NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Assessment Programme

Exploratory economic modelling of SARS-CoV-2 viral detection point of care tests and serology tests

Final scope

July 2020

1 Introduction

The Department of Health and Social Care (DHSC), NHS England and NHS Improvement requested support from NICE to do exploratory economic modelling of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral detection point-of-care tests and serology tests. This was approved by NICE's senior management team. A systematic review on the diagnostic accuracy of different point-of-care viral tests and serology tests will not be done in this assessment. The economic modelling is deemed to be exploratory because it will not result in guidance on specific tests at this stage.

The final scope was informed by discussions at the scoping workshop held on 2 July 2020. A glossary of terms and a list of abbreviations are provided in appendices A and B.

2 Description of the technologies

The focus of this project is to undertake exploratory economic modelling of hypothetical SARS-CoV-2 viral detection point-of-care (POC) tests and serology tests, to identify the parameters that are most influential on cost-effectiveness modelling results. The assessment will include modelling of the Medicines and Healthcare products Regulatory Agency's (MHRA) target product profiles (TPP) rather than particular tests, which will allow the utility of various use cases to be explored. The TPPs outline the desired profile or characteristics of the COVID-19 tests. This assessment should help inform DHSC's, NHS England and NHS Improvement's COVID-19 diagnostic strategy, and the need for further research or audit commissioning on key data that are missing or found to be highly uncertain. The assessment will provide a framework to enable accelerated evaluation of such tests in the future for guidance development.

This section describes the purpose and potential properties of the hypothetical diagnostic technologies based on information provided to NICE by experts. NICE has not carried out an independent evaluation of this description.

2.1 Purpose of the medical technologies

2.1.1 Viral detection tests

Pillars 1 and 2 of the UK government testing strategy aim to increase viral testing capacity in the NHS and other sectors. Currently, diagnostic testing for the coronavirus disease (COVID-19) is largely reliant on laboratory-based tests which can have a turnaround time of several days. This means a person who has COVID-19 may not know their result for some days and may continue to spread the virus if they do not isolate.

The COVID-19 pandemic poses a capacity challenge for laboratory-based virus detection. POC viral detection tests for SARS-CoV-2 are intended to be rapid detection tests for SARS-CoV-2 virus, the causative virus of COVID-19. Accurate point-of-care viral detection tests can potentially increase testing capacity outside the laboratory, reduce time to obtain results and support early identification of at least some infected persons. Subsequently, asymptomatic, or mildly symptomatic people can self-isolate to avoid the spread of the virus and those with severe symptoms can be treated in an appropriate healthcare setting. As part of NHS Test and Trace contact tracing can be used to identify people who may be at risk of having the virus because of exposure to someone infected with SARS-CoV-2. Routine testing of frontline and key workers may reduce hospital or community acquired infection. People who work in safety critical environments, for example oil rigs may need routine testing.

2.1.2 Serology tests

Pillar 3 of the UK government testing strategy aims to promote antibody testing. A SARS-CoV-2 serology test can be used to determine if someone has previously been exposed to SARS-CoV-2 and now has antibodies against the virus. The serology test may be useful to identify people who have recovered from SARS-CoV-2 infection that was suspected but not confirmed by a viral detection test, or who may have had asymptomatic COVID-19. It will potentially also be positive in people who have recovered from SARS-CoV-2 infection that was confirmed by a viral detection test, and in people who have been vaccinated against SARS-CoV-2. The serology test may be used to identify potential donors of convalescent plasma for COVID-19. It is currently unclear if a previous COVID infection provides any level of future immunity. If the SARS-CoV-2 antibodies provide immunity, it is not certain how long this

immunity will last and how this should influence government's decisions on social distancing.

2.2 Product properties

2.2.1 Viral detection tests

Conventional laboratory-based tests for detecting SARS-CoV-2 identify viral ribonucleic acid (RNA) or antigens in samples collected through nasal or throat swabs or saliva. POC viral tests may amplify genetic material using technologies such as loop-mediated isothermal amplification (LAMP) reaction or other methodologies. The likelihood of detecting SARS-CoV-2 may depend on the time and location from which the test sample is collected. A study by Zou L et al. (2020) suggests that nasal swabs may have higher viral load than throat swabs and that viral load may be elevated shortly after onset of symptoms. In contrast, results of a modelling analysis undertaken by He X et al. (2020) suggests that infectiousness starts 2.3 days before the onset of symptoms and reaches its peak at 0.7 days before onset of symptoms. The proportion of pre-symptomatic transmission was 44%.

