

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

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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.

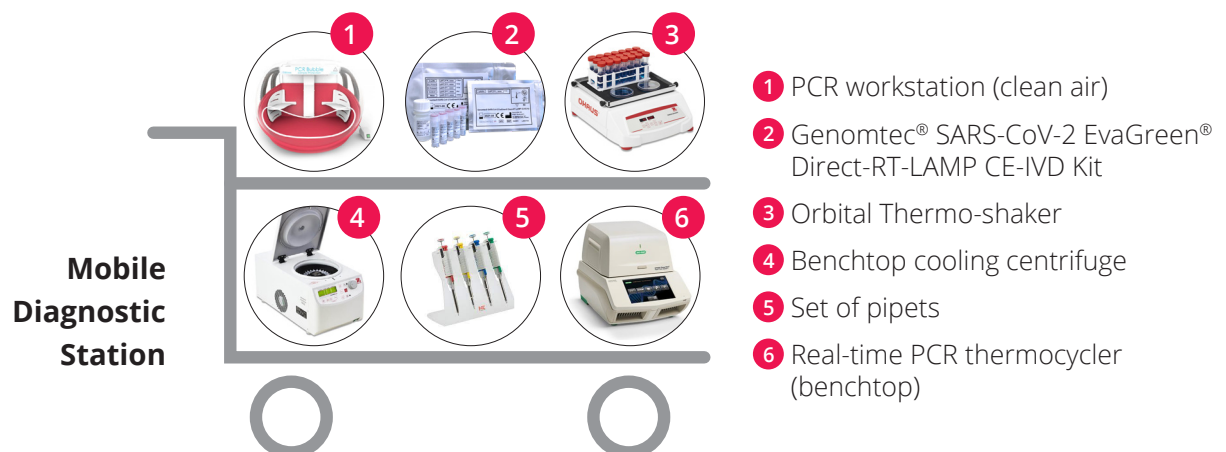
Unique benefits:

- Biosafety ensured by thermal lysis of pathogens present in a saliva sample
- Offers portable lab set up
- Adds speed and performance to laboratory workflow
- Operability by one / two minimally trained staff

Genomtec® Direct RT-LAMP Kit simple requirements enable fast molecular testing for SARS-CoV-2

Equipment	Personnel	Genomtec® Direct RT-LAMP Kit
<p>(portable) fume hood</p> <p>Benchtop rt-PCR thermocycler</p> <p>Benchtop cooling centrifuge & cooling bag</p> <p>Thermo-shaker with heating options</p>	<p>Needed undergrads or lab technicians (1-2)</p> <p>Unsupervised sample collection</p> <p>No swabbing = increased biosafety for personnel</p> <p>2 days training (for unexperienced person)</p>	<p>Robust for impurities & contamination</p> <p>Streamlined sample prep (10' total)</p> <p>Rapid amplification (40' protocol)</p> <p>Easy analysis in 1 fluorescent channel</p>

PROCESS	<ul style="list-style-type: none"> • "Wheel it in" and connect to the mains • No laboratory nucleic acid purification needed 	<ul style="list-style-type: none"> • Saliva samples are donated by patients with no sampling required from personnel • Option for remote saliva sample delivery or at collection point 	<ul style="list-style-type: none"> • Simple and quick saliva processing that can be done in ambient temperature • Unused reagents can be disposed or store in cool place until placed in a freezer
RISK	<ul style="list-style-type: none"> • Electricity failure • Not enough flat space (e.g. desk) to place equipment 	<ul style="list-style-type: none"> • Human errors during assaying • Some training required for inexperienced operator 	<ul style="list-style-type: none"> • Reagents thawed and reached room temp. for prolong time
ADVANTAGE	<ul style="list-style-type: none"> • Ultra-fast setup that can be performed in any laboratory or other space, including mobile laboratory. • No investment in core equipment. 	<ul style="list-style-type: none"> • No additional hires in laboratory. • Training provided to science & technology students towards future specialised profession. 	<ul style="list-style-type: none"> • 60' time-to-result for up to 46 samples tested**. • Incorporates seemingly in PCR laboratory workflow. • Fast result analysis in one fluorescent channel.



