

SARS-CoV-2 Infections

Genomtec® SARS-CoV-2 RT-LAMP/N CE-IVD Laboratory Kit

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Laboratory Kit is Real-Time Reverse Transcription Loop-Mediated Isothermal Amplification (RT-LAMP) test for qualitative detection of nucleic acid from 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:

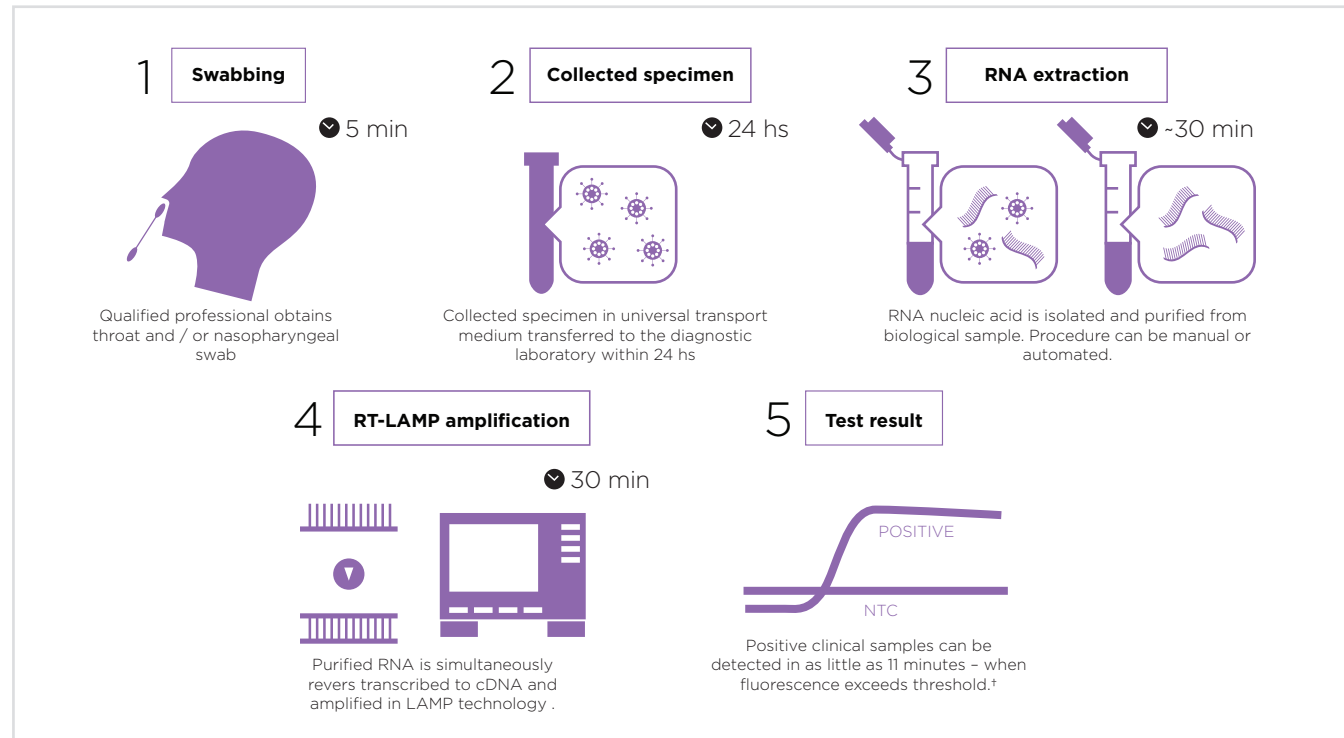
100% sensitivity & specificity confirmed when compared to Real-Time RT-PCR CE-IVD test ††

Clinically Validated specimen types include nasopharyngeal and oropharyngeal swabs.

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

KIT DESCRIPTION:

- Double-well, dual target assay covering highly conserved region within N gene
- Superb diagnostic performance provided by five LAMP primers recognising seven conservative fragments of SARS-CoV-2 N gene enable specific virus detection compared to just three oligonucleotides in single-gene Real Time RT-PCR assays
- 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 IF00AUKr1

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	DetectionMix, ControlMix, Positive Control, Nuclease-free water
Number of primer/probe mix	2 - DetectionMix (target - SARS-CoV-2) & ControlMix (target - specific fragment of the human genome)
Thermalcycler	All equipped with FAM/green fluorescence channel
Storage / shipment	-22°C to -15°C / dry ice

Diagnostic features

Reaction time & volume	30 minutes / 20µl
Limit of Detection (LOD)	147 gene copies / reaction (95% CI: 112 - 271)
Diagnostic Sensitivity (SE) ⁺⁺⁺	100%
Diagnostic Specificity (SP) ⁺⁺⁺	100%

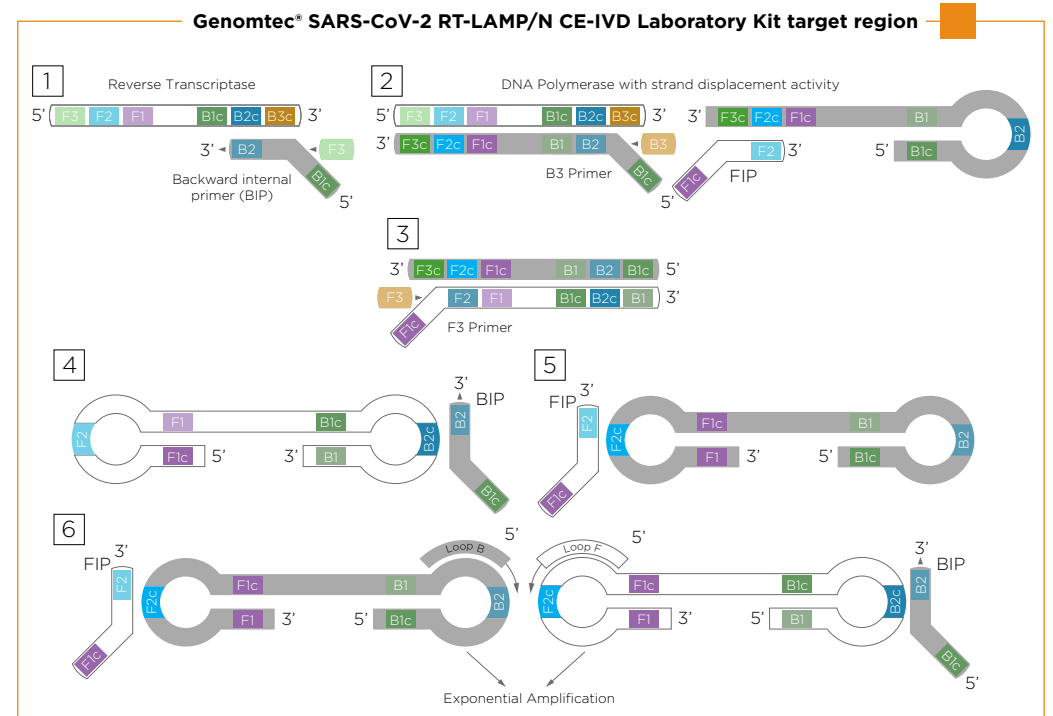
⁺⁺⁺ It has been confirmed that Genomtec(R) SRAS-CoV-2 RT-LAMP/N test exhibits 100% sensitivity and specificity compared with a standard (two gene) laboratory RT-qPCR diagnostic test when detecting presence or absence of the SARS-CoV-2 virus in 67 included clinical specimens. Both, the PPV and NPP were 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).



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