The expected performance of POC viral detection test that will be used in the exploratory economic modelling will be based on the TPP set out by MHRA (Table 1). In the current TPP for point of care SARS-CoV-2 detection tests, the intended use of testing is to aid in triage of current SARS-CoV-2 infection. Clinical experts commented that the POC viral detection tests can also be used to diagnose COVID-19 if the test performance is good enough.

The TPPs will be reviewed and potentially updated as more information is gathered about COVID-19.

Assays are being released that test for SARS-CoV-2 and other potential causes of respiratory illness (for example, other coronaviruses, influenza, respiratory syncytial virus [RSV] etc.) to help provide a differential diagnosis. This functionality may provide reassurance that a negative SARS-CoV-2 result for someone with symptoms suggestive of the condition is not a false negative if the test is positive for another potential cause.

Table 1 Target product profile point of care SARS-CoV-2 detection test

Test	Sample type (Desired)	Sample type (Acceptable)	Analyte (Desired)	Analyte (Acceptable)	Time to result (Desired)	Time to result (Acceptable)	Clinical (diagnostic) sensitivity (or Positive Percent Agreement) (Desired)	Clinical (diagnostic) sensitivity (or Positive Percent Agreement) (Acceptable)	Clinical (diagnostic) specificity (or Negative Percent Agreement) (Desired)	Clinical (diagnostic) specificity (or Negative Percent Agreement) (Acceptable)
POC test	Sputum, saliva or other method not using invasive swab	Nasopharyngeal or oropharyngeal swabs, lower respiratory tract aspirates, bronchoalveolar lavage, nasopharyngeal wash/aspirate or nasal aspirate	Dual (or more) SARS-CoV-2 RNA or antigen targets	Single SARS-CoV-2 RNA or antigen target	<30 minutes from sample to result	<2 hours from sample to result	> 97% (within 95%CI of 93-100%)	> 80% (within 95%CI of 70 - 100%)	>99% (within 95%CI 97-100%)	>95% (within 95%CI 90-100%)

TPP last accessed on 6 July 2020

2.2.2 Serology test

Serology tests for SARS-CoV-2 are intended to detect the presence of antibodies (IgG or total antibodies [IgG, IgA, IgM]) specific to SARS-CoV-2. Currently these tests can be done in a laboratory. Public Health England (PHE) has published laboratory evaluations of serological assays. The test may also be done as POC which could potentially be useful if wider testing is to be implemented. The MHRA has published TPPs for serology POC tests, self-tests and laboratory tests which specify desired and acceptable characteristics of the tests. There is currently a temporary ban by MHRA on laboratory-based COVID-19 antibody testing services using capillary blood collected by a fingerprick, until home collection of this sample type has been validated. Some of the test performance and features of the serology tests specified in the TPPs are highlighted in table 2.

Table 2. Target product profile of serology tests for SARS-CoV-2

Test	Sample type (Desired)	Sample type (Acceptable)	Analyte (Desired)	Analyte (Acceptable)	Time to result (Desired)	Time to result (Acceptable)	Sensitivity*	Specificity**
POC or near patient test	Capillary whole blood from fingerstick sample or venous blood, serum or plasma	Capillary whole blood from fingerstick sample	IgG antibodies	Total antibody (IgA, IgM and IgG)	≤ 15minutes	≤ 20 minutes	>98% (with 95%CI of 96-100%)	>98% (within 95%CI 96-100%)
Self-test	Capillary whole blood from fingerstick sample	Capillary whole blood from fingerstick sample	IgG (neutralising antibodies)	Total antibody (IgA, IgM and IgG)	≤ 5 minutes	≤ 20 minutes	>98% (with 95%CI of 96-100%)	>98% (within 95%CI 96-100%)
Enzyme Immunoassay (laboratory based)	Whole blood, plasma and serum	Whole blood, plasma and serum	IgG antibodies	Total antibody (IgA, IgM and IgG)	Not known	Not known	>98% (with 95%CI of 96-100%)	>98% (within 95%CI 96-100%)

* On specimens collected 20 days or more after the appearance of first symptoms. Statistics are based on testing of at least 200 confirmed positive cases.