Displayed equipment is for the comparative purposes only and Genomtec is not its manufacturer, nor reseller. Optional substitutes may be available in your geographical area that may vary from shown appearance due to different manufacturer.

** based on one 96-well PCR plate run, includes time used for saliva sample prep, pipetting necessary for reactions set up on a microplate and 40' amplification on any open source Real-Time PCR thermocycler

GENOMTEC® DIRECT RT-LAMP KIT CAN AID IN:

1. Creating portable fast-lab almost everywhere

It is possible to setup quickly and of a minimal maintenance laboratory in spaces like:

- rooms in Polyclinics, or other small medical facilities,
- schools and University campuses,
- residential blocks, hotels or even factory-facilities

Competitive advantage: inexpensive equipment that can be relocated to another place if needed, with minimal human operations and wider **population acceptance** for testing due to non-invasive sampling executed directly by patient.

2. Upgrade of existing lab performance

It is possible to increase your throughput by streamlining laboratory sample preparation based on saliva and achieve 40' isothermal amplification protocol resulting in:

- Increase of testing capacity even by 60%
- No reconfiguration of current laboratory workflow
- Cost saving due to cheap saliva collection and no RNA purification kit used

Competitive advantage: and quicker laboratory turnaround time increases outbreak surveillance and superb diagnostic performance provided by eleven **LAMP primers** recognising fifteen conservative fragments of SARS-CoV-2 N & S genes, including 12 variants.

VARIANTS RECOGNIZED INCLUDE:

Genomtec® Direct-RT-LAMP Kit can detect the wild type virus as well as mutant strains of SARS-CoV-2 including:

Accession number	Variant	WHO classification
EPI_ISL_723044	B.1.1.7	Alfa
EPI_ISL_825139	B. 1.351	Beta
EPI_ISL_792680	P.1	Gamma
EPI_ISL_2650470	B.1.617.2	Delta
EPI_ISL_2631197	B.1.427/B.1.429	Epsilon
EPI_ISL_2614193	P.2	Zeta
EPI_ISL_1563854	B.1.525	Eta
EPI_ISL_1122452	P.3 (version: 2021-04-01)	Theta
EPI_ISL_2647531	B.1.526	Iota
EPI_ISL_1415353	B.1.617.1	Kappa
EPI_ISL_2536799	C.37	Lambda
EPI_ISL_1259297	Breton (hCoV-19/France/ BREIPP04233/2021)	N/A

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.

PROTOCOL DIRECT KIT

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.

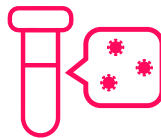
1 Sampling



🕒 1 min.

Saliva sample is donated in an unsupervised mode

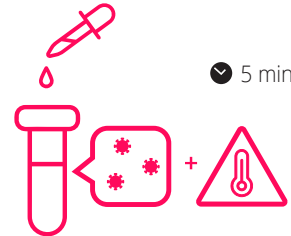
2 Collected specimen



🕒 15 min.

Collected saliva is delivered to place of testing within minutes and is stable up to 5 hours in 30°C

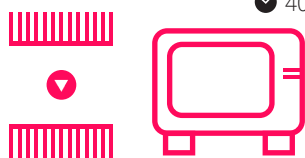
3 Lysate total RNA prep



🕒 5 min.

Add LysBuffer to saliva and heat for 5 min. at 95°C to prepare RNA-enriched supernatant. This step completely neutralises any pathogens present in processed sample.[†]

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 with one fluorescent channel for results analysis.

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.^{***}

ASSAY SPECIFICATION

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

^{***} 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)

PRODUCT TABLE

Size	50 tests / 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 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.



† 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%.

Legal Manufacturer:

Genomtec SA

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