Laboratory Scientist (156/196)
Overall (526/793)