

The Top Performing Rapid Antigen Tests We Currently Recommend to Customers

EXCALIBUR
Healthcare Services



 SureScreen Diagnostics



PBM
Princeton BioMeditech Corporation



EntroGen **SureDx™**



THE NON-INVASIVE LOLLY TEST!

Rapid Covid-19 Testing Options - Introduction & Contents

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INTRODUCTION:

Rapid Lateral flow Antigen tests are for testing to see if an individual is currently infectious with Covid-19.

TEST KIT EXPRESS supply only the very best performing tests. This document summarises the 5 tests that we currently recommend to our customers. The purpose of this document is to enable you to make an informed choice of the best test for you.

There are currently no other tests that we recommend, however we will continually update our advice as product innovation continues.

The rapid test market has recently seen some significant product innovation that solve different market needs.

At the beginning of the pandemic the most pressing need was to develop an accurate and fast rapid test. In this case, the clear recommendation was the Excalibur Rapid SARS-CoV-2 Antigen (Nasopharyngeal) swab test. We still recommend Excalibur if your absolute priority is to use the most accurate test.

However, given that all the tests that we recommend are highly accurate, other factors can sometimes outweigh absolute accuracy.

For example, SureScreen have developed a highly accurate and fast Anterior Nares (lower nostril) Swab. We now recommend the Surescreen Anterior Nares for most general testing situations where individuals are especially sensitive to Nasopharyngeal swabs.

Another reason for an innovative new test was to develop a test that doesn't require the processing of tests in mini-plastic test tubes. Processing in mini-test tubes is very easy and suitable for most situations, however sometimes it makes testing more difficult. In response to this, SureDX have developed the highly accurate and fast V-Chek Lolly Test which we are recommending for some situations.

Another innovation is the Princeton Rapid SARS-CoV-2/Influenza A+B Antigen Panel Test that simultaneously tests for Covid-19 and Influenza A+B. There are some customers such as Care Homes who might also want to prioritise testing for Flu.

Another requirement is accreditation, specifically our US customers who favour the excellent Princeton Rapid SARS-CoV-2 Test because it is highly accurate and fast and also has FDA approval.



Rapid Covid-19 Testing Options – Terminology Explained

TERMINOLOGY EXPLAINED:

Sensitivity:

Sensitivity refers to the proportion of individuals who are currently infectious with Covid-19 who will be identified as positively infectious by the test.

It is very important to note that the sensitivity figures quoted are for all levels of infectiousness weighted equally. However, in reality all the tests are actually much more sensitive at picking up more highly infectious individuals and the overall sensitivity figures are skewed much lower by individuals who are technically infectious but are significantly less likely to infect others because their viral load is much lower. For example, although the Ct values are not an exact sliding scale, to quote Science Magazine “a CT value of 12 starts out with more than 10 million times as much viral genetic material as a sample with a CT value of 35.

The below example shows how the Excalibur rapid test sensitivity average of 97% was derived. However, as you can see the sensitivity is 100% for the most infectious individuals and 99% for moderately infectious individuals. Sensitivity drops to 96% for slightly infectious individuals and below 90% only for the very least infectious individuals.

| | POS (Ct5-10) | POS (Ct11-15) | POS (Ct16-20) | POS (Ct21-25) | POS (Ct26-30) | POS (Ct30-35) |
|---------------|-----------------|------------------|------------------|------------------|------------------|------------------|
| % Sensitivity | 100 | 100 | 100 | 99.2 | 95.8 | 78.5 |

Specificity:

Specificity is the degree to which the test only identifies Covid-19 as Covid-19 and doesn't confuse it with a similar viral strain. In other words, a specificity of 100% means all test results showing as positively infectious will genuinely be infectious with Covid-19. A specificity of 99% would mean that 1% of the tests that show an individual as being infectious with Covid-19 would not actually have Covid-19. These are known as 'false positives'.

Rapid Covid-19 Testing Options - Excalibur Nasopharyngeal Test

TEST KIT OPTION 1

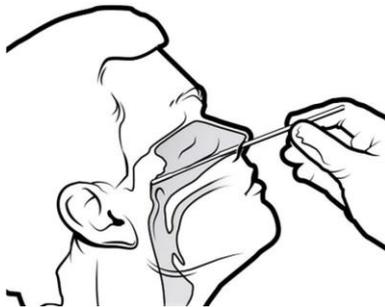
NAME: Excalibur SARS-CoV-2 Rapid Antigen Test

TESTS FOR: Individuals currently infectious with Covid-19

NUMBER OF TESTS PER BOX: 20 or 5

SAMPLE METHOD: Nasopharyngeal nasal swab

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PROCESSING METHOD: Place mini plastic test tube in holder provided. Add drops of buffer solution. Take Nasopharyngeal swab and mix with buffer solution in mini plastic test tube. Place lid on mini plastic test tube and squeeze drops into the hole in the cassette reader. Wait 15 minutes for result which is simple to read. A positive result might be observed as fast as 2 minutes and if so will be a valid positive result.