** Statistics are based on testing of at least 200 confirmed negative cases or from testing of specimens collected at least 6 months before the known appearance of the virus.

TPPs last accessed on 6 July 2020

3 Target condition

COVID-19 is an infectious disease caused by a novel coronavirus, known as SARS-CoV-2 virus. Common symptoms of COVID-19 include a high temperature, a new, continuous cough or a loss or change of normal sense of taste or smell. Symptoms may be mild in some people and others may have no symptoms. However, other people may have severe symptoms (including shortness of breath, chest pain, loss of speech or movement) and may become very unwell, developing severe pneumonia. Less severe forms of the disease may also remain for a long time and be associated with a long recovery phase for some people. COVID-19 disease is associated with a significant mortality rate. According to the Office for National Statistics, 180,586 people died in England and Wales between 1 March and 31 May 2020. Around 25% of these deaths were linked to COVID-19. People with compromised immune systems or underlying medical conditions such as hypertension, kidney disease and diabetes and the elderly are most likely to become very unwell and have the greatest risk of adverse outcomes. SARS-CoV-2 can spread when droplets from saliva or nasal discharge move from an infected person to susceptible mucosal surfaces of a recipient or from contaminated surfaces or objects (NHS website, WHO website).

Although some common symptoms of COVID-19 are known, they may not be particularly discriminatory. Findings from a recent study suggest that the full spectrum of symptoms have not been characterised and that there may be a case for prioritising testing in people with multiple or complex symptoms Drew (2020).

4 Use cases

There are likely to be many potential different uses of the POC viral detection tests in a variety of settings (for example, care homes with or without nursing, ambulance, primary or secondary or community dental care, general practice, prison, hospital, hospital-at-home, hospice, work places, independent laboratory, general public). Within the National Institute for Health Research's (NIHR's) COVID-19 National Diagnostic Research and Evaluation Platform (CONDOR) programme, the Newcastle and Leeds NIHR MedTech and In vitro diagnostics Co-operatives (MICs) undertook a survey across the UK to identify important use cases for diagnostic testing of COVID-19 in various settings. Table 3 summarises use cases identified from the survey and additional use cases discussed at the scoping workshop. These use cases will be considered in the exploratory economic modelling. Following the scoping workshop stakeholders were asked to prioritise settings to be modelled. Results of the poll showed that hospitals and care homes were the top priorities.

Table 3. Uses of POC viral detection

Setting	Use case
Hospital	A test for: • People presenting to or being admitted to hospital (for example, in emergency department, critical care): o without symptoms COVID-19 o with symptoms of COVID-19 or multiple respiratory illnesses (for example, Flu A, Flu B, RSV, SARS-CoV-2) • People about to have surgery (for example, heart surgery or transplant) • Symptomatic or asymptomatic staff that have had contact with someone with confirmed COVID-19 • In-patients who develop new clinical features of COVID-19 during their hospital stay (for example in critical care wards) • Informing safe return to work (for hospital staff) • At discharge to other care setting (for example care home or hospice)
Care home	A test for: • Newly admitted residents • Symptomatic or exposed asymptomatic staff that have had contact with someone with confirmed COVID-19

	• Asymptomatic care home residents that have had contact with someone with confirmed COVID-19 • Symptomatic care home residents
Dental care	A test for: • Asymptomatic patients to support safe attendance at urgent dental appointments to guide the appropriate use of PPE and aerosol generating procedures • Asymptomatic patients to support safe attendance at routine dental appointments • Symptomatic and asymptomatic staff that have had contact with someone with confirmed COVID-19 • Informing safe return to work for staff with confirmed COVID-19
General practice	A test for • Differential diagnosis in people with respiratory symptoms • Symptomatic or asymptomatic staff that have had contact with someone with confirmed COVID-19 • Symptomatic patients presenting to a general practice
Prison	A test for: • Symptomatic or asymptomatic prisoners who have had contact with someone with confirmed COVID-19 • Newly admitted prisoners to prevent transmission to existing prisoners

