



SARS-CoV-2

Real Time PCR detection kit

CE IVD



**Omicron and Omicron
Stealth variant detection**

One step detection and Omicron variant calling: Why just call it “a positive”?

CoronaMeltVAR is a new IVD Real Time PCR detection kit for SARS-CoV-2 virus, designed for high sensitivity detection and simultaneous genotyping of viral RNA in samples derived from nasopharyngeal, oropharyngeal swabs and SALIVA.

CORONA  MELT Var

Intercalating dye and melting curve: sensitivity and specificity

Detection of the amplification signal is obtained through the use of an intercalating dye.
The assay is designed to amplify:

- one viral targets on the ORF1ab gene for a sensitive and universal detection of the virus
- one amplicon specific to identify the presence of $\Delta 69-70$ deletion (UK Variant B.1.1.7 and new Omicron Variant)
- One amplicon designed on the E484K region with three possible melting peaks identifying the Omicron Stealth, or the wild type/Delta or the South African Brazil variants
- an endogenous control, targeting human GAPDH gene.

Target identity is confirmed by melting curve analysis. The combination of targets chosen produces a double positive amplification in presence of any of the three variants or the wild type virus.

Samples must undergo magnetic bead or column RNA extraction before PCR amplification.

Cases	ORF1ab gene	S Gene				Result
		$\Delta 69/70$	E484K			
	82°	77°	70°	71°	72°	
1	+	-		+		Positive WT/Delta
2	+	+		+		Positive Alfa (UK)
3	+	-	+			Positive Beta/Gamma (SA/BZ)
4	+	+			+	Positive Omicron BA.1
5	+	-			+	Positive Omicron BA.2

Table 1 showing the interpretation results

Endogenous control: results confidence

Human RNA expressed by the GAPDH housekeeping gene in the epithelial cells, 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.

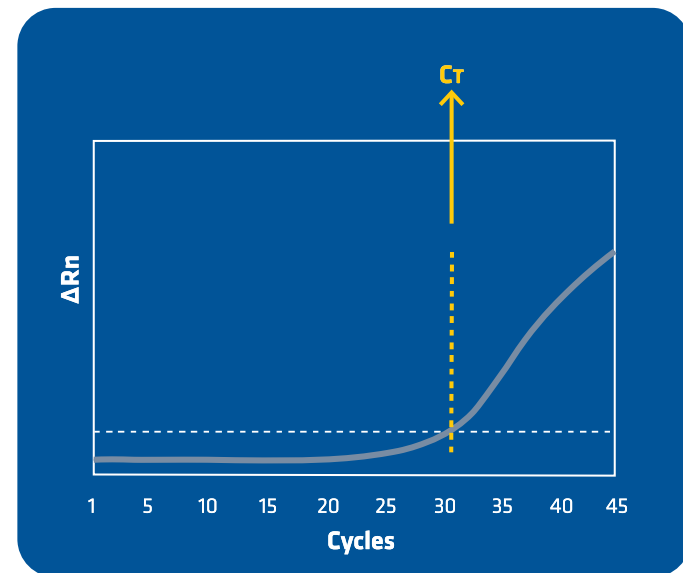
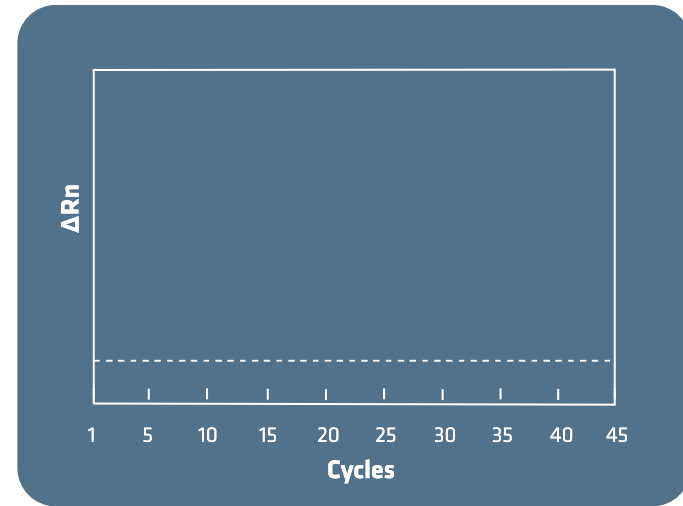


Fig.1 The presence of the endogenous control curve (below) indicates that the process was working correctly both at the sampling and the analytical level. In case of absence of the control curve (above) and of the viral target the sample is considered invalid and has to be repeated. The GAPDH gene is a highly expressed housekeeping gene, both in oro-nasopharyngeal epithelial cells and in saliva cells.



Automation friendly: easy to use

CORONA  MELT Var

CoronaMeltVAR can be implemented on the Menarini Omnia series liquid handling workstations, which enables to process **24 or 46 samples** from-VTM-tube-to-PCRplate including magnetic-bead RNA extraction.

The system allows full process automation **from primary VTM tubes to a ready-to-go real time PCR plate**. Plate configuration is automatically transferred to the thermal Cycler and to the LIS system for safe and error free tracing. The Omnia platforms have on board barcoding reader for samples and reagents as well as a UV lamp for DNA/RNA decontamination function.

SPECIFICATIONS



RNA Extraction
magnetic beads or
column purification



Analytical Sensitivity
10 genome equivalent
copies / reaction



Clinical Sensitivity
98.6% on 77
positive samples



Less than 90 minutes
including melting curve analysis



CORONA MELT Var

SARS-CoV-2

Real Time PCR detection and genotyping kit

Ordering information

CODE	description	Q.ty
54504	CoronaMeltVAR SARS-CoV-2 RT PCR	100 tests
52180	OMNIA PRO	-

For professionals only



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diagnostics