ACCREDITATIONS/REGISTRATIONS + PERFORMANCE STATS:

| CE Mark | MHRA Reg. | FDA Apprvd. | Sensitivity | Specificity | Speed (Mins) |
|---------|-----------|-------------|-------------|-------------|--------------|
| Y | Y | Not Yet | 97.4% | 100% | 2-15 |

Overall sensitivity 97%. 100% sensitivity for highly infectious individuals and 99% for moderately infectious individuals. Sensitivity drops below 99% only for individuals with a much lower, less infectious viral load.

Specificity of 100% means no misdiagnosed "false positives" and **speed is just 2-15 minutes.**

The above stats mean the **Excalibur Nasopharyngeal Nasal Test** offers incredibly high levels of performance.

SITUATIONS BEST FOR: All situations where every last bit of accuracy is prioritised.

TEST KIT EXPRESS use the Excalibur SARS-CoV-2 Rapid Antigen Test for when providing managed on-site solutions for companies such as Amazon. The reason for this is due to its incredible levels of accuracy and because Excalibur who provide outstanding levels of training to the Healthcare professionals who administer the tests.

SITUATIONS LESS SUITABLE FOR: If FDA approval is important, i.e. you are based in the US or Canada.

Also, occasionally there might be a situation where the test is for very highly sensitive individuals or children who might find the Nasopharyngeal swab very slightly uncomfortable.

COST: £6.25 per test (discounts are available depending on volumes)

Rapid Covid-19 Testing Options - SureScreen Anterior Nares Test

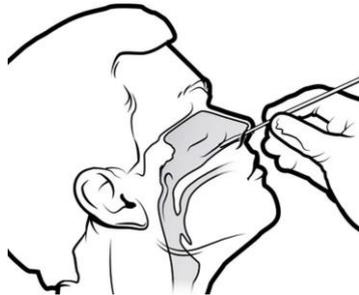
TEST KIT OPTION 2

NAME: SureScreen SARS-CoV-2 Rapid Antigen Test

TESTS FOR: Individuals currently infectious with Covid-19

NUMBER OF TESTS PER BOX: 25

SAMPLE METHOD: Anterior Nares nasal swab



PROCESSING METHOD: Place mini plastic test tube in holder provided. Add buffer solution. Take swab from 1.5-2.5 cm into nostril and mix with buffer solution in mini plastic test tube. Place lid on mini plastic test tube and squeeze drops into the hole in the cassette reader. Wait 15 minutes for result which is simple to read. A positive result might be observed as fast as 2 minutes and if so will be a valid positive result.

ACCREDITATIONS/REGISTRATIONS + PERFORMANCE STATS:

| CE Mark | MHRA Reg. | FDA Apprvd. | Sensitivity | Specificity | Speed (Mins) |
|---------|-----------|-------------|-------------|-------------|--------------|
| Y | Y | Not Yet | 96.1% | 99% | 4-15 |

Sensitivity of 96.1% and Specificity of 99% and results within 4-15 minutes means the **SureScreen Anterior Nares Test** offers incredibly high levels of performance.

SITUATIONS BEST FOR: All situations where very high levels of accuracy as well as speed are prioritised but also where there is a need for total comfort, e.g. vulnerable individuals or children.

SITUATIONS LESS SUITABLE FOR: If FDA approval is important, i.e. you are based in the US or Canada.