	• Symptomatic and exposed asymptomatic staff
Schools and colleges	Specific use cases yet to be defined at time of writing.
Points of departure and entry (for example airports)	Specific use cases yet to be defined at time of writing.
Community	A test for: • People who develop COVID-19 symptoms after being told to isolate by the test and trace services • People entering a closed environment, in close proximity to others (for example an oil rig) • Testing in local outbreaks

If used for triage, pending the result of a confirmatory laboratory test, people with positive results are asked to isolate at home or receive appropriate care in a health care setting depending on how severe their symptoms are. People with a negative result would not need to isolate if the negative predictive value of the test is high enough. False positive results may lead to unnecessary quarantine, hospitalization, over-use of personal protective equipment and other resources. It could also result in putting patients without COVID at risk of transmission by cohorting with COVID patients. False negative results mean there is a risk of further spread of the virus.

In the winter season, when circulation of respiratory pathogens increases, POC viral detection tests may have a useful role to play in the differential diagnosis of other respiratory conditions which have similar symptoms to COVID-19, however this use case is outside the current TPP for POC viral detection.

Serology tests may have utility in detecting antibodies that signify previous exposure to SARS-CoV-2. If antibodies provide a significant level of immunity, then people with positive results may not need to observe strict social distancing rules, or self-isolate whenever they have been exposed to an infected person. There is currently limited evidence to support the existence or persistence of antibody derived immunity to SARS-CoV-2. A Public Health England study called SIREN is underway which will help to establish whether antibodies indicate immunity to COVID-19. There is a growing body of evidence to suggest that some people may have pre-existing antibody or T-cell derived immunity to SARS-CoV-2. This means that a negative SARS-CoV-2 specific antibody test may not mean that a person has no immunity. Clinical experts commented that serology tests may have a role in detecting response to vaccines, identifying potential convalescent plasma donors and for retrospective contact tracing.

4.1 Diagnostic and care pathway

COVID-19 can be managed in a variety of settings. NHS England and NHS Improvement have produced coronavirus guidance for clinicians and NHS managers working in primary and secondary care, and community-based health, social care, mental health trusts and ambulance services. NICE has produced rapid guidelines making recommendations to help manage COVID-19 symptoms, complications and conditions that increase risk of poor outcomes and for the optimal delivery of services during the COVID-19 pandemic.

PHE published COVID-19 guidance for sampling and for diagnostic laboratories. Samples required for the initial diagnostic test according to the

guidance include upper respiratory tract samples (single swab for the throat then nose into one pot of viral transport medium or a nose swab and a throat swab combined into one pot of viral transport medium) or sputum. In addition, serum samples will be collected from people on hospital admission for serology testing. The turnaround time for laboratory tests could mean that, if a person is infected appropriate decisions on isolation or transfer from a hospital holding ward or contact tracing may not be made on time thereby putting more people at risk of getting infected. POC diagnostic tests may be useful in providing rapid results thereby leading to benefits in terms of resource use, for example, people can move out of holding wards quicker to a COVID-19 ward or a non-COVID-19 ward depending on test results and at risk contacts can be traced quickly thereby reducing transmission rates. In addition, PPE can be used appropriately.

4.2 Patient issues and preferences

People who have false negative viral detection results may be falsely reassured that they do not have the virus and they may go on to infect other people. Whereas people with false positive results may feel anxious about having the virus and could unnecessarily isolate or quarantine or cohort with infectious people, potentially leading to lost productivity and reduced quality of life.

A false positive antibody test may give a false reassurance to people who will think they have immunity and may make decisions based on this false information, potentially putting themselves and others at risk of COVID-19 infection. The same is true for true positive results if the antibody does not confer immunity or if the immunity wanes over time. A false negative result could result in people continuing to restrict social interactions unnecessarily (if the test result does give an indication of immunity), which could potentially result in reduced productivity and quality of life.

5 Comparators

The comparators for the economic modelling of POC viral detection tests are the use of laboratory-based assays only as part of a strategy to detect SARS-CoV-2 or no testing (depending on the use case for POC testing being assessed and current practice) (table 4). The laboratory-based assay used for SARS-CoV-2 will differ between sites, as will the time taken to get results from a laboratory based assay (in terms of how long the assay takes to run and time taken to get the assay to a laboratory for testing).

For serology tests the comparator strategies will be no testing or laboratory based serology testing for serology POC and self-test (table 5).

