

SARS-CoV-2 Infections

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

Genomtec® SARS-CoV-2 EvaGreen® RT-LAMP CE-IVD Duo Kit is Real-Time Reverse Transcription Loop-Mediated Isothermal Amplification (RT-LAMP) test for qualitative detection of nucleic acid from two genes of SARS-CoV-2 virus.* Simultaneous RNA transcription and cDNA amplification utilizing standard Real-Time PCR instrument workflow (detection in FAM channel), assay can generate positive results within less than 20 minutes.†

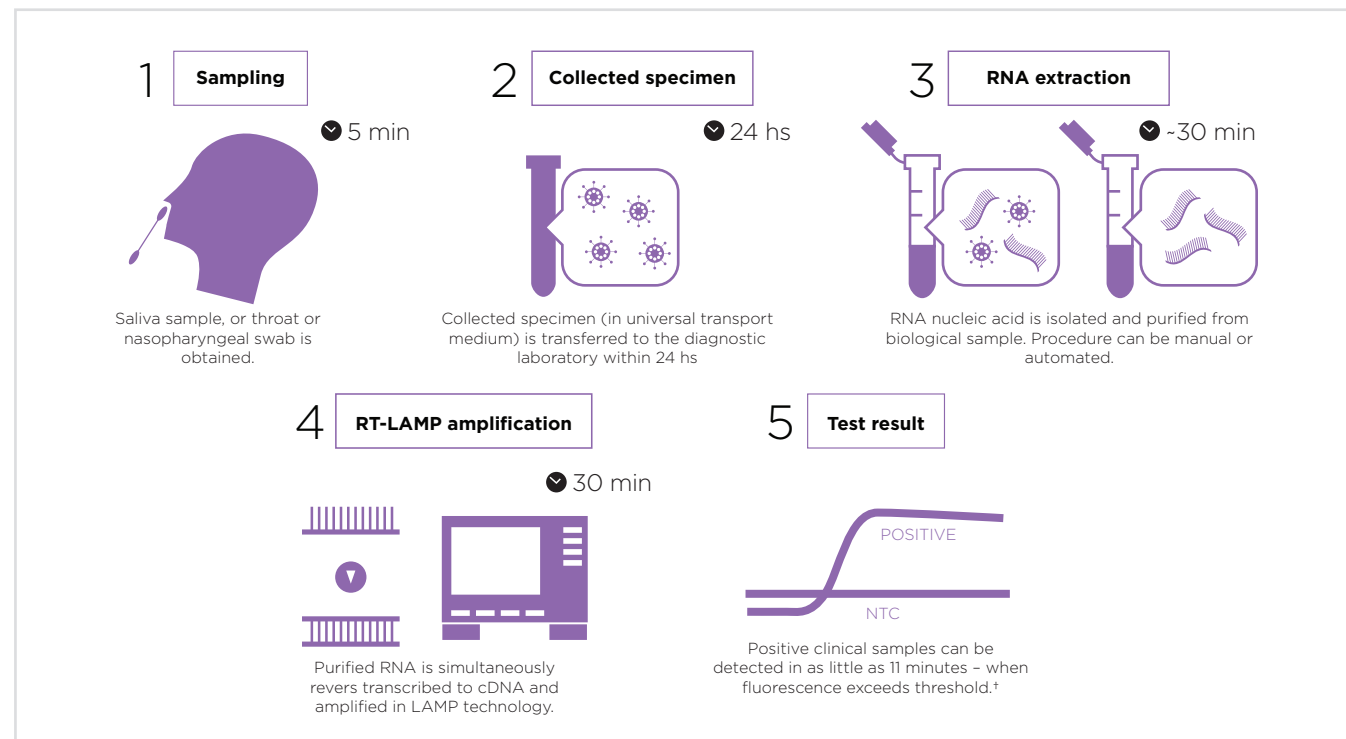
CLINICAL EVALUATION:
100% sensitivity & specificity confirmed when compared to Real-Time RT-PCR CE-IVD test ††

Validated specimen types include saliva, nasopharyngeal and oropharyngeal swabs†††

Assay	Target Region	Detection Channel
SARS-CoV-2	N/S	FAM
	Human RNA	FAM

KIT DESCRIPTION:

- Double-well, triple target assay covering highly conserved region within N & S genes
- Superb diagnostic performance provided by eleven LAMP primers recognising fifteen conservative fragments of SARS-CoV-2 N & S genes enable specific virus detection
- Melting peak analysis possible
- More Robust, rapid and inhibitor-tolerant amplification system without thermal-cycling requirement.



