SARS-CoV2
Real Time PCR detection kit

CE IVD

CoronaMelt is a new Real Time PCR detection kit for SARS-CoV2 virus, designed for high sensitivity detection of viral RNA particles in samples derived from nasopharyngeal and oropharyngeal swabs.

CORONA MELT

Intercalating dye and melting curve:
sensitivity and specificity

Detection of the amplification signal is obtained through the use of an intercalating dye and the confirmation of target identity through a melting curve analysis. The system is designed to amplify 2 viral targets on the ORF1ab gene and an endogenous control, targeting human GAPDH gene. Viral targets and the control are amplified in two separate microwells from two aliquots of the same RNA sample. Samples must undergo magnetic bead or column RNA extraction before PCR amplification.

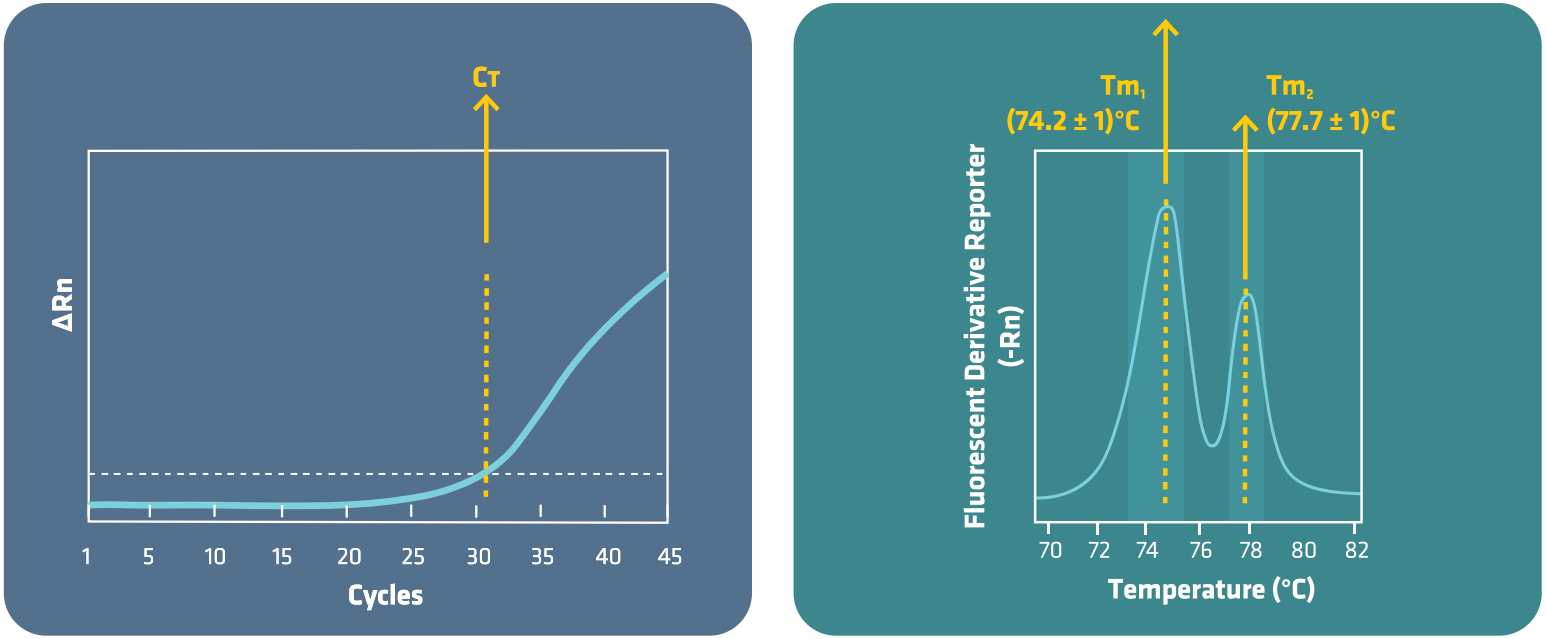

Fig.1 Melting curve analysis post amplification. The PCR products, which are generated during the real time detection amplification step, are slowly denatured by using a temperature gradient from 60 to 95°C; this generates a " fingerprint" profile of each of the amplicons present in the tube. This process provides a confirmation regarding the identity of the amplified products.