6 Scope of the assessment

Table 4 Scope of the assessment: point of care viral detection

Decision question	What is the clinical and cost-effectiveness of the point-of-care testing to help detect SARS-CoV-2?
Populations	People with COVID-19 symptoms (that is, fever, new or persistent cough and loss or change of sense of taste and smell) or people who are asymptomatic . If data are available, the following subgroups will be included: • Older people • People with compromised immunity • People with underlying health conditions • People with chronic lung conditions • People with learning disability • Children • People from black and south asian family origin
Intervention	Strategies that involve the use of point-of-care viral detection test for SARS-CoV-2, which can be used alone or in conjunction with confirmatory laboratory-based testing
Comparators	Strategies that do not involve the use of point-of-care viral detection tests for SARS-CoV-2, that involve: - Laboratory based testing - No testing
Settings	• Hospital • Care homes and other residential facilities • Dental care • General practice • Prison • Points of departure and entry (for example airports) • Schools and colleges • Workplaces • Community
Outcomes (which may be impacted on by use of POC viral tests)	• Diagnostic accuracy / concordance with laboratory based testing • Time to result • Test failure rate • Uptake of testing • Diagnostic yield • Number of tests done per hour/day

	• Length of stay in hospital (to include delays to discharge to care homes while waiting for COVID-19 test result) • Length of stay in isolation/holding ward with suspected COVID-19 (in hospital, care home, prison) • Time to definitive bed placement from admission to hospital • Number of admissions • Antibiotic use • Length of time self-isolating/not going to work • Number of people in contact with someone with COVID-19 • Number of people with COVID-19 / rate of transmission of COVID-19 • Capacity of isolation/holding wards • Closure of (all or part of) hospitals, care homes, dentists, GP practice, prisons • Number of people contacted by contact tracing • Impact of POC testing on decision to - Isolate - Cohort - Escalate care - De-escalate care - Discharge - Return to work - Use PPE
	Clinical outcomes for consideration may include: • Mortality • Morbidity
	Patient-reported outcomes for consideration may include: • Usability of test kits • Behaviour modification, for example decisions about social interactions • Health-related quality of life
	Costs will typically be considered from an NHS and Personal Social Services perspective. Costs for consideration may include: • Cost of testing (request, consumables, delivery and collection of test kits) • Cost of personal protective equipment • Staff time and training • Costs of confirmatory test • Cost associated with resource use, such as length of hospital stay (which will vary between hospital settings) and treatment

	The cost-effectiveness of interventions should be expressed in terms of incremental cost per quality-adjusted life year. Other model outputs which may be relevant are the impact of viral POC tests (compared to comparator) on: • Time in isolation ward/single occupancy room etc. (especially for people without COVID-19) • Time in self-isolation/off-work (especially for people without COVID-19) • Ward capacity • Number of people with COVID-19 • Time to definitive bed placement from admission to hospital • Volume of PPE use
Time horizon	The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

Table 5 Scope of the assessment: serology tests

Decision question	What is the clinical and cost-effectiveness of antibody serology testing?
Populations	• People who have recovered from suspected SARS-CoV-2 infection • People who may have had asymptomatic SARS-CoV-2 infection • People who have been vaccinated against SARS-CoV-2 If data are available, the following subgroup will be included: • Older people • People with compromised immunity • People with underlying health conditions • People with chronic lung conditions • People with learning disability • Children • People from black and south asian family origin
Intervention	Serology tests to detect IgG or total antibodies (IgG, IgA, IgM) specific to SARS-CoV-2, that can be used as: • Point-of-care or near patient test • Self-testing • Laboratory based enzyme immunoassay

Comparators	For laboratory based testing: • No testing For serology POC and self-tests: • Laboratory based testing • No testing
Setting	• Hospital • Care homes and other residential facilities • Dental care • GP • Prison • Points of departure or entry (for example airports) • Schools and colleges • Workplaces • Community
Outcomes (which may be impacted on by use of serology tests)	• Diagnostic accuracy • Time to result • Test failure rate • Uptake of testing • Diagnostic yield • Number of tests done per hour/day • Proportion of population who have been infected – useful for public health surveillance
	Clinical outcomes for consideration may include: • Impact of antibodies on immunity
	Patient-reported outcomes for consideration may include: • Behaviour modification, for example decisions about social interactions • Usability of test kits • Health related quality of life
	Costs will typically be considered from an NHS and Personal Social Services perspective. Costs for consideration may include: • Cost of testing (test kits, request and delivery of test kits) • Cost associated with resource use • Staff time and training • Wider societal costs associated with government policy on social distancing may be considered
	The cost-effectiveness of interventions should be expressed in terms of incremental cost per quality-adjusted life year.

