

VitaPCR™ Molecular
Point of Care Platform
NEW COVID-19 rapid PCR test
Generation 2



VitaPCR™
SARS-CoV-2 Gen 2 Assay

**Second generation SARS-CoV-2 PCR test
introducing improvements in sensitivity and usability
without losing speed, accuracy and safety**

3000
2000
1000

Coronavirus outbreak

● Cumulative reported cases
● Daily increase in cases



New VitaPCR™ COVID-19 rapid PCR test Generation2

One year and 2 million tests after the introduction of first generation SARS-CoV-2 VitaPCR™ Rapid Test,^{1,2} A.Menarini Diagnostics introduces a higher sensitivity second generation assay to meet the requirement of a rapid and accurate diagnosis at the point of need.

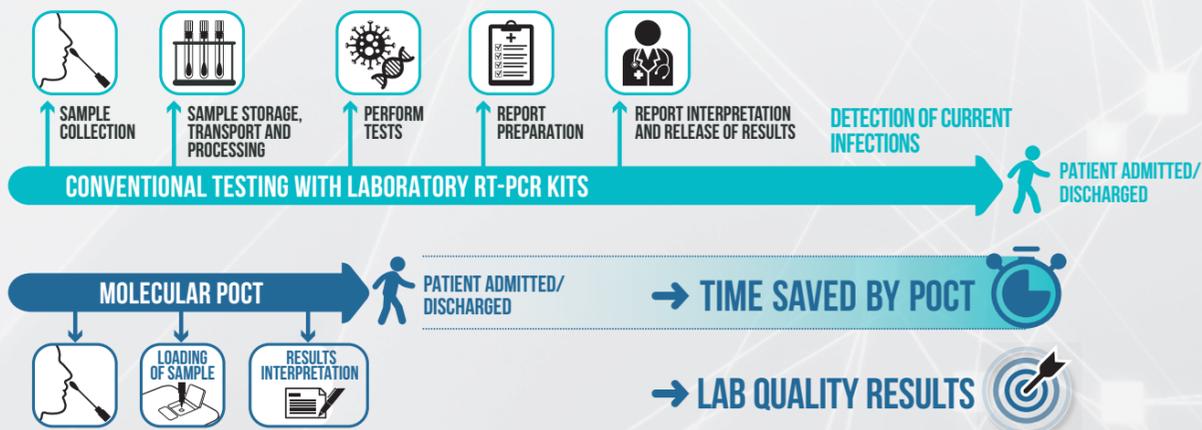


VitaPCR™ MOLECULAR PLATFORM

Real Time-PCR is the most sensitive and specific technique to detect viral RNA in patients with suspected infections but a centralized laboratory workflow doesn't provide rapid answers. VitaPCR™ is a molecular point-of-care platform based on fast Real Time-PCR for rapid molecular detection, directly from oro and nasopharyngeal swabs, of SARS-CoV-2 and other respiratory viruses. The system combines high sensitivity with ease of use, delivering accurate and actionable results in just 20 minutes, exactly where they are needed.

WORKFLOW MANAGEMENT

VitaPCR™ enables the real time management of patients undergoing an evaluation at healthcare facilities making the greatest impact in the creation of reliable and streamlined workflow.



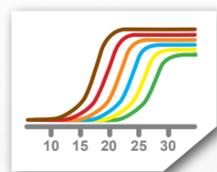
SPEED

With its 20 minutes response time, combined with sensitivity levels very close to Laboratory PCR, the VitaPCR™ SARS-CoV-2 Gen2 rapid Real Time PCR test is the ideal solution for monitoring both symptomatic and asymptomatic patients at the point of need such as ER, critical wards or point-of-entry such as airports or seaports and in any key decision point for admission to clean areas.



SENSITIVITY

The new SARS-CoV-2 Gen2 rapid PCR test kit reduces the Limit of Detection down to 30 copies/ reaction, positioning the VitaPCR™ system at the top sensitivity levels for molecular point-of-care testing.

