FastProof™ 30 min-TTR SARS-CoV-2 RT-LAMP Kit (Catalog no. ZE-P14)

Product description

FastProof™ 30 min-TTR SARS-CoV-2 RT-LAMP Kit used Colorimetric RT-LAMP (Reverse-Transcription Loop-Mediated Isothermal Amplification) technique, targeting N gene of SARS-CoV-2 and human RNase P gene as an internal control, allows fast, sensitive and specific detection of SARS-CoV-2 RNA under the controllable cost with 30 min Time-to-Test Results (TTR).

Intended Use

FastProof™ 30 min-TTR SARS-CoV-2 RT-LAMP Kit is a qualitative *in vitro* diagnostic test for the detection of nucleic acids from SARS-CoV-2 in nasopharyngeal and oropharyngeal (throat) swab from individuals who are suspected of COVID-19.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during infection. Positive results are indicative of SARS-CoV-2 RNA.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Product Components

FastProof™ 30 min-TTR SARS-CoV-2 RT-LAMP Kit contains sufficient reagents for 120 reactions (60 tests).

Includes:

Components	Volume (μL)
Color LAMP-TTR (ZE-P15)	1,200 μL
N primers mix-TTR (ZE-16)	300 μL
RNase P primers mix-TTR (ZE-P17)	300 μL
Positive control-TTR (ZE-P18)	60 μL
Negative control-TTR (ZE-P19)	60 μL

Storage Condition: Store all components at -20°C.

Instruction Manual

1. Thawing of solutions. Take the Color LAMP-TTR, Primers mix-TTR, positive control-TTR, and negative control-TTR (RNase-free water) out from -20°C. Thaw all tubes at room temperature and place all tubes on cold rack at 4°C or on ice.

2. Preparation of RT-LAMP supermix for LAMP reactions

(Carry out in a biosafety cabinet, a laminar flow cabinet, or a clean closed-system cabinet such as a PCR cabinet workstation)

2.1 Mix 10 μL the Color LAMP-TTR (ZE-P15) with 5 μL of Primers mix-TTR. Pipette up and down gently several times to mix the solution.

2.2 Aliquot 15 μL of the RT-LAMP supermix into each of the PCR tubes.

2.3 Add 5 μL of extracted RNA to one of the reaction PCR tubes in the following order: Negative control-TTR, clinical specimen(s), and Positive control-TTR. Cover each well, spin down the reaction PCR tubes. For 5 seconds.

*This step of adding RNase-free water into the supermix (negative control) should be performed prior to adding RNA extracted from the tested samples and the RNA positive control.

Note: To prevent cross contamination, finish aliquoting the RT-LAMP supermix into the reaction tubes and preparing the negative control-TTR prior to touching the RNA templates for testing. Also, the work area for the preparation of the RT-LAMP supermix (always clean) and the work area for all activities involved with the tested RNA should be separated.

	N gene			RNase P gene		
	Negative	Positive	Tested sample	Negative	Positive	Tested sample
Color LAMP-TTR	10 μL	10 μL	10 μL	10 μL	10 μL	10 μL
N Primers mix-TTR	5 μL	5 μL	5 μL	-	-	-
RNase P primers mix-TTR (internal control)	-	-	-	5 μL	5 μL	5 μL
Positive control-TTR	-	5 μL	-	-	5 μL	-
Negative control-TTR	5 μL	-	-	5 μL	-	-
Extracted RNA**	-	-	5 μL	-	-	5 μL

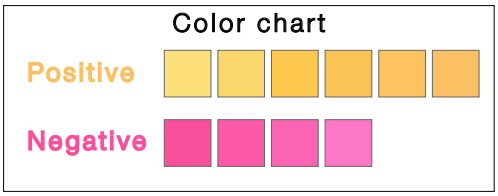
**Check at assay specification

2.4 Incubate the reaction PCR tubes at **65°C for 30 minutes** in a thermal cycler or heating block.

Result Interpretation

1. If the reaction solution turns yellow or orange, interprete as positive result or detected.
2. If the reaction solution remains pink, interprete as negative result or not detected.

N	RNase P (Internal control)	Result
+	+	SARS-CoV-2 Positive
-	+	SARS-CoV-2 Negative
+/-	-	Invalid/Re-test



Materials to be Supplied by the User

0.2-mL PCR Tubes, RNase-Free, 1.5 – 2 mL Microcentrifuge Tube, Automatic Pipettes, Filtered Tips
Mini-centrifuge Machine, Thermal Cycler Machine or Heat Block

Assay Specification

Specimen	Nasopharyngeal swab and Throat swab
Target gene	N gene and human RNase P gene
RNA extraction from clinical sample	MagDEA® Dx reagents (Precision System Science, Japan), GENTi™ Viral DNA/RNA Extraction Kit (GeneAll, Korea), QIAamp™ Viral RNA Mini Kit (Qiagen, Germany), QIAamp MinElute Virus Spin Kit (Qiagen, Germany), Sera-Xtracta Virus/Pathogen Kit (Cytiva, USA)
Controls included	Positive control, Negative control and Internal control
Limit of detection (LOD)	17 copies/reaction (1,526 copies/mL)
Analytical reactivity	Do not cross react with Influenza A/H1 virus, Influenza A/H3 virus, Influenza B virus, Respiratory Syncytial virus A, Respiratory Syncytial virus B, Human metapneumovirus, Coronavirus HKU1, Coronavirus OC43, Coronavirus 229E, and Coronavirus NL63

Troubleshooting

Problem	Solution
Precipitation of the master mix after repeated freeze/thaw cycles.	Vortex or invert the tube several times until the precipitates disappear.
Negative control turns yellow (False positive).	Clean your working space and equipment. Change RNase free water. Check the temperature control system of the thermal cycler machine. Do not let the master mix and the reaction expose to air for too long by leaving the lid open during preparation of the master mix and the reaction. Always keep the master mix and the reaction at 4°C.

Symbols

IVD	In vitro diagnostic medical device
	Date of manufacture
	Expiratory date (last date of month)

RESEARCH AND MANUFACTURED BY
Zenostic Co., Ltd.
272 Rama VI Road, Ratchathewi District, Bangkok 10400, THAILAND