OGUK

COVID-19 Testing

Technical Note

03
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Acknowledgments

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List of Abbreviations

Abbreviations	Definitions
CT	Cycle threshold
LAMP	Loop-mediated isothermal amplification
PCR	Polymerase Chain Reaction
PHE	Public Health England
PHS	Public Health Scotland
RDT	Rapid Diagnostic Testing
WHO	World Health Organisation

Introduction

The information below is correct on the date shown and is intended to provide a brief overview of the Covid-19 testing landscape.

This is a rapidly changing marketplace, with new and emerging technologies being developed at a fast rate. Therefore, we cannot guarantee that the information in this document is current, although we will endeavour to keep it relevant and up-to-date.

It is worth noting that, for the most part, the following technologies were developed for diagnosis of Covid-19 for those displaying symptoms, and not for use as part of a general screening program.

The UK Government has a National technical validation process for manufacturers of SARS-CoV-2 (Covid-19) tests, and the results of the validation process can be found on their website:

https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/coronavirus-covid-19-serology-and-viral-detection-testing-uk-procurement-overview#publication-of-results

The OGUK guidance on pre-mobilisation testing within the Oil & Gas industry has now been published, and can be found here: https://oilandgasuk.co.uk/product/covid-19-testing-guidelines/ .

1 Operation Moonshot

It is likely that some of the following technologies are being assessed by UK Government as part of Operation Moonshot. If the trials are successful, the technologies could be considered as validated and therefore a preferred option for a testing regime, however, availability of the validated technologies may be an issue due to Government demand.

Operation Moonshot acknowledges the limitations of the trial. In reference to the non-PCR tests, it is repeatedly noted that "new types of test are likely to be less accurate [than PCR], introducing some level of risk." In terms of how testing would affect behaviour, the documents say that regular testing "might make people behave in safer ways, by building covid-safe routines into their daily lives, or less safely by giving false a degree of comfort."

However, the documents also say, "We will need to take some risks, experiment and evaluate carefully, and find out what works and what does not."

2 PCR laboratory testing

PCR laboratory testing is available to all symptomatic individuals, or symptomatic member(s) in the household of an asymptomatic 'key workers', via the NHS testing programme, or if directed to do so via email, text or phone call by "test and protect".

Some Operators are choosing to include pre-mobilisation PCR laboratory testing of asymptomatic individuals as one of their barriers for prevention of COVID transmission on an offshore installation.

3 Rapid Diagnostic Testing

The WHO released a statement recommending RDT is not used except for in a research setting.

WHO statement regards emerging technologies (rapid testing kits)

"At present, based on current evidence, WHO recommends the use of these new point-of-care immunodiagnostic tests only in research settings. They should not be used in any other setting, including for clinical decision-making, until evidence supporting use for specific indications is available.

Based on experience with antigen-based RDTs for other respiratory diseases such as influenza, in which affected patients have comparable concentrations of influenza virus in respiratory samples as seen in COVID-19, the sensitivity of these tests might be expected to vary from 34% to 80%."

This statement was released in April 2020 and has been updated to reflect changes in technology.

However, the WHO have also approved rapid diagnostic tests for procurement and use in Africa under their Emergency Use listing. The rapid antigen tests are an addition to PCR tests, not a replacement for them, and WHO recommends tests that are above 80% accurate. They are more reliable in patients who are symptomatic, with a high viral load, or a lot of virus in their upper respiratory tract.

A statement from PHE clarifies their position on their evaluation of COVID-19 tests, which is that although they may evaluate products, they do not provide accreditations of any testing laboratories or provide approvals, validations or endorsements of any particular products including any COVID-19 diagnostic assay.

