GENOMTEC

The right diagnosis, right away, at the right price

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

Genomtec® SARS-CoV-2 EvaGreen® Direct-RT-LAMP CE-IVD 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 with a streamlined biological sample processing that is CE-IVD labelled for diagnostic use in the EU.* It features rapid RNA isolates preparation in conjugation with the simultaneous RNA transcription and cDNA amplification utilizing standard Real-Time PCR instrument workflow (detection in FAM channel), with sample to result time in approx. 50 minutes of which amplification stage takes only 40 minutes.

Multiple benefits

- Comfort, accuracy and speed **for patients testing**
- Increased level of safety **for medical personnel**
- Faster, easier and cost effective process **for laboratories**
- increased efficiency and lower cost of laboratory work **for healthcare system**

*SARS-CoV-2 IFU: Current Revision IF00CUKrB

With Genomtec® Direct RT-LAMP we bring new quality of testing for SARS-CoV-2.

For Patients it means

- greater comfort due to lack of swabbing e.g. from the nasopharynx
- test performance regardless of SARS-CoV-2 variant present
- faster results

For Medical Personnel it means

- decreased risk of exposure to infectious agents
- no specialized skills and equipment required while sampling

For Laboratory it means

- rapid biological material processing and 40 minutes isothermal amplification protocol
- no thermal-cycling requirement
- increased cost effectiveness (no swabs, no extensive RNA purification kit, no doctor's swabbing)
- obtained RNA-enriched supernatant directly used for amplification reaction setup
- double-well, triple target assay covering highly conserved regions within N & S genes as well as internal control targeting human gene
- superb diagnostic performance provided by eleven LAMP primers recognising fifteen conservative fragments of SARS-CoV-2 N & S genes enable specific virus detection

For Healthcare System it means

- quicker laboratory turnaround time increases outbreak surveillance
- wider population acceptance for testing due to non-invasive sampling
- less expensive and more robust method for SARS-CoV-2 molecular testing
- minimal laboratory experience required and possibility for fast re-training for the operator

CLINICAL EVALUATION:

92.31% sensitivity and 100% specificity confirmed when compared to Real-Time RT-PCR CE-IVD test.

Validated specimen types include saliva, nasopharyngeal and oropharyngeal dry-swabs. Clinical validation was performed on saliva samples.**

VARIANTS RECOGNIZED INCLUDE:

Genomtec® Direct-RT-LAMP Kit can detect the wild type virus as well as mutant strains of SARS-CoV-2 including but not limited to: B.1.1.7 (EPI_ISL_723044), Breton (hCoV-19/France/BRE-IPP04233/2021) (EPI_ISL_1259297), P1 (EPI_ISL_792680), B. 1.351 (EPI_ISL_825139), B.1.525 (EPI_ISL_1563854), P.3 (EPI_ISL_1122452) and B.1.427 (EPI_ISL_1592298), B.1.617 (EPI_ISL_1415353).

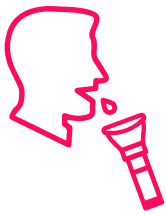
ASSAY SPECIFICATION

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

PROTOCOL DIRECT KIT - increases throughput by streamlining laboratory processing

1 Sampling

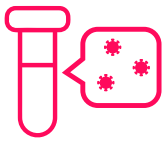
5 min.



Saliva sample, or throat or naso-pharyngeal dry swab is obtained.

2 Collected specimen

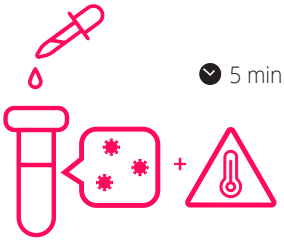
24 hs



Collected specimen (saliva or dry swab) is transferred to the diagnostic laboratory within 24 hs.

3 Lysate total RNA prep

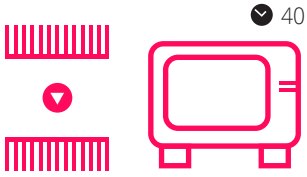
5 min.



Add LysBuffer to saliva or dry swab and heat for 5 min. at 95°C to prepare RNA-enriched supernatant.†

4 RT-LAMP amplification

40 min.



Purified RNA is simultaneously reverse transcribed to cDNA and amplified in LAMP technology.

5 Test result

Positive clinical samples can be detected in as little as 20 minutes – when fluorescence exceeds threshold.

** as per IFU Section 9.5; dry swab processing is described in Section 6.2 of IFU.
† Saliva / dry swab sample preparation stage with LysBuffer takes 5 minutes onto the heat block (pipetting excluded)

Genomtec® Direct-RT-LAMP kit increases your throughput by streamlining laboratory sample preparation and 40 minutes isothermal amplification protocol achieved on any open Real-Time PCR thermocycler.

