

SARS-CoV-2 Infections

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

Genomtec® SARS-CoV-2 EvaGreen® RT-LAMP/N CE-IVD 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.†

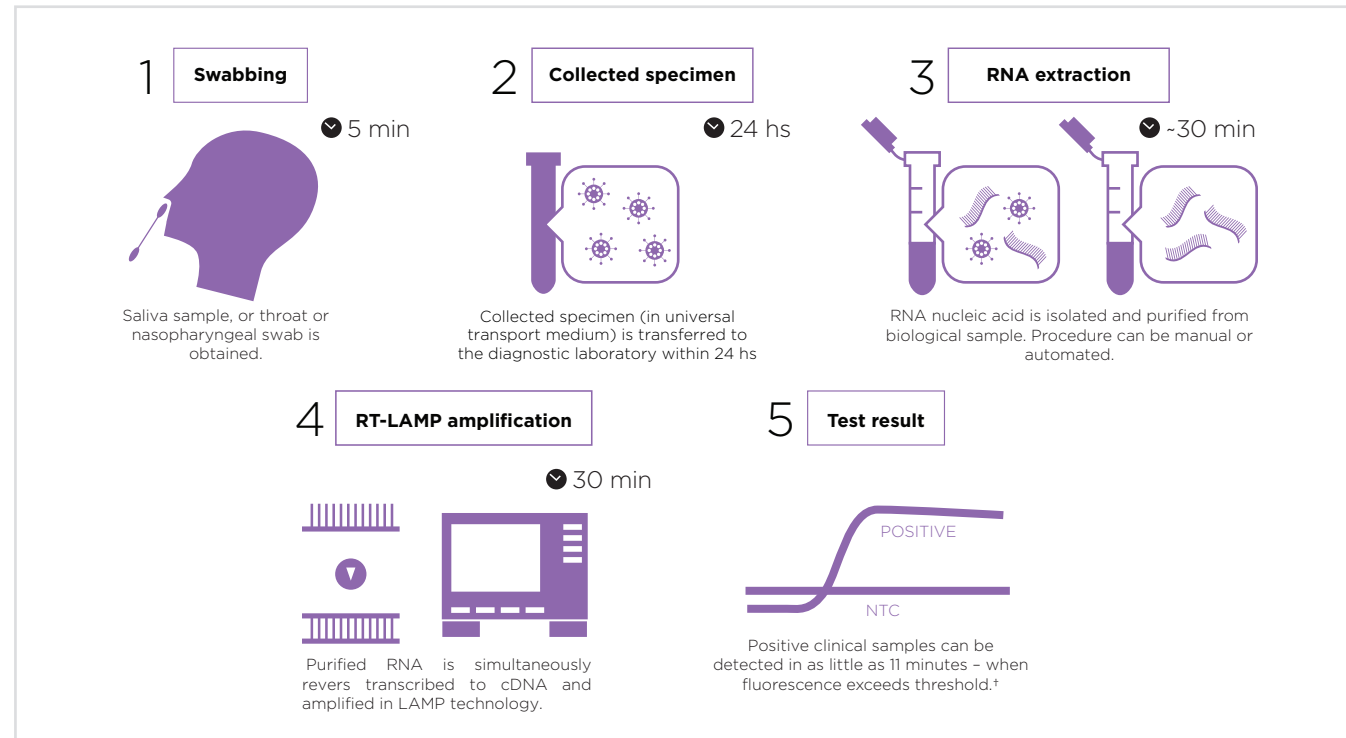
CLINICAL EVALUATION: 100% sensitivity & specificity confirmed when compared to Real-Time RT-PCR CE-IVD test ††

Validated specimen types include saliva, 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 IF00AUKrB; ††† Clinical validation was performed on nasopharyngeal and oropharyngeal swabs, as per IFU Section 9.4

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 D-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 and specific fragment of the human genome) |
| Thermalcycler | 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) | 135 gene copies / reaction (95% CI: 102 - 256) |
| Diagnostic Sensitivity (SE) ⁺⁺⁺ | 100% |
| Diagnostic Specificity (SP) ⁺⁺⁺ | 100% |

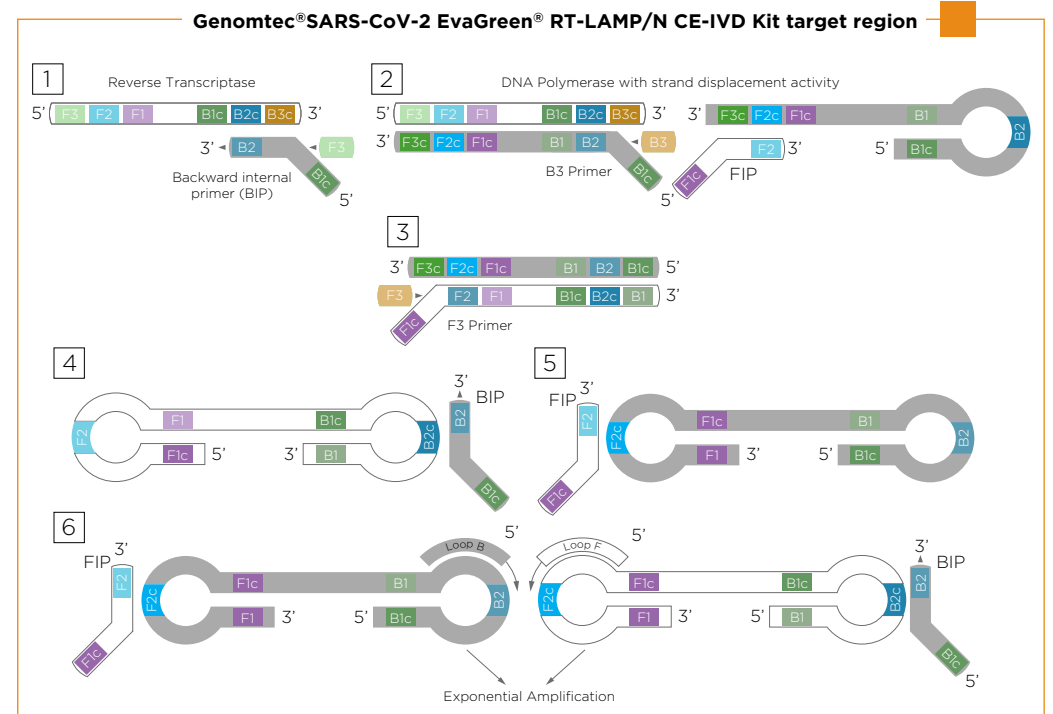
⁺⁺⁺ It has been confirmed that Genomtec® SARS-CoV-2 RT-LAMP/N test exhibits 100% sensitivity and specificity compared with a standard (at least two gene) laboratory RT-PCR CE-IVD diagnostic test when detecting presence or absence of the SARS-CoV-2 virus in 67 included clinical specimens. The accuracy, 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).



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