Target Product Profile

Rapid Breath Tests for the direct and indirect detection of SARS-CoV-2

Version Control

Version	Date Issued	Description
1.0	3 March 2021	Initial Document

The purpose of a Target Product Profile "TPP"

According to the World Health Organisation (WHO), a target product profile (TPP) outlines the desired 'profile' or characteristics of a target product that is aimed at a particular disease or diseases. TPPs state intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics. Such profiles can guide product research and development (R&D).

- In industry, target product profiles (TPPs) are used as planning tools that guide development towards desired characteristics.
- In the regulatory context, TPPs are considered as tools to frame development in relation to submission of product dossiers.
- In the context of public health, TPPs set R&D targets for funders and developers.

In broader terms, a TPP outlines the characteristics a new product must have to align with the clinical need. A TPP provides a common foundation for the development of new tests and contains sufficient detail to allow device developers, and key stakeholders, to understand the characteristics a successful test should have when aligned with the intended use scenario. Included is a description of the desired and minimally acceptable profiles based on the intended use scenarios and users, with respect to the performance and operational characteristics expected of the target products. As new scientific evidence is generated, this TPP may require further review and revision.

TPPs for COVID-19

These target product profiles have been developed to assist manufacturers in designing and delivering new tests to support the UK's COVID-19 testing strategy. How closely a product matches the profile may also inform procurement and regulatory decision making. Any deviation from the acceptable criteria within this TPP must be fully justified. Aspects such as production lead time may also factor into decision making.

Intended Use Scenario for this TPP

A highly specific, rapid and easy-to-use test to identify people with SARS-CoV-2 infection, may more quickly allow for immediate implementation of isolation and other efforts to arrest transmission of the virus (for example, to rule-in i.e. identify people with virus infection rather than rule-out i.e. exclude people free from infection).

This TPP may be helpful for the following possible scenarios:

- Generally, low-risk and low prevalence (<1%) settings, such as workplaces, schools and universities, where there is a high likelihood of repeat testing (e.g. everyday).
- At large-scale events where tests may need rapid deployment in high numbers to identify positive cases (e.g. sports events, theatres).

Manufacturers should consider how their test will be used and the potential for misuse. For example, a test intended only to **find** positives should consider the potential misuse as a test to identify negative people who are free from infection.

This TPP is **not** for tests for other purposes, such as in the following possible scenarios:

- Testing to 'enable' (identifying true negative cases).
- Point of care tests to be performed by a health professional in a healthcare setting.
- Self-tests to be performed by a lay individual.
- Rapid laboratory tests to augment clinical laboratory capacity and turnaround time.

- Provide a confirmatory diagnosis of patient's current SARS-CoV-2 infection status.
- Prognose a patient's likely outcome, including disease severity or survival.
- Predict or monitor a patient's likely response to treatment.
- Differentially diagnose SARs-CoV-2 from other common febrile or influenza-like disease pathogens, through the use of multiplex assays.

It should be noted that for each of these intended use scenarios, a different TPP could apply.

These TPPs are profiles based on the information available at the time of writing, and it needs to be noted that the science and use requirements will change if new information and findings indicate that this is needed. Consequently, all concerned should ensure that they are always working to the most recently published TPP.

Performance requirements

This specification outlines acceptable performance requirements for rapid COVID-19 detection tests using breath as the sampled matrix. It sets out the requirements based on the consensus of what is 'minimally acceptable' in the opinion of UK In-vitro Diagnostics (IVD) industry, healthcare professionals and medical device regulators given the emergency situation. A detection test using breath samples with specifications outside of this TPP may not be suitable to support the UK testing strategy.

The acceptable criteria for clinical sensitivity and specificity are an initial estimate of the minimally acceptable performance based on current expert opinion in a limited number of use cases.