3.1 Rapid diagnostic testing summary

Make & model	Technology	Time	Claimed Sensitivity*	Claimed Specificity*	Sample type
Randox Vivalytic	PCR	2.5 hours	98%	100%	Nose or throat swab
DnaNudge	PCR	1 hour	95%	100%	Nose swab
VitaPCR	PCR	20 minutes	95%	Unknown	Nose or throat swab
Samba ii	PCR	Under 90 minutes	98.7%	100%	Nose or throat swab
NADAL COVID-19 Rapid Test	PCR	15 minutes	97.56%	99.9%	Nose or throat swab
Optigene Genie HT	LAMP	20 minutes	Unknown	100%	Saliva or nose / throat swab
Nanopore LamPORE	LAMP	Under 2 hours	99.1%	99.6%	Saliva
Oxsed Ravid (Prenetics)	LAMP	20 seconds	100%	100%	Nose or throat swab
FRANKD (Geneme)	LAMP	30 minutes	97%	100%	Nose or throat swab
SD Biosenser	Non-machine lateral flow	Within 15 minutes	Unknown	Unknown	Saliva / swab
Innova Tried and Tested	Non-machine lateral flow	Within 15 minutes	96%	100%	Nose or throat swab
Healgen Antigen Rapid Test	Non-machine lateral flow	Within 15 minutes	Unknown	Unknown	Nose swab
Abbott Panbio	Non-machine lateral flow	Within 15 minutes	91.4%	99.8%	
Virolens	Holographic imaging	20 seconds	99.8%	96.7%	Saliva swab

3.2 Rapid diagnostic testing - PCR

3.2.1 Randox Vivalytic RDT (in collaboration with Bosch)

Link

Turnaround time: 2.5 hours

Claimed* sensitivity: 98%

Claimed* specificity: 100%

Sample type: Nose or throat swab

PHE have assessed the Randox Vivalytic RDT. The assessment is in no way a validation or endorsement of the RDT, therefore this RDT remains unvalidated by UK Government. The unit is mobile and can perform up to ten tests in 24 hours.

Also tests for nine other respiratory viruses.

3.2.2 DnaNudge / NudgeBox Analyser RDT

Link

Turnaround time: one hour

Claimed* sensitivity: 95%

Claimed* specificity: 100%

Sample type: Noes or throat swab

The device has been given MHRA (Medicines and Healthcare products Regulatory Agency) approval under “Medical devices given exceptional use authorisations during the COVID-19 pandemic”.

Currently being used across eight London hospitals.

Further assessment information has been published in The Lancet. Note that this Lancet study was predominantly in *symptomatic* patients (n=295) and a small (less than 91, precise number not stated) number of asymptomatic hospital patients. Symptomatic patients of course have a much higher pre-test probability of having Covid-19.

3.2.3 VitaPCR

Link

Turnaround time: 20 minutes

Claimed* sensitivity: $\geqslant$ 95%

Claimed* specificity: Unknown

Sample type: Nose or throat swab

No information could be found about its current validation journey.

3.2.4 Samba II

Link

Turnaround time: Under 90 minutes

Claimed* sensitivity: 98.7%

Claimed* specificity: 100%

Sample type: Nose or throat swab

Developed by University of Cambridge, the University website states that the test has been validated by PHE, although evidence of the validation has not been viewed by OGUK. The technology is an in vitro nucleic acid amplification test for the qualitative detection of SARs-CoV-2 in human nasal and throat swabs.

3.2.5 Nadal Covid-19 Rapid Test

Link

Turnaround time: 15 minutes

Claimed* sensitivity: 97.56%

Claimed* specificity: 99.9%

Sample type: Nose or throat swab

No information could be found about its current validation journey.

3.3 Rapid Diagnostic Testing - LAMP

3.3.1 Optigene (Genie HT)

Link

Turnaround time: 20 minutes

Claimed* sensitivity: No information found

Claimed* specificity: No information found

Sample type: Saliva or nose / throat swab

A UK Government trial of an RDT developed by Optigene (Genie HT) began in May, using LAMP (loop-mediated isothermal amplification) instead of PCR technology. Validation for the LAMP test using RNA extract has already been carried out in a clinical setting at Hampshire Hospitals NHS Trust. The trial was taking place in Hampshire and was running for 6 weeks (completed in July 2020) and has now entered phase 2.

Optigene advise that they can only supply existing customers due to high demand. They advise that the Genie HT requires a trained operator in a controlled environment. It is NOT a lateral flow device or designed to be used by the general public.