* CE-IVD labeled for diagnostic use in the EU; † whole diagnostic protocol takes 30 minutes; ††SARS-CoV-2 IFU: Current Revision IF00BUKRE; ††† Clinical validation was performed on nasopharyngeal and oropharyngeal swabs, as per IFU Section 9.4; saliva RNA processing described in Section 7.1.2

Incomparable speed and throughput guaranteed by 30 minutes amplification protocol on a standard Real-Time PCR systems.

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Size	50 test / kit
Kit components	Genomtec® SARS-CoV-2 AmpMix Genomtec® SARS-CoV-2 Duo-Primers Genomtec® SARS-CoV-2 C-Primers Genomtec® SARS-CoV-2 Control + DNase/RNase-Free Water
Number of primer/probe mix	1 AmpMix & 2 Primers mixes (target - SARS-CoV-2 genes and specific fragment of the human genome)
Thermocycler	All equipped with FAM/green fluorescence channel
Storage / shipment	-22°C to -15°C / wet (<24) / dry (>24h) ice

Diagnostic features

Reaction time & volume	30 minutes / 20µl
Limit of Detection (LOD)	20 GE / reaction (at 95% CI for either N or S genes)
Diagnostic Sensitivity (SE) ***	100%
Diagnostic Specificity (SP) ***	100%

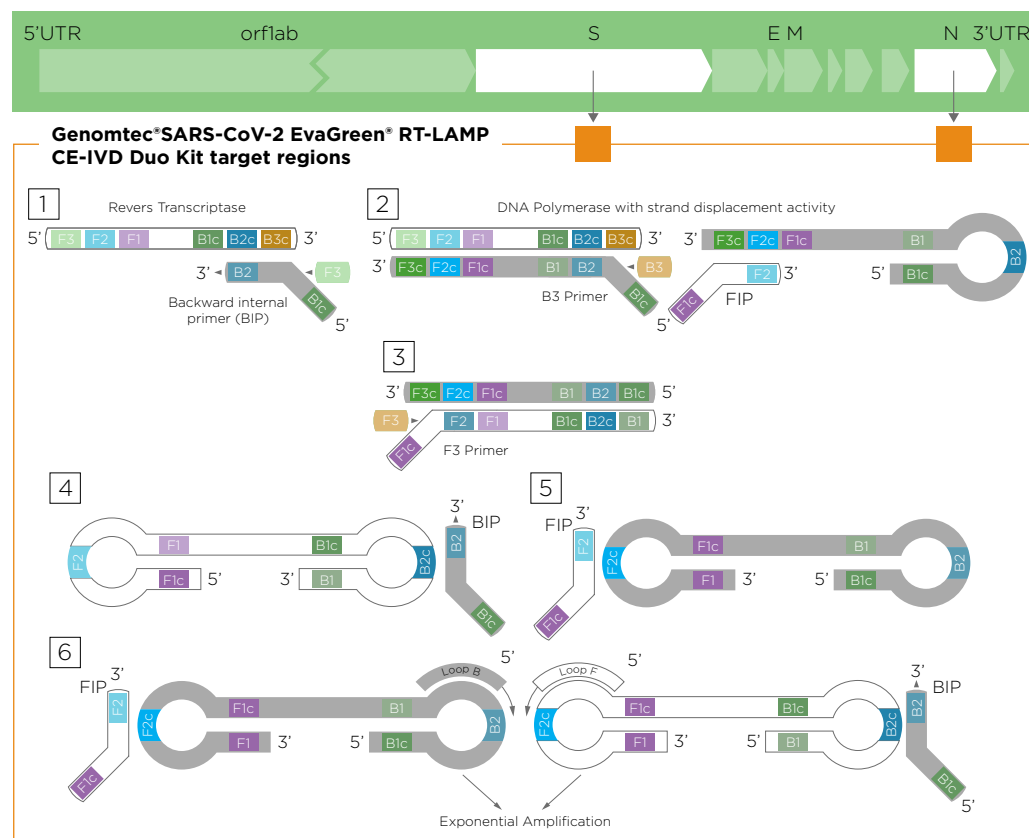
*** It has been confirmed that Genomtec® SARS-CoV-2 RT-LAMP Duo test exhibits 100% sensitivity and specificity compared with a standard (at least two gene) laboratory RT-PCR CE-IVD diagnostic test when detecting presence or absence of the SARS-CoV-2 virus in 39 included clinical specimens. The accuracy, PPV and NPP were also obtained at level 100%.

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Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

It is now possible to speed up your diagnostic process while preserving its consistency.

Thanks to utilization of the best enzymes and individual compositions we can offer a rapid yet of unmatched diagnostic parameters genetic test that can be swiftly implemented onto your current laboratory workflow, enhancing your throughput and reliability (false negative samples occurrence limited due to use of the LAMP primers).



Legal Manufacturer:

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