

GENOMTEC

Genomtec® SARS-CoV-2 EvaGreen® RT-LAMP CE- IVD Duo Kit Catalogue Number GA00B

A qualitative Reverse Transcription Loop-Mediated Isothermal Amplification assay detecting SARS-CoV-2 RNA (encoding gene N & S) in throat swab and nasopharyngeal swab specimens.



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IVD



REF

GA00B
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Storage, shipping & stability

Reagent	Quantity	Volume	Part Number	Storage condition	Shipping condition	Shelf life
Genomtec® SARS-CoV-2 AmpMix	1 vial	1350µl	0BM	-22°C to -15°C	Dry/wet ice	3 months
Genomtec® SARS-CoV-2 D-PrimerMix	1 vial	100µl	0BH	-22°C to -15°C	Dry/wet ice	3 months
Genomtec® SARS-CoV-2 C-PrimerMix	1 vial	100µl	0BJ	-22°C to -15°C	Dry/wet ice	3 months
Genomtec® SARS-CoV-2 Control +	1 vial	40µ	0BC	-22°C to -15°C	Dry/wet ice	3 months
DNase/RNase-Free Water	1 vial	1000µl	0BD	-22°C to -15°C	Dry/wet ice	3 months

(Amplification Mix and Control Primers are stable for three thaw-freezing cycles).

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Reaction plate set-up

Reagent	Analyte	Inhibition control	Positive control	Negative Control
Genomtec® SARS-CoV-2 AmpMix	13.5µl	13.5µl	13.5µl	13.5µl
Genomtec® SARS-CoV-2 Duo-Primer Mix	1.5µl	-	1.5µl	1.5µl
Genomtec® SARS-CoV-2 C-Primer Mix	-	1.5µl	-	-
Sample RNA	5µl	5µl	-	-
Genomtec® SARS-CoV-2 Control +	-	-	5µl	-
DNase/RNase-Free Water	-	-	-	5µl
Total volume	20µl	20µl	20µl	20µl

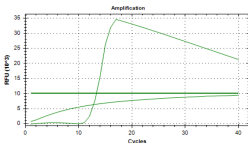
The PCR instrument must operate on 20 µl volume in a PCR tube / multi-well plate. The real time PCR instrument must detect fluorescence in FAM (green) channel.

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Real time PCR instrument settings

Step	Temp. (°C)	Time (sec.)	Cycles/repeats
Amplification 1	62	30	30
Amplification 2	62	30	

To interpret results of the assay please follow the guidance presented in Table 3, Section 8 of IFU. IFU can be downloaded from <http://genomtec.com/support>



Example of standard S-curves for positive and negative samples, and the threshold.

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