# Q-POC™ SARS-CoV-2 Assay

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# The Need

COVID-19 testing is set to be a long-term requirement.

## What is the need for a rapid PCR SARS-CoV-2 Assay?

Whilst mass testing is reducing, there are many reasons an urgent PCR test may be needed - such as to undergo scheduled or unscheduled medical procedures or to attend a workplace and many more. This can be stressful for the individual, and complex for testing providers.

The Q-POC SARS-CoV-2 Assay will:

- Provide clear diagnosis, enabling rapid triage and effective treatment strategies, particularly in at-risk groups of patients
- Facilitate effective infection control and risk assessment in clinical areas for staff and patients, enabling staff to resume routine healthcare procedures
- Provide clinical teams with rapid, accurate results at the Point of Need, without waiting hours to days to receive laboratory results

# The Q-POC™ SARS-CoV-2 Assay

**The Q-POC SARS-CoV-2 Assay reduces stress and suffering caused by testing delays by providing accurate results in approximately 30 minutes at the Point of Need, on the user friendly, portable Q-POC™ platform.**

**From collecting samples to reading results, the Q-POC™ SARS-CoV-2 Assay has been developed considering patient and user experience at every step of the testing process.**

- High quality multiplex PCR testing with the simplicity and speed of a lateral flow test
- Actionable rapid results you can trust in approximately 30 minutes
- Empower healthcare professionals to treat efficiently and effectively with on demand rapid accurate results
- Everything you need for safe testing at the Point of Need is provided, reagents are contained within the sealed cassette

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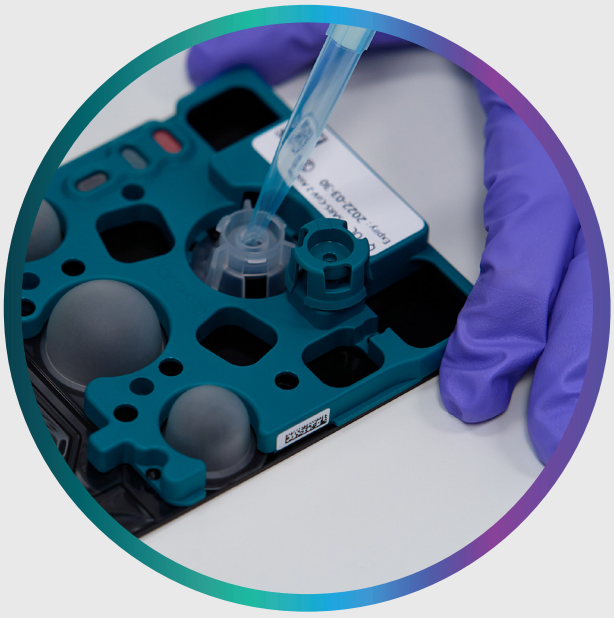
# Why Should you Choose the Q-POC SARS-CoV-2 Assay?

## Q-POC offers the optimum solution for sustainable COVID-19 infection control, thanks to its speed, simplicity and accuracy.

Swab collection kits and testing cassettes can be stored at room temperature for your convenience

Uses gene assay targets that will not be impacted by vaccines, therapeutics or mutations so you can test with confidence in the face of emerging variants, with an assay designed for the future

Reassurance with quality controls built into every test, ensuring any user will know they have collected the sample and run the test correctly, preventing false negatives



> Rapid tests to diagnose infectious diseases are essential for the optimal management of the patients, since it has been shown that in severe infections the rapid treatment is associated with a decrease in mortality. COVID-19 has reinforced the importance of rapid tests for the diagnosis of infectious diseases.

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# Q-POC™ SARS-CoV-2 Assay Technical Specifications

QuantuMDx

## Contents

| | |
|---|---|
| **Test cassette** | Q-POC™ SARS-CoV-2 Assay test cassette, individually sealed in foil pouch |
| **Sample collection kit** | Copan flexible FLOQSwabs® and sample collection tube containing 3ml of Mswab™ |

## Assay

| | |
|---|---|
| **Specimen type** | Nasal mid-turbinate |
| **Assay targets** | S, N, Orf1<br>100% coverage of all currently known SARS-CoV-2 sequences* |
| **Internal controls** | Sample process control<br>Rehydration control |
| **Results** | Positive<br>Negative<br>Invalid |

## Time to Result

| | |
|---|---|
| **Hands on time** | Less than 3 minutes |
| **Walk away time** | 30 minutes |

## Storage conditions

| | |
|---|---|
| **Temperature** | 0 – 25°C |
| **Relative humidity** | Up to 95% relative humidity (non-condensing) |
| **Shelf life** | 12 months |
| **Disposal** | Biohazardous waste |

## Functional specifications

| | |
|---|---|
| **Detection method** | Direct-to-PCR, 6 channel fluorescence detection |
| **Optics** | AF350, FAM, HEX, ROX, CY50, AF750 |

## Performance

| | |
|---|---|
| **Analytical sensitivity (LOD)** | 50 copies/rxn |
| **Clinical sensitivity, utilising reference test Ct cut off of 35** | 96.9% (95% CI: 83.8% - 99.9%) |
| **Clinical specificity, utilising reference test Ct cut off of 35** | 98.3% (95% CI: 93.9% - 99.8%) |
| **Agreement, utilising reference test Ct cut off of 35** | 98.0% |
| **Clinical sensitivity, overall** | 80.0% (95% CI: 64.4% - 91.0%) |
| **Clinical specificity, overall** | 99.1% (95% CI:94.9% - 100%) |
| **Inclusivity** | >99% |
| **Cross-reactivity** | 0% |
| **Interfering substances** | No interference |
| **Reproducibility** | >99% |

* At time of publishing - April 2022

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