The intended use of detection tests that match these profiles (or one that does not yet meet the specifications but looks promising) is to aid in the triage of people with a current SARS-CoV-2 infection by detection of SARS-CoV-2 in human samples. Ideally, products should be designed to achieve as many of the desired characteristics as are feasible, while still satisfying the minimal criteria for all defined features. However, a test that does not yet meet all these profiles may still have a role in supporting the UK testing strategy and can be considered on a case by case basis.

To ensure ongoing public safety and value for money, procurement and deployment of tests should take into account consideration of the specific decision pathway the test is being used to make, the current and future prevalence of SARS-CoV-2 within the intended test population, as well as the potential consequences of false positives and false negatives. The acceptable clinical sensitivity and specificity may need to be higher for some uses of the tests. For example, in populations with a low prevalence of COVID-19 an even higher specificity may be needed to prevent the "positive predictive value (the likelihood that a positive test result is a true positive)" from being unacceptably low.

Annex 2 provides tables which may be useful in supporting decision making, by demonstrating the impact of changing sensitivity, specificity and prevalence on the numbers of false positives and negatives. For example, tests with a low sensitivity are unlikely to be useful for identifying people who are free from infection (i.e. 'ruling-out' people with SARS-CoV-2), especially given the risks associated with false negatives, namely the unknowing exposure of others to infection. Similarly, tests with a low specificity are unlikely to be useful for identifying people with SARS-CoV-2 (i.e. 'ruling-in' people) and may result in people having to isolate unnecessarily following a false positive result.

It may be possible to reduce the potentially harmful consequences of an insensitive or unspecific test, by confirming negative or positive results using a more accurate, but slower

diagnostic test, such as conventional lab-based methods. The advantage of tests here could be that at least a proportion of people with, or without, COVID-19 can be informed of their health status, which would hopefully lead to the use of self-imposed risk reduction techniques, if indicated.

These specification criteria are based on similar Target Product Profiles published by the World Health Organisation, PATH (formerly known as Program for Appropriate Technology in Health), and Foundation for Innovative New Diagnostics (FIND) for in vitro diagnostic tests to other diseases. Each of these organisations has extensive experience with establishing TPPs for simple, rapid diagnostic tests.

Future developments

As our knowledge and understanding of the disease changes and the UK clinical needs change, so will the specifications. It is important to note that this TPP may need to be updated at short notice. A test that meets this version of the TPP may not meet future versions. When assessing options of available test refer to the latest version of TPP published.

As the market matures, it is expected that test formats will adapt – for example, SARS-CoV-2 may be included in respiratory panels.

Key to Table

Acceptable: Defines the minimum acceptable feature.

Desired: Highly desirable features of considerable benefit. As time is of the essence, if omitting one of these features significantly accelerates development and production it can be considered.

TARGET PRODUCT PROFILE
COVID-19
Rapid Breath Tests for the direct and indirect detection of SARS-CoV-2

Key Feature	Desired	Acceptable	Comment
Test Design Characteristics			
Intended Use	**Direct** detection of current SARS-CoV-2 infection in samples from people of all ages at any point during active infection.	**Indirect** detection of current SARS-CoV-2 infection by the detection of significant and specific changes in metabolism caused by SARS-CoV-2 virus from people of all ages during the active phase of infection.	**Active infection**: an infection in which the causative organism of the disease is reproducing. The person may be asymptomatic or symptomatic. **Direct detection** refers to a test that measures SARS-CoV-2 RNA and/or antigens. **Indirect detection** identifies SARS-CoV-2 infection by means other than the direct detection. For example, volatile organic compounds associated with inflammatory responses and/or by-products of metabolism.
Target Population	People of all ages with or without clinical signs associated with SARS-CoV-2 infection.		
Target User	A lay person with no knowledge of the testing technology.	A lay person with training or under supervision.	The target user shall administer the test to others. There may be some scope for supervised self-sampling where the sample collection device is CE, CE UKNI or UKCA marked for this purpose. For further information on device marking which is accepted on the UK market, please see our guidance. Full training appropriate to the intended user is required. Evidence of usability testing should be provided.
Target Use Setting	Non-healthcare settings (e.g. schools, workplaces, universities, airports, weddings, sports events, religious events, cruise ships).		