	Other model outputs related to use of the tests may also be beneficial for committee decision-making, depending on the use case assessed.
Time horizon	The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

7 Other issues for consideration

While no review of the diagnostic accuracy of specific commercially available tests will be done in this assessment, most evidence for POC tests identified during scoping assessed the assay concordance between point-of-care test and laboratory-based test results rather than the clinical sensitivity and specificity. The assay concordance provides information about the overall percent agreement and the positive and negative percent agreement of both tests. When laboratory tests and POC tests are discordant, for example if point-of-care is positive and the laboratory test is negative, further analysis may be required to check if the laboratory test has missed a case. Laboratory-based RT-PCT has been said to have a high false negative rate (Li et al 2020), meaning some cases may be missed.

NICE's reference case for assessing health technologies takes the perspective of the NHS and personal and social services, societal impacts are not considered. However, it may be important that modelling studies show the impact of COVID-19 testing on societal outcomes (for example, employment and productivity). Clinical experts highlighted the importance of considering the impact of testing on business and the wider economy.

Assessing the performance of POC tests in asymptomatic people may pose a challenge because this population may have a lower viral load and available sensitivity and specificity estimates are mainly obtained from a symptomatic population whose viral load could be potentially higher.

Clinical experts commented that the throughput of some viral POC tests is low, which may limit their use when large volumes of testing are needed. Economic modelling should consider the impact of POC viral test throughput in assessment of this technology.

POC testing offers a potential advantage over centralised laboratory-based testing because results are available quicker. However, how much quicker (and the amount of any benefit from this) will depend on how long it takes to get result back from laboratory-based testing. This is likely to vary between

settings and between sites. This likely variation should be considered in the economic assessment.

The prevalence of COVID-19 will change overtime, and this may mean that POC tests will only be cost effective (using NICE's standard perspective) when viral prevalence exceeds a certain level.

Considerations around study design and reference standards to assess diagnostic accuracy can be found in the diagnostic test evidence standards framework.

8 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

People over 65, people with underlying health conditions, men, black people and people from Bangladeshi or Pakistani family origin are disproportionally affected by COVID-19 (Beyond the data: Understanding the impact of COVID-19 on BAME groups). Pregnant women with significant heart disease may be at increased risk of adverse outcomes because of COVID-19, and those in the third trimester should minimise social contact with others. Age, disability, sex, race and pregnancy are protected characteristics under the Equality Act (2010).

In this project we will be examining some target product profiles and use cases that have a wider economic perspective than the standard NICE reference case. Factors referred to in the PHE report 'Beyond the Data' may therefore be relevant. This could include where individuals from BAME groups are more at risk through working in occupations with a higher risk of COVID-19 exposure (including in the NHS or social care); or where discriminatory practices might lead them to be placed at higher risk.

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Appendix A Glossary of terms

Convalescent plasma
Convalescent plasma is the antibody-rich plasma of someone who has recovered from a virus, in this case COVID-19

COVID-19
COVID-19 is a disease caused by a new strain of coronavirus (SARS-CoV-2)

Diabetes
Diabetes is a condition in which blood glucose level is too high

Hypertension
Hypertension is a condition in which the blood vessels have persistently raised pressure

Point of care testing
A diagnostic test performed near to or at the site of patient care

SARS-CoV-2
SARS-CoV-2 is the strain of coronavirus that causes COVID-19

Serology
Serology is the diagnostic examination of blood serum

Appendix B Abbreviations

COVID-19	Coronavirus
MHRA	Medicines and Healthcare products Regulatory Agency
PCR	Polymerase chain reaction
POC	Point of care
PPE	Personal protective equipment
RNA	Ribonucleic acid
RT-PCR	Reverse transcription polymerase chain reaction
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
TPP	Target product profile

Appendix C References

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