COST: £6.50 per test (discounts are available depending on volumes)

Rapid Covid-19 Testing Options - Princeton Nasopharyngeal Test

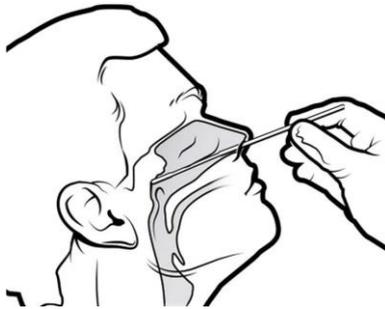
TEST KIT OPTION 3

NAME: Princeton SARS-CoV-2 Rapid Antigen Test

TESTS FOR: Individuals currently infectious with Covid-19

NUMBER OF TESTS PER BOX: 25

SAMPLE METHOD: Nasopharyngeal nasal swab



PROCESSING METHOD: Place mini plastic test tube in holder provided. Add drops of buffer solution. Take Nasopharyngeal swab and mix with buffer solution in mini plastic test tube. Place lid on mini plastic test tube and squeeze drops into the hole in the cassette reader. Wait 15 minutes for result which is simple to read. A positive result might be observed as fast as 2 minutes and if so will be a valid positive result.

ACCREDITATIONS/REGISTRATIONS + PERFORMANCE STATS:

| CE Mark | MHRA Reg. | FDA Apprvd. | Sensitivity | Specificity | Speed (Mins) |
|---------|-----------|-------------|-------------|-------------|--------------|
| Y | Not Yet | Y | 94.0% | 100% | 15 |

Sensitivity of 94% and **Specificity of 100%** and **results within 15 minutes** means the **Princeton Nasopharyngeal Test** offers high levels of performance.

SITUATIONS BEST FOR: All situations where accuracy as well as speed are prioritised and specifically where you require the leading test kit with FDA approval.

SITUATIONS LESS SUITABLE FOR: Suitable for all situations unless MHRA registration is required. Also, occasionally there might be a situation where the test is for very highly sensitive individuals or children who might find the Nasopharyngeal swab very slightly uncomfortable.

COST: £6.50 per test (discounts are available depending on volumes)



Rapid Covid-19 Testing Options – SureDX Saliva LollyTest

TEST KIT OPTION 4

NAME: SureDX V-CHEK SARS-CoV-2 Rapid Antigen Test

TESTS FOR: Individuals currently infectious with Covid-19

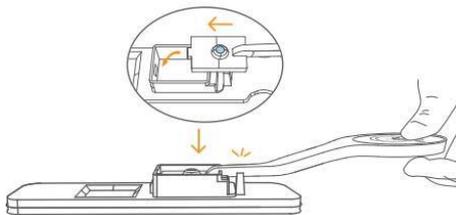
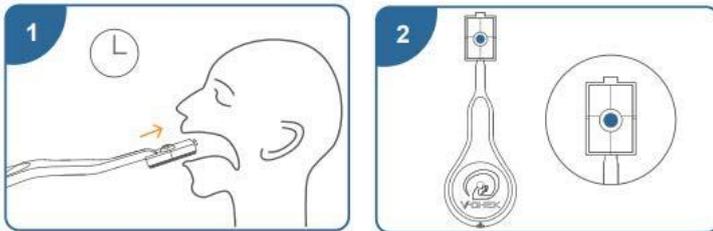
NUMBER OF TESTS PER BOX: 1 or 5 or 10 or 15 or 20

SAMPLE METHOD: Lolly (sponge) Saliva sample

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THE NON-INVASIVE LOLLY TEST!



PROCESSING METHOD: 1. Insert the sponge lolly into the mouth and swab in the mouth at least 90 seconds to collect the oral fluid. 2. Remove the saliva swab from the mouth when the sponge become fully saturated and the inductor turn blue. 3. Insert the saliva swab into the test cassette holder and push down the swab. Wait 10 minutes for result which is simple to read.

ACCREDITATIONS/REGISTRATIONS + PERFORMANCE STATS:

| CE Mark | MHRA Reg. | FDA Apprvd. | Sensitivity | Specificity | Speed (Mins) |
|---------|-----------|-------------|-------------|-------------|--------------|
| Y | Not Yet | Not Yet | 95.7% | 98.4% | 15 |

Sensitivity of 95.7% and **Specificity of 98.4%** and **results within 10 minutes** means the **SureDX Lolly Saliva Test** offers high levels of performance.

SITUATIONS BEST FOR: All situations where accuracy as well as speed are prioritised and where a CE Mark is required or sufficient for use.

Especially suitable for situations where there isn't an area to process the test, such as a table to place mini-test tubes on. Exceptionally low price for such a high performing test means it is especially suitable for governments or organisations where a low cost is the overriding top priority.

SITUATIONS LESS SUITABLE FOR: Great for all situations other than where MHRA registration or FDA approval is required.

COST: £3.95 per test (discounts are available depending on volumes)

Rapid Covid-19 Testing Options – Contact US

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