Test Format and Sample Collection Equipment	A standardised kit that contains all materials required for the procedure in a self-contained kit. All accessories needed to perform the assay and sample collection included.		All accessories need to be validated and CE, CE UKNI or UKCA marked through the appropriate regulatory route for use with the test. For further information on the regulation of medical devices on the UK market, please see our guidance.
Target Analyte	SARS-CoV-2 specific RNA and/or antigens. (direct detection).	Analytes that identify SARS-CoV-2 infection by means other than direct detection. For example, volatile and semi-volatile organic compounds (VOCs) associated with inflammatory responses and/or by-products of metabolism. (indirect detection)	A combination of both direct and indirect detection methods may also be considered.
Sample Type	Gaseous-phase breath samples.	Gaseous, aerosol or liquid-phase breath samples (e.g. exhaled breath condensate).	Clinical sensitivity and specificity must be determined for each claimed specimen type. Sample equivalence must be shown.
Result Output	Semi-quantitative.	Qualitative.	The result output should be simple to understand by the identified user. For Competent personnel with the appropriate level of training, the output should be a digital readout with clearly interpretable results (i.e. a binary positive or negative output).
Size (of device)	Handheld.	Desktop and portable or free standing for larger systems that may have a higher capacity for sample processing.	
Power Requirement	Uses a rechargeable and replaceable battery.	Standard mains power supply	
Internal Controls	Required to confirm validity of test and any processing and clearly identify invalid results as invalid.		Invalid results may be due to sampling technique or the presence of exogenous interferents.
Technical Failure Rate	Less than 1%.	Less than 5%.	Demonstrated through post market surveillance. Higher failure rates can lead to delays and lack of confidence with end users. Low test failure rates are more important in settings where users have difficulty repeating tests.
Training, ease of use and result interpretation.	No training required.	Less than 4 hours of training required.	Training content and style should be suitable for target user groups.

Need for Calibration	No external calibration required.	Regular calibration with material by the manufacturer.	Remote or auto-calibration preferable. The device should be amenable to external quality control assurance schemes.
Identification Capability	Ability to record individual results. Unique barcode or equivalent for integration into electronic systems.	Ability for the user to record individual results.	
Performance Requirements			
Clinical (diagnostic) sensitivity (or Positive Percent Agreement)	97% (with 95% two-sided confidence interval greater than or equal to 93%). This would mean that in a community of 10,000 people with a prevalence of 1000 cases per 100,000 (1%), 3 case of SARS-CoV-2 could be missed, and 97 cases detected.	Greater than 70% (with 95% two-sided confidence intervals greater than 65%). This would mean that in a community of 10,000 people with a prevalence of 1000 cases per 100,000 (1%), 30 cases of SARS-CoV-2 could be missed, and 70 cases detected.	At least 150 confirmed positive samples. The samples should cover a meaningful range of viral loads (i.e. should be from people with high, medium and low viral load) that represents the population the test is intended to be used in. The lower acceptable levels may allow for the use of tests to rule people in rather than out. Tests with lower sensitivity may still be useful for specific use cases not considered within this version of the TPP. The risks of false negatives versus the benefits of true positives should be considered carefully for each intended use scenario claimed by the manufacturer.
Clinical (diagnostic) specificity (or Negative Percent Agreement)	Greater than 99.9% (within 95% confidence intervals of 99-100%). In a community of 10,000 people with a prevalence of 1%, up to 10 test results could be incorrectly positive at each testing round. Should testing be conducted twice per week for 6 months, 520 test results could be incorrectly positive in total.	Greater than 99% (within 95% confidence intervals of 97-100%). In a community of 10,000 people with a prevalence of 1%, up to 99 test results could be incorrectly positive at each testing round. Should testing be conducted twice per week for 6 months, 5,148 test results could be incorrectly positive in total.	At least 250 confirmed negative samples. For tests with lower specificity, it is envisaged that when used in practice, people with positive results will need confirmatory checking by an additional test.

