



# SARS-CoV-2

Real Time PCR detection kit

CE IVD



## One step detection and 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 for the UK Variant (B.1.1.7)
- one specific for either wild type or the Brazilian (P.1)/South African (B.1.351)
- an endogenous control, targeting human GAPDH gene.

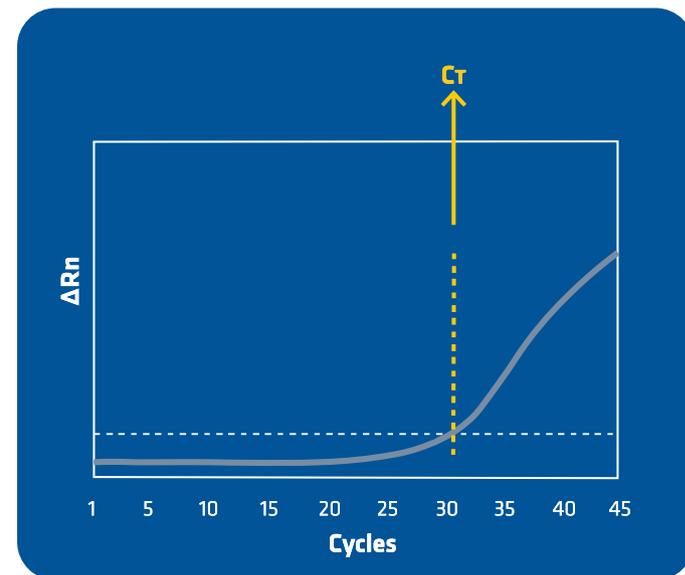
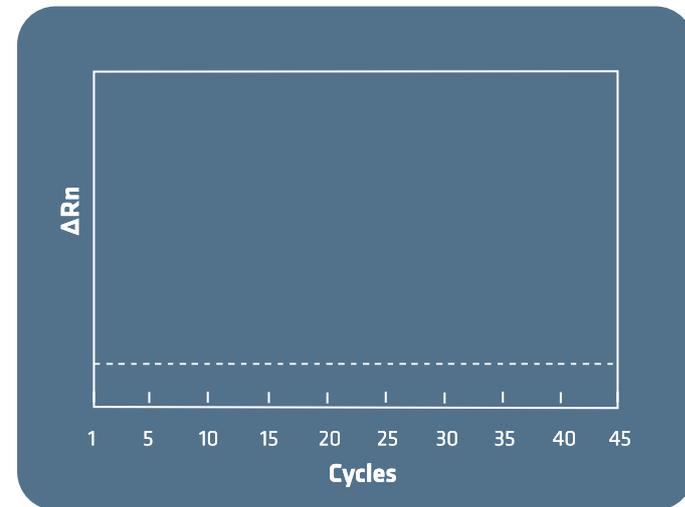
Target identity is confirmed by melting curve analysis. The combination of targets chosen produces a double positive amplification in presence of any of the three variants or the wild type virus. Samples must undergo magnetic bead or column RNA extraction before PCR amplification.

Cases	Targets					Result
	orf1ab gene	UK	SA/BZ		GAPDH	
		H69/V70 del	E484K WT	E484K mut		
1	+	-	+	-	+	Positive WT
2	+	+	+	-	+	Positive UK
3	+	-	-	+	+	Positive SA/BZ
4	-	-	-	-	+	Negative
5	-	-	-	-	-	Invalid

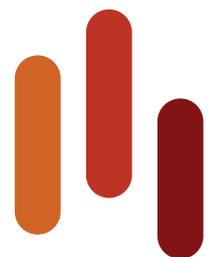
Table 1 showing the interpretation results

# 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

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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

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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



**A.MENARINI**  
diagnostics