

Q-POC™ SARS-CoV-2 Assay



QuantuMD_g

Multiplex Diagnostics for the Real World



A.MENARINI
diagnostics

The Need

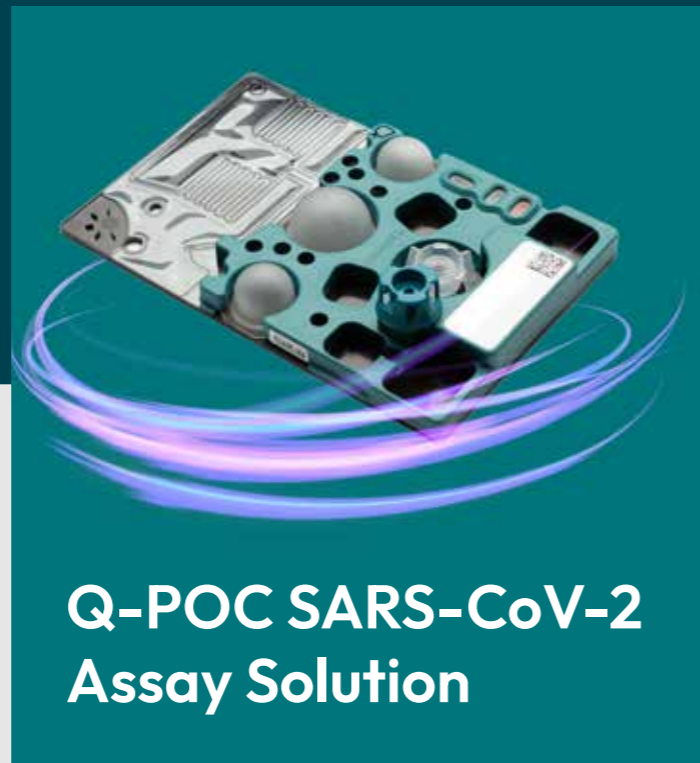
COVID-19 testing is set to be a long-term requirement.



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 travel, undergo scheduled or unscheduled medical procedures, attending 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



Q-POC SARS-CoV-2 Assay Solution

The Q-POC SARS-CoV-2 Assay test 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

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.



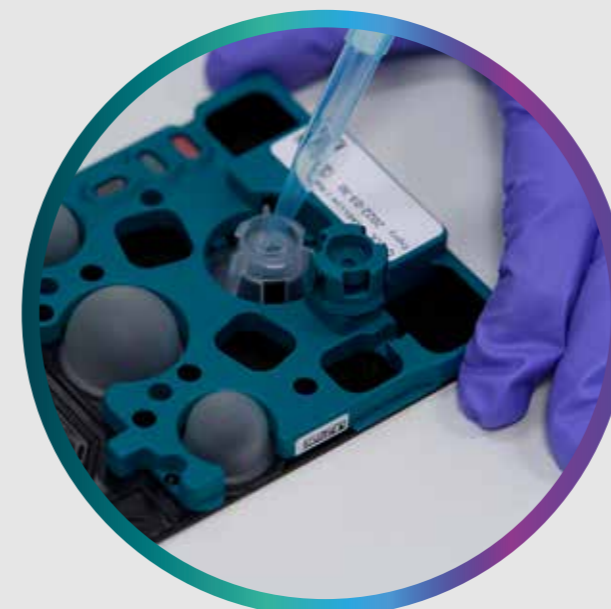
Swab collection kits and testing cassettes can be stored at room temperature for your convenience



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



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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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Jordi Vila

Professor of Microbiology
Head of the Department of Clinical Microbiology
Biomedical Diagnostic Center (CDB)
Hospital Clinic
School of Medicine, University of Barcelona

Q-POC SARS-CoV-2 Assay Technical Specifications

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	S, N, Orf1 100% coverage of all currently known SARS-CoV-2 sequences*
Internal controls	Sample process control Rehydration control
Results	Positive Negative Invalid

Time to Result

Hands on time	1 minute
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
Temperature hold accuracy	± 0.15°C for hold times up to 1 hour
Temperature accuracy	± 0.25°C
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 - January 2022