Comparison method	A validated CE, CE UKNI or UKCA marked laboratory method in current clinical use that itself performs within the MHRA TPP criteria for Laboratory-Based SARS-CoV-2 Viral Detection Tests, against which the Negative/Positive Percent Agreement is calculated.		Comparison test should be for use in asymptomatic and symptomatic people with demonstrated sensitivity and specificity across clinical range of viral loads. (e.g. RT-PCR). A composite clinical reference standard, against which the clinical sensitivity and specificity are calculated may be considered if supported by evidence of acceptability. For samples in which the test is positive and comparison method is negative, further testing should be done to explain the discordant result (for example, repeating the sample run on both tests or using a third method, if available).
Analytical specificity	No clinically relevant cross reactivity or interference.	No clinically relevant cross reactivity to common seasonal respiratory pathogens.	The effect of any interference to the test caused by interferents that may be in the sample at clinically relevant concentrations should be known and described. See annex 1 for a list of examples of interferents.
Analytical sensitivity (limit of detection, LoD)	An appropriate unit of measurement equivalent to a viral load of less than 1000 SARS-CoV-2 copies/mL of sample.	An appropriate unit of measurement equivalent to a viral load of less than 1,000,000 SARS-CoV-2 copies/mL of sample.	The LoD is the lowest concentration of analyte that can be consistently detected in ≥95% of samples tested under routine laboratory conditions and in the appropriate sample matrix. This concentration must yield an assay value that can be reproducibly distinguished from values obtained with samples that do not contain the analyte. Where an appropriate certified reference material or reference measurement procedure is available for the analyte(s) this should be used. If there are no comparative reference methods available, different approaches may be used, if demonstrated to be appropriate,

			such as comparison with dPCR or a composite reference standard. To demonstrate equivalence of the analyte(s) with viral load in copies/mL, samples (e.g. breath condensate) or matched samples (i.e. parallel throat swab from the same participant at the same time) should be used. The quantity value and measurement uncertainty of these samples should be assigned using an appropriate reference method (e.g. dPCR).
Clinical utility	Evidence that using the test improves system and outcomes for people (for example, use of pre-cautionary COVID-19 isolation facilities).		Refer to NICE evidence standards for further information.
Invalid Test Rate	No more than 0.1%.	No more than 1%.	Invalid test rate is the proportion of tests where the result was indeterminate and/or inconclusive.
Test Procedure Characteristics			
Hands on time (Total time using the device for 1 test)	Less than 40 seconds.	Less than 2 minutes.	Hands on time includes warming up, cleaning and the exchange of consumables. Real-world evidence required to demonstrate meeting this criterion in the intended use scenario.
Time from Sample to Result	Immediately or less than 15 seconds from sample to result.	Less than 90 seconds from sample to result.	Real-world evidence required to demonstrate meeting this criterion in the intended use scenario.
Throughput (Number of tests per hour per device)	More than 67 tests per hour.	More than 22 tests per hour.	The throughput assumes an efficiency of 75% at achieving the respective hands on time.
Sample processing and handling	No processing steps externally to the machine.	Up to 4 standardised sample-processing steps external to the instrumentation, but these must not take longer than 2 minutes nor require additional laboratory equipment (centrifuge, vortex, pipette etc).	Sample processing should include steps taken to ensure viral inactivation. Processing steps must be risk assessed and must not compromise biosafety.
Biosafety	Standard PPE and safety procedures need to be followed. No need for BSL 2 or 3 laboratory facilities.		The evidence provided to support compliance to this requirement should be relevant to the test being developed.