PRODUCT TABLE

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 + Genomtec® SARS-CoV-2 LysBuffer 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)
Sample preparation	includes LysBuffer reagent; 50 reactions / kit
Thermocycler	All equipped with FAM / green fluorescence channel
Storage / shipment	–22°C to –15°C & 5±3°C LysBuffer / wet ice (<48) or dry ice & ambient LysBuffer (>48h)

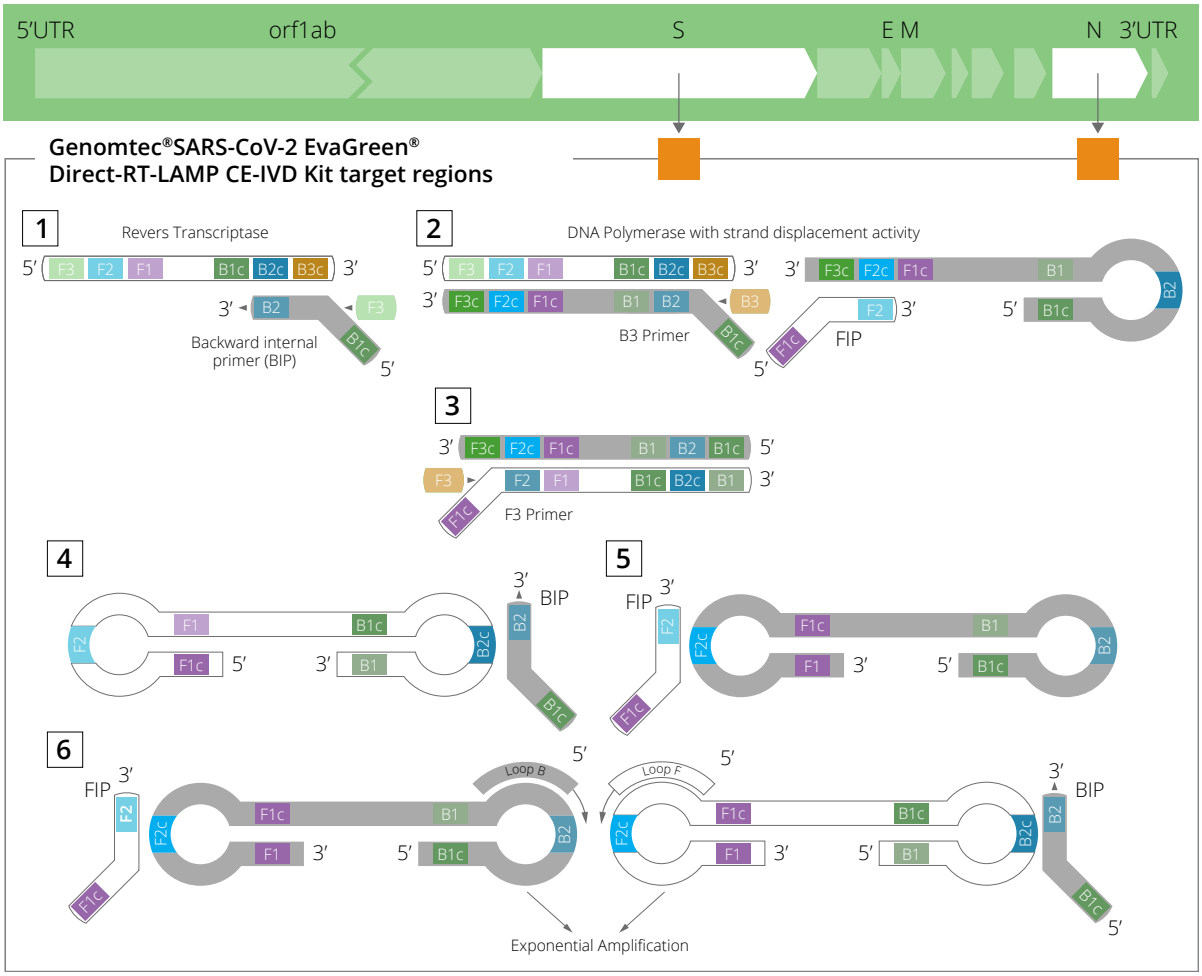
DIAGNOSTIC FEATURES

Reaction time & volume	40 minutes / 25µl
Limit of Detection (LOD)	2 viral copies / reaction for saliva & 10 viral copies / reaction for dry-swab (at 95% CI for either N or S genes)
Diagnostic Sensitivity (SE) ‡	92.31%
Diagnostic Specificity (SP) ‡	100%

‡ It has been confirmed that Genomtec® SRAS-CoV-2 Direct-RT-LAMP test exhibits 92.31% sensitivity and 100% 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 57 mixed clinical and contrived positive saliva samples. Test accuracy is 96.49%, PPV 100% and NPP 93.94%.

It is now possible to speed up your diagnostic process while preserving its consistency & providing cost efficacy.

Thanks to utilization of LysBuffer for streamlined sample preparation†, best in-class enzymes, and individual compositions we can offer a rapid yet of unmatched diagnostic parameters genetic test that can be swiftly implemented into your current laboratory workflow. Gain throughput, customer satisfaction and RT-LAMP reaction reliability.



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