Recent news articles (November 2020) state that Scientists with Greater Manchester's mass testing expert group (MTEG) raised significant concerns about the accuracy of the OptiGene Direct RT-Lamp tests this week, and said the technology should not be widely used as intended in hospitals or care homes.

3.3.2 Nanopore LamPORE

Link

Turnaround time: Under two hours for between 1-96 samples

Claimed* sensitivity: 99.1%

Claimed* specificity: 99.6%

Sample type: Saliva

LamPORE saliva test assay can be read by two devices; minION and gridION; these devices are of different size and sample analysis capability.

As well as targeting three specific genes of the SARS-CoV-2 virus, a control target (actin) is included in the assay. This acts as confirmation of successful collection of human cell material, and if not detected implies a sample collection error rather than absence of the virus as an explanation for a negative result.

3.3.3 Oxsed Ravid (recently purchased by Prenetics)

Link

Turnaround time: 20 seconds

Claimed* sensitivity: 100% sensitivity in extracted RNA and at 92% as a direct swab, without RNA extraction.

Claimed* specificity: 100%

Sample type: Nose or throat swab

Developed by Oxford University, Oxsed RaVid Direct is a rapid nucleic acid amplification test (NAAT) utilising patent-pending OxLAMP technology. The website states that the technology is peer reviewed and validated, but provides no details of who has conducted the peer review or validation.

3.3.4 FRANKD (Geneme)

Link

Turnaround time: 30 minutes

Claimed* sensitivity: 97%

Claimed* specificity: 100%

Sample type: Nose or throat swab

Part of the Heathrow Airport testing trials, FRANKD is RT-LAMP NAAT (Nucleic Acid Amplification Test).

*'Claimed' – the figures given here are those quoted in product literature and/or websites by manufacturers, typically on 'contrived' specimens in small numbers. As is clearly implied by the SAGE Task and Finish group on Mass Testing (para 18) here, operational (i.e. 'real-life' clinical performance) figures may well be different, and in practice this means lower.

3.4 Rapid Diagnostic Testing – non-machine lateral flow

These tests are quite simple and do not require any other equipment, they are very similar to a home pregnancy test. They do not provide CT values and do not currently publish details of sensitivity or specificity.

3.4.1 Completed / nearly completed UK Government validation process

- Innova Tried and Tested SARS-Cov-2 antigen test
- Healgen Coronavirus antigen rapid test (passed phases 1&2, phase 3 underway)

3.4.2 Completed UK Government validation process and approved by WHO

- SD Biosensor lateral flow

3.4.3 Not being assessed by UK Government, approved by WHO

Abbott Panbio is another lateral flow device which has been approved by WHO. Their website is quite clear about the use of the technology, stating: "*For patients suspected of current COVID-19 infection… May also be useful for supporting public health strategies, such as contact tracing and large-scale testing of people suspected of having an active infection.*"

3.5 Other technologies

3.5.1 Virolens

Link

Turnaround time: 20 seconds

Claimed* sensitivity: 99.8%

Claimed* specificity: 96.7%

Sample type:

Part of the Heathrow Airport testing trials, the Virolens Covid-19 screening device uses microscopic holographic imaging and artificial intelligence (AI) software technology to detect the presence of the Covid-19 virus from a saliva swab test.

The Virolens system is a holographic microscope designed to look at nano-scale structures and look at the light diffracted off the surface of each cell in the testing sample. The outcoming data is run through a computer trained AI to identify the virus.

4 Pending technologies

- Oxford Nanoimaging
- MAP Sciences
- Avacta

5 Interpreting results

Regardless of the type of test used, the result (whether positive or negative) will require interpretation. Testing was developed for the purpose of clinical diagnosis of patients – i.e. people who are ill, with symptoms – and when tests are applied to people who are not unwell, and who do not apparently have infection, it is necessary to consider how confident we can be that the result is meaningful – how sure can we be that the result tells us what we want to know?