			The risks from exhaled breath in the testing environment and between-patient infection control should be considered.
Operational Characteristics			
Test kit storage and stability conditions	No cold chain (0 to 30˚C). 80% relative humidity. .		Packaging to be as compact as possible to facilitate storage. Must be made clear if reagents can withstand freeze and thaw and will not be detrimental to the assay.
Assay end point stability (time window during which signal remains valid)	Up to 1 hour.	Up to 30 minutes.	Results which are captured digitally may not require this criterion.
Operating conditions	0 to 30˚C. 80% relative humidity.		Should it be reasonably foreseeable that the testing procedure may be undertaken outdoors, a lower temperature limit may be required.
Connectivity and information governance	Connectivity into NHS LIMS systems or an alternative track and trace system.		Demonstrable continuity of connectivity required for all wirelessly connected devices. The responsibility to report positive results should be aligned with current Government Track and Trace requirements.
Presentation of results	Automatic interpretation of results, easy to capture and able to record public health data.	Human interpretation of results, easy to capture and able to record public health data.	
Software Requirements	Compliance with the following standard: • BS EN 62304:2006+A1:2015 Medical device software — Software life-cycle processes In adherence to the above standards software development must be planned with system requirement specifications to be translated into software requirement specifications. Risks must be determined and analysed through a Failure Mode and Effect Analysis (FMEA) approach, and risk control measures must be identified to address these. These could include ways to address secure data protection/transfer, cybersecurity aspects, device working under specific/unexpected environment conditions, use of SOUP (software of unknown provenience), solutions for data storage/cloud-based systems to prevent data loss. The implementation and effectiveness of the risk control measures implemented into software requirements must be verified and validated. The outputs of the software must be		

	reviewed against the software requirements prior to the release of the software for clinical use. If the device is intended to be connected with the NHS Network Systems, compliance with the following additional standards should also be considered for Clinical Risk Management: • DCB0129: Application in the Manufacture of Health IT Systems • DCB0160: Application in the Deployment and Use of Health IT Systems		
Reproducibility	More than 95% between repeats at LoD. More than 99% at higher concentrations.		Manufacturers should consider ISO 5725-1 when evaluating reproducibility.
Disposal requirements	Waste disposal requirements must be stated.		Requirements for safe disposal of consumables must be stated in the Instructions for Use (IFU)
Interferences	Interferents should be included in risk evaluation from endogenous and exogenous sources.		See Annex 1 for possible examples. Regular background air measurements may be required depending on the type of technology.
Time period for abstention from exogenous interferents prior to test.	No required abstention from exogenous interferents.	Less than 60 minutes abstention from exogenous interferents.	
Other			
Immediate supply volumes (within 4 weeks)	100,000 tests per day.	10,000 tests per day.	Supply volume refers to the number of individual tests which may be single disposable tests or performed with a reusable device.
Label and Instructions for Use	In line with Part IV of the UK MDR 2002, Annex I (as modified by Schedule 2A to the UK MDR 2002)		Certain components, including those used for sample collection, may be considered to be under the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) and in such cases, the product should conform to the relevant sections of that regulation.
Regulatory status	UKCA, CE UKNI or CE marked.	Exempt according to Regulation 12 of the UK MDR 2002.	For further information on the regulation of medical devices on the UK market, please see our guidance.
Maintenance	Preventive maintenance should not be needed until after 1 year or 295,000 samples (whichever is soonest). An alert should be included to indicate when maintenance is needed.	Preventive maintenance should not be needed until after 1 year or 95,000 samples (whichever is soonest). an alert should be included to indicate when maintenance is needed.	Assuming the equipment is used at capacity for at least 12 hours a day, seven days a week.
Design and manufacturing environment	ISO 13485:2016 ISO 14971:2019		

ANNEX 1: ASSAY VALIDATION

Establishing Performance Characteristics

It is recommended that the following aspects are considered when designing and validating the assay.

