

Q-POC™ SARS-CoV-2, Flu A/B & RSV Assay



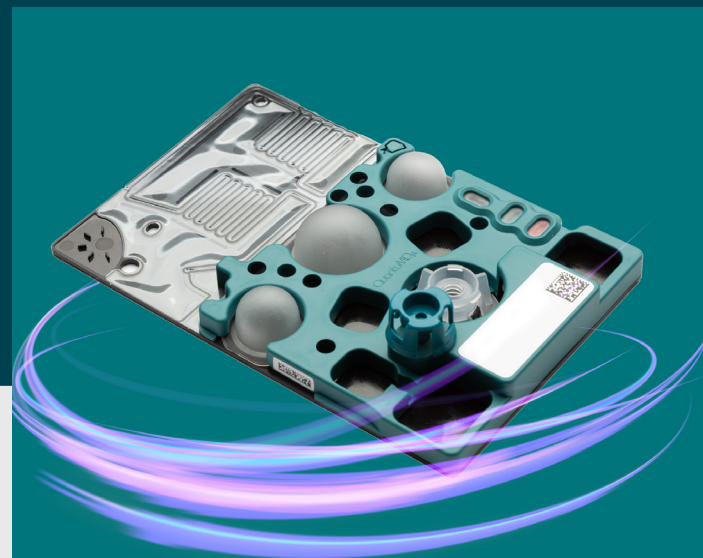
A.MENARINI
diagnostics

The Need

Diagnosing, treating and managing clinically similar respiratory infections can be challenging.

What is the need for a rapid PCR Respiratory Panel?

- Flu, RSV and SARS-CoV-2 all present with similar symptoms. **The PCR Respiratory Panel** will provide a clear differential diagnosis and enable rapid triage and effective treatment strategies, particularly in at-risk groups of patients
- Flu, RSV and SARS-CoV-2 therapies require detection for each individual pathogen and identification of co-infection is important particularly in at risk groups
- To facilitate effective infection control and risk assessment in clinical areas for staff and patients to enable staff to resume routine healthcare procedures
- To 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, Flu A/B & RSV Assay

From collecting samples to reading results, the Q-POC SARS-CoV-2, Flu A/B & RSV Assay has been developed considering patient and user experience at every step of the testing process.

The panel delivers rapid PCR results in approximately 35 minutes at the Point of Need, on the accurate and portable Q-POC platform.

- High quality multiplex PCR testing with the simplicity and speed of a lateral flow test
- Actionable rapid results you can trust in approximately 35 minutes
- Empower health care 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 Choose the Q-POC SARS-CoV-2, Flu A/B & RSV Assay



Q-POC offers the optimum solution for sustainable respiratory 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

“

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.

”

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, Flu A/B & RSV Assay

Technical Specifications

Contents

Test cassette	Q-POC™ SARS-CoV-2, Flu A/B & RSV Assay 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 or Nose and throat
----------------------	--

Assay targets

SARS-CoV-2	Orf1, S gene and N gene
Flu A	Matrix protein
Flu B	Nonstructural protein
RSV	Nucleoprotein; matrix protein

Internal control	Specimen Process Control
-------------------------	--------------------------

Time to Result

Hands on time	Less than 3 minutes
Walk away time	35 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
-------------------------	---

Performance

Analytical sensitivity (LOD)

SARS-CoV-2	250 copies/ml
Flu A	1000 copies/ml
Flu B	1250 copies/ml
RSV A	4000 copies/ml
RSV B	1500 copies/ml

Clinical Sensitivity (PPA)

SARS-CoV-	93.6% (95% CI: 89-96)
Flu A	100% (95% CI: 57-100)
Flu B	100% *
RSV	100% (95% CI: 21-100)

Clinical Specificity (NPA)

SARS-CoV-2	100% (95% CI: 98-100)
Flu A	100% (95% CI: 99-100)
Flu B	98.9% (95% CI: 97-100)
RSV	99.2% (95% CI: 98-100)

* Contrived sample data only