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 | 6 months |
| Genomtec® SARS-CoV-2 Duo-PrimerMix | 1 vial | 100µl | 0BH | -22°C to -15°C | Dry/wet ice | 6 months |
| Genomtec® SARS-CoV-2 C-PrimerMix | 1 vial | 100µl | 0BJ | -22°C to -15°C | Dry/wet ice | 6 months |
| Genomtec® SARS-CoV-2 Control + | 1 vial | 40µ | 0BC | -22°C to -15°C | Dry/wet ice | 6 months |
| DNase/RNase-Free Water | 1 vial | 1000µl | 0BD | -22°C to -15°C | Dry/wet ice | 6 months |

(Amplification Mix and Primers are stable for at least 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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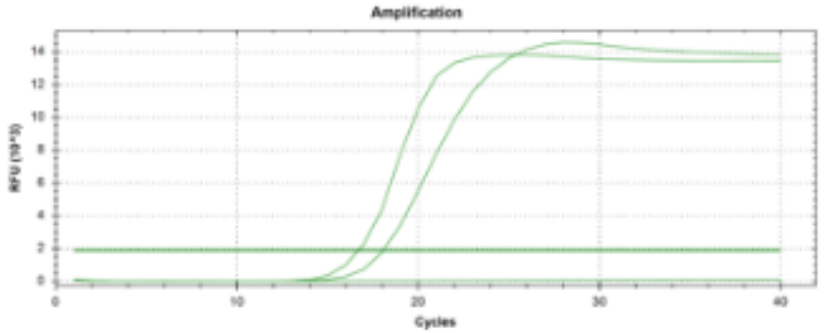
## Real time PCR instrument settings

| Step | Temp. (°C) | Time (sec.) | Cycles/ repeats |
|---|---|---|---|
| Amplification 1 | 64 | 30 | 30 |
| Amplification 2 | 64 | 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 amplification curve for positive and negative samples, and the threshold.

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