- When available, reference material should be used to establish performance, including standard validation panels, quality control materials and proficiency testing materials.
- When establishing the performance of the test, manufacturers must consider the analytical sensitivity and specificity of the test to SARS-CoV-2 Variants Under Investigation and of Concern, including but not exclusively 202012/01 (B1.1.7 lineage) and 20C/501Y.V2 (B.1.351 lineage). A full up to date list of variants can be found at https://www.gisaid.org/
- When establishing analytical specificity, manufacturers should consider the effect of relevant respiratory infections and diseases, such as:
    - other coronaviruses for example SARS-CoV-1
    - hCoV 229E, OC43, HKU1, NL63 epitopes
    - Adenovirus (e.g. C1 Ad. 71)
    - Human Metapneumovirus (hMPV)
    - Parainfluenza virus 1-4
    - Influenza A & B
    - Enterovirus (e.g. EV68)
    - Respiratory syncytial virus
    - Rhinovirus
    - Middle East Respiratory Syndrome (MERS)
    - Rubella IgM
    - Epstein Barr Virus (EBV)
    - *Chlamydia pneumoniae*
    - *Haemophilus influenzae*
    - *Legionella pneumophila*
    - *Mycobacterium tuberculosis*
    - *Streptococcus pneumoniae*
    - *Streptococcus pyogenes*
    - *Bordetella pertussis*
    - *Mycoplasma pneumoniae*
    - *Pneumocystis jirovecii (PJP)*

Potential interferents may originate from the following endogenous and exogenous sources. Manufacturers should declare if any other endogenous/exogenous substances will impact the assay. The following should not be considered exhaustive:

Endogenous Substances

- Haemoglobin
- Protein
- Triglycerides
- Haematocrit

Exogenous Substances

- Background air pollution and contaminants (examples include: propan-2-ol, siloxanes, 1,4,dichlorobenzene, limonene, ethanoic acid)
- Common dietary substances (for example alcohol containing beverages, tea, coffee)

- Substances originating from smoking or vaping
- Mouthwash
- Commonly used non-prescription throat sprays or medications
- Medications for breathing conditions, e.g. substances used with inhalers
- Recommended anticoagulants
- Nasal sprays or drops
- Nasal corticosteroids
- Nasal gel
- Throat lozenges, oral anaesthetic and analgesic
- Methyl salicylate
- Ammonia containing formulations

ANNEX 2: DIAGNOSTIC ACCURACY CONSIDERATIONS

When considering procurement and deployment of devices for any given clinical use-case, it is recommended to consider the maximum number of false positives and false negatives that would be acceptable for the new test based on the possible consequences of these misdiagnoses.

The table below presents the numbers of false positives and negatives in a cohort of fixed size (10,000) with varying prevalence of COVID-19 (NPV/PPV rounded to nearest whole number).

Therefore, for a test with a sensitivity of 80% and specificity of 99%.

COVID-19 prevalence	**False Positives**	**Positive predictive value*** (proportion of people with positive results who have COVID-19)	**False Negatives**	**Negative predictive value*** (proportion of people with negative results that don't have COVID-19)
0.1%	99	45%	20	100%
0.5%	95	81%	100	99%
1%	90	90%	200	98%
2%	50	99%	1000	83%

* Figure rounded to nearest whole number

It should also be noted that sensitivity and specificity values estimated in a particular population (i.e. university students) may not be generalisable to other populations (i.e. sport event attendees) with a different prevalence of COVID-19, if these populations are made up of people with less or more severe COVID-19. For example, accuracy estimates generated in a population of people with early symptoms of COVID-19 may be higher, due to viral load, than a test would achieve in a population of people with no symptoms of the condition.

