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 of SARS-CoV-2 virus directly from nasal swabs, or directly from saliva.

The SARS-CoV-2 Direct RT-LAMP assay detects both the N gene and S gene and includes necessary controls. The test detects all variants currently listed by WHO.*

The kit features a rapid RNA extraction step in conjunction with the simultaneous RNA transcription and cDNA amplification, with test results available in approx. 50 minutes.

Multiple benefits

- Easy, non-invasive and more comfortable saliva sample collection **for patients**
- Increased efficiency and lower costs compared to other molecular methods **for healthcare system**.
- One-step reagents for streamlined operations of **laboratories**

* Alfa (B.1.1.7; EPI_ISL_723044); Beta (B.1.351; EPI_ISL_825139); Gamma (P.1; EPI_ISL_792680); Delta (B.1.617.2; EPI_ISL_2650470); Epsilon (B.1.427/B.1.429; EPI_ISL_2631197); Zeta (P.2; EPI_ISL_2614193); Eta (B.1.525; EPI_ISL_1563854); Theta (P.3 (version: 2021-04-01); EPI_ISL_1122452); Iota (B.1.526; EPI_ISL_2647531); Kappa (B.1.617.1; EPI_ISL_1415353); Lambda (C.37; EPI_ISL_2536799); Breton (hCoV-19/France/BRE-IPP04233/2021; EPI_ISL_1259297); Omicron (B.1.1.529; EPI_ISL_6590782); Mu (B.1.621; EPI_ISL_6811664).

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Genomtec® SARS-CoV-2 EvaGreen® Direct-RT-LAMP kit streamlines your laboratory operations with 5 minutes sample prep and 40 minutes isothermal amplification protocol achieved on any open Real-Time PCR thermocycler.

PRODUCT INFORMATION

Catalog no.	GA00C	
Size	50 tests / kit	
Kit Components and Storage Conditions	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	Pouch 1, Store at -20°C
	Genomtec® SARS-CoV-2 LysBuffer	Pouch 2, Store at 4°C
Thermocycler	All equipped with FAM / green fluorescence channel	

CLINICAL PERFORMANCE that matches Real-Time RT-PCR CE-IVD test.

Sensitivity (as per IFU)	93.75%
Specificity (as per IFU)	100%
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)
Run time	40 minutes

Validated specimen types include saliva, nasopharyngeal, oropharyngeal dry swabs. Clinical validation was performed on saliva samples (as per IFU).

PROTOCOL that speeds up your laboratory processing with one step reagents.

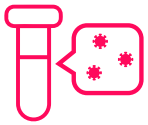
1 Sampling

5 min.

Saliva sample, or throat or nasopharyngeal dry swab is obtained.

2 Collected specimen

up to 24 Hrs



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

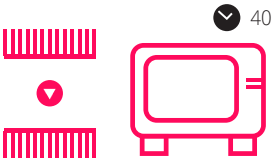
3 Lysate total RNA prep

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.



Extracted 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.

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CE IVD
For In vitro Diagnostic Use

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