If we want to be sure that the person does not have infection, the key concept is 'negative predictive value (NPV)', and if we want to confirm a suspicion that someone has the virus, the key concept is 'positive predictive value (PPV)'. This is why sensitivity and specificity are important, because these technical aspects of the test are part of the calculation of NPV and PPV. NPV and PPV can be used to answer the questions 'how confident can I be that this negative test means the person really does not have infection?' and 'how confident can I be that this positive test means the person really does have the virus?'

It is obviously important that the assumptions made about sensitivity and specificity of the test are as accurate as possible, but the other important concept in calculating NPV and PPV is the 'pre-test probability' that the person has infection. In simple terms, during a 'wave' of infection, with many people being admitted to hospital, pre-test probability will be higher than between 'waves', when far fewer cases are apparent. The 'pre-test probability' of infection makes a significant difference to interpretation of results, even when sensitivity and specificity remain the same.

These concepts are well understood from screening programmes for breast and bowel cancer for example, and the clinician with overall responsibility for a screening programme for any condition, including Covid-19, should be well able to explain the effect of changes in sensitivity, specificity and pre-test probability in interpreting test outcomes, and should be able to calculate and explain NPV and PPV for test results.

6 Antibody testing

Dr Gregor Smith (Chief Medical Advisor for Scottish Government) has advised health boards not to offer on-demand antibody testing.

7 COVID-19 Study

OGUK are collaborating with the London School of Hygiene and Tropical Medicine in order to undertake a review of barrier health in terms of its impact on reducing COVID-19 infections risks on offshore asset.

Preliminary findings are inconclusive, mainly due to a lack of data. It has been recommended by the PSG Testing Subgroup that the study continues with a renewed effort to collect more data.

Appendices

A Testing processes – summary

	Home test kit		Test at embarkation point	Test at test centre	Test offshore		Antibody test
Symptoms?	No	Yes	No	Yes	Yes or No	Yes	No
National testing programme?	No	Yes	No	Yes	No	Yes	No
Technology	LAMP or PCR Laboratory	LAMP or PCR Laboratory	LAMP, PCR or non-machine lateral flow Laboratory or PoC	PCR Laboratory	LAMP, PCR or non-machine lateral flow PoC	PCR Laboratory	
	• Kit sent to individuals home 7 days prior to trip • Relies on individual taking sample correctly • Sample returned to private lab	• Available to those with symptoms or if otherwise instructed by T&T • Kit relies on appropriate testing technique	• For all asymptomatic personnel (symptomatic personnel should not be at embarkation point) • Testing may be via lab, in which case personnel need to isolate in hotels / accommodation, or via PoC, in which case personnel need to isolate until result is known.	• Available to those with symptoms or if otherwise instructed by T&T	• Could be used in assessment of Cat C to contribute to diagnosis. Or could be used for asymptomatic testing of personnel on installation.	• Could be used offshore with sample sent back to onshore lab for rapid turnaround • Can be used by Cat C cases on return to onshore (local to heliport)	• Not in common use and mainly reserved for research • Blood sample required • Evidence to suggest immunity decay over time • Only informs that individual has been infected in past • Does not inform whether a person is infectious • Does not indicate immunity to future infection

B Revision Tracker

Issue	Change
Issue 2 August 2020	Transfer onto formal OGUK Technical Note template
	Addition of VitaPCR PCR RDT
	Addition of Nanopore LamPORE LAMP RDT
Issue 3 November 2020	Addition of "Operation Moonshot" section 1.
	Removal of 1.1 – PCR Saliva Testing
	Reconfiguration of document to split into different testing types
	Addition to Section 3 on WHO approval of diagnostic tests and additional information on PHE statement on test validation
	Addition of Summary table at section 3.1
	Addition of Samba ii, Nadal, Optigene, Oxsed Ravid and Frankd Geneme tests
	Addition of section on Non-Machine Lateral Flow tests at section 3.4
	Addition of Other Technologies at section 3.5
	Addition of Interpreting Results at section 5.0
	Update of Covid study progress
	Addition of Appendix A – testing overview
	Addition of Appendix B – Revision Tracker

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