Prevalence 2%								
		Numbers per 10,000 tested	**SENSITIVITY**					
			99.9%	99.5%	99%	98%	97%	95%
		Test Result						
SPECIFICITY	99.9%	False Positives	10	10	10	10	10	10
		False Negatives	<1	1	2	4	6	10
	99.5%	False Positives	49	49	49	49	49	49
		False Negatives	1	2	4	6	10	20
	99%	False Positives	98	98	98	98	98	98
		False Negatives	2	4	6	10	20	30
	98%	False Positives	196	196	196	196	196	196
		False Negatives	4	6	10	20	30	40
	97%	False Positives	294	294	294	294	294	294
		False Negatives	6	10	20	30	40	60
	95%	False Positives	490	490	490	490	490	490
		False Negatives	10	20	30	40	60	80

Prevalence 1%

Numbers per 10,000 tested

SPECIFICITY	Test Result		SENSITIVITY 99.9%	99.5%	99%	98%	97%	95%
	99.9%	False Positives	10	10	10	10	10	10
		False Negatives	<1	<1	1	2	3	5
	99.5%	False Positives	50	50	50	50	50	50
		False Negatives	<1	1	2	3	5	10
	99%	False Positives	99	99	99	99	99	99
		False Negatives	1	2	3	5	10	15
	98%	False Positives	198	198	198	198	198	198
		False Negatives	2	3	5	10	15	20
	97%	False Positives	297	297	297	297	297	297
		False Negatives	3	5	10	15	20	30
	95%	False Positives	495	495	495	495	495	495
		False Negatives	5	10	15	20	30	40

Prevalence 0.5%

Numbers per 10,000 tested

SPECIFICITY	Test Result		SENSITIVITY 99.9%	99.5%	99%	98%	97%	95%
	99.9%	False Positives	10	10	10	10	10	10
		False Negatives	<1	<1	<1	1	2	3
	99.5%	False Positives	50	50	50	50	50	50
		False Negatives	<1	<1	1	2	3	5
	99%	False Positives	100	100	100	100	100	100
		False Negatives	<1	1	2	3	5	8
	98%	False Positives	199	199	199	199	199	199
		False Negatives	1	2	3	5	8	10
	97%	False Positives	299	299	299	299	299	299
		False Negatives	2	3	5	8	10	15
	95%	False Positives	498	498	498	498	498	498
		False Negatives	3	5	8	10	15	20

Prevalence 0.1%

Numbers per 10,000 tested

SPECIFICITY	Test Result	SENSITIVITY 99.9%	99.5%	99%	98%	97%	95%
99.9%	False Positives	10	10	10	10	10	10
	False Negatives	<1	<1	<1	<1	<1	<1
99.5%	False Positives	50	50	50	50	50	50
	False Negatives	<1	<1	<1	<1	<1	1
99%	False Positives	100	100	100	100	100	100
	False Negatives	<1	<1	<1	<1	1	2
98%	False Positives	200	200	200	200	200	200
	False Negatives	<1	<1	<1	1	2	2
97%	False Positives	300	300	300	300	300	300
	False Negatives	<1	<1	1	2	2	3
95%	False Positives	500	500	500	500	500	500
	False Negatives	<1	1	2	2	3	4

ANNEX 3: GLOSSARY

AUROC	Area under receiver operating characteristic curve
BSL	Biological Safety Level
dPCR	Digital polymerase chain reaction
LoD	Limit of Detection
LIMS	Laboratory Information Management System
PPE	Personal Protective Equipment
VOC	Volatile organic compound

Analytical sensitivity: Selectivity of a measurement procedure capability of a measuring system, using a specified measurement procedure, to provide measurement results for one or more measurands which do not depend on each other nor on any other quantity in the system undergoing measurement.

Clinical (Diagnostic) Sensitivity: Ability of an IVD examination procedure to identify the presence of a target marker associated with a particular disease or condition.

Clinical (Diagnostic) Specificity: ability of an IVD examination procedure to recognise the absence of a target marker associated with a particular disease or condition.

(the above definitions of performance characteristics taken from BS EN ISO 18113-1:2011, In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling): Terms, definitions and general requirements)

Positive Percent Agreement: calculated in the same way as Clinical (Diagnostic) Sensitivity but indicate that a non-reference standard was used.

Negative Percent Agreement: calculated in the same way as Clinical (Diagnostic) Specificity but indicate that a non-reference standard was used.