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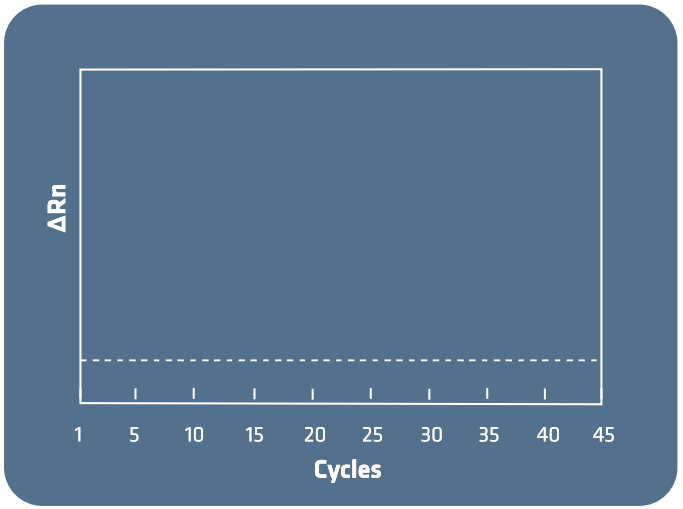
Endogenous control: results confidence

Human RNA expressed by the GAPDH housekeeping gene in the epithelial cells, which were collected from the patient at the sampling step, is used as a process control, which allows to check all variables from sample collection, through transportation, extraction, and amplification. This ensures higher confidence in determining negatives, allowing to exclude sampling errors or inappropriate conservation during the transportation of samples to the laboratory.



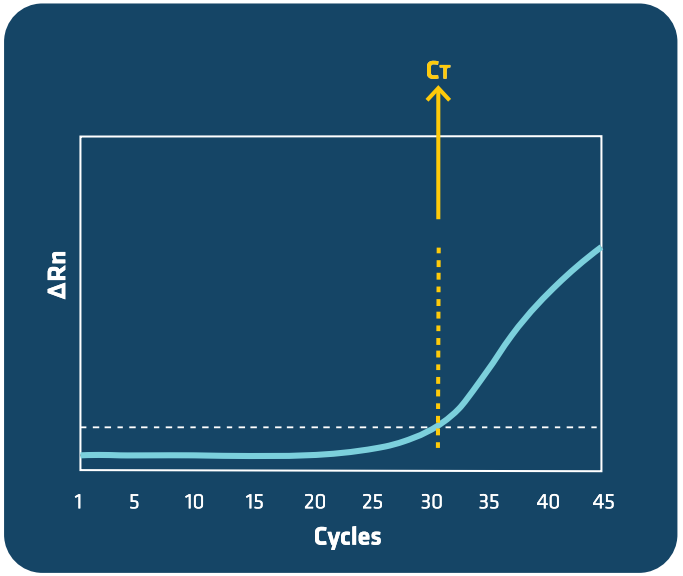


Fig.2 The presence of the endogenous control curve (below) indicates that the process was working correctly both at the sampling and the analytical level. In case of absence of the control curve (above) and of the viral target the sample is considered invalid and has to be repeated. The GAPDH gene is a highly expressed housekeeping gene, both in oro-nasopharyngeal epithelial cells and in saliva cells.

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Automation friendly:
easy to use

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CoronaMelt can be used with an easy manual protocol or it can be implemented on the Menarini Omnia PRO automatic workstation, which enables to process **48 samples** from-VTM-tube-to-PCR-plate in **less than 3 hours**, including magnetic-bead RNA extraction compatible with the use of viral inactivation media.

The system allows full process automation **from primary VTM tubes to a ready-to-go real time PCR plate**. Operator time is reduced to just a few steps to set up the platform, load reagents and barcoded samples. Plate configuration is automatically transferred to the thermal Cycler and to the LIS system for safe and error free tracing.
The Omnia PRO platform has on board barcoding reader for samples and reagents as well as a UV lamp DNA/RNA decontamination function.

SPECIFICATIONS

RNA Extraction
magnetic beads or column purification

Clinical Sensitivity
98.6% on 77 positive samples

Analytical Sensitivity
20 genome equivalent copies / reaction

60 min **Thermal cycle**

>90 min **Less than 90 minutes including melting curve analysis**

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Ordering information

CODE	description	Q.ty
52261	CoronaMelt SARS-CoV2 RT PCR	100 tests
52180	OMNIA PRO	1

For professionals only

A.MENARINI diagnostics