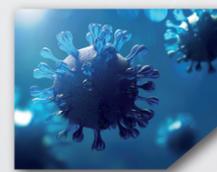


VARIANT ANALYSIS

The Gen2 Sample Collection Buffer is very gentle with RNA and allows safe storage of samples up to a week at 4°C. This enables the same sample to be directly loaded, without further extraction steps, into the Menarini's CoronaVar assay master mix, for variant genotyping of the positive samples with a Laboratory Real Time PCR instrument.

Typical sensitivity levels and time to result of different methods for SARS-CoV-2 viral detection

	Typical LoD levels (viral copies/reaction)	Typical Time to Result
Rapid Lateral flow Antigen test	4000-5000 copies	15 min
VitaPCR™ Rapid PCR test Gen 2	30 copies	20 min
Laboratory Real Time PCR test	10 copies	2-4 hours



MULTITEST CAPACITY

Additional kits are available to differentiate SARS-CoV-2 from other respiratory infections. The new family of rapid respiratory kits includes:

- FLU A/B
- SARS CoV2 + FLU A/B
- FLU A/B + RSV
- STREP-A



CONNECTIVITY

VitaDataLink connection pack supports the HL7 messaging standard, allowing to interface VitaPCR™ to LIS, middleware, EMR and point of care data manager.

VitaPCR™

SARS-CoV-2 Gen 2 Assay



1. COLLECT

NP OR OP SWABS
SAMPLE COLLECTION



2. LYSE

STIR THE SWAB
IN THE COLLECTION
BUFFER



3. TRANSFER

USE THE
DISPOSABLE
PIPETTE



4. START

RESULTS DELIVERED
IN LESS THAN 20 MINUTES



VitaPCR™ Technical Specifications

Size	15.5x16.5x20.5 cm (H*W*D)
Weight	1.2kg
Power Supply	12V, 5A
Color Touch Screen	4" capacitive touch LCD display
Fluorescence Channels	4 channels
Sample Well	1 sample/run
Operating Environment	10-38°C ; 10-80%RM
Adapter	AC100-240V~2.0A Max, 50-60Hz

VitaPCR™ Product List

CODE	DESCRIPTION
51572	VitaPCR™ Instrument
52957	SARS-CoV-2 Gen2 Assay
51574	SARS-CoV-2 (Gen1) Assay
51573	Flu A+B Assay
52182	Influenza/SARS-CoV-2 Assay
52253	Strep A Assay
52254	Flu/RSV Assay
52289	SARS-CoV-2 Gen2 External Control Set
51699	SARS-CoV-2 (Gen1) External Control Set
54373	Thermal Printer
52207	Rack (tube holder)



SARS-CoV-2-Gen2 Assay Specifications

Specimen	NP/OP SWABS
Eluted specimen storage	+2°C/+8°C up to 7 days
SARS-CoV-2 inactivation time	< 5 min
LoD	30 copies/reaction (1000 copies/ml SCB)
External Negative Control	RNA-free sample collection buffer
External Positive Control	RNA transcript of SARS-CoV-2 gene sequence (not included in the kit)
Gene Targets	1) SARS-CoV-2: specific region located in N gene ->FAM 2) SARS-like: conserved region located in N gene ->VIC 3) Internal Control ->ROX

References

- 1- Fournier PE, et al. Contribution of VitaPCR™ SARS-CoV-2 to the emergency diagnosis of COVID-19. *Journal of Clinical Virology*. 2020; 133: 104682. doi.org/10.1016/j.jcv.2020.104682
- 2- Fenollar F, et al. Evaluation of the Panbio Covid-19 rapid antigen detection test device for the screening of patients with Covid-19. *Journal of Clinical Microbiology*. 2021; 59(2):e02589-e02620. doi:10.1128/JCM.02589-20

VitaPCR™ is distributed by A.Menarini Diagnostics in the following countries:

Portugal, Spain, Uk, Eire, Netherlands, Belgium, Germany, Sweden, Denmark, Austria, Italy, Greece and France

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