Instruction Manual

Fastproof™ GoPlus SARS-CoV-2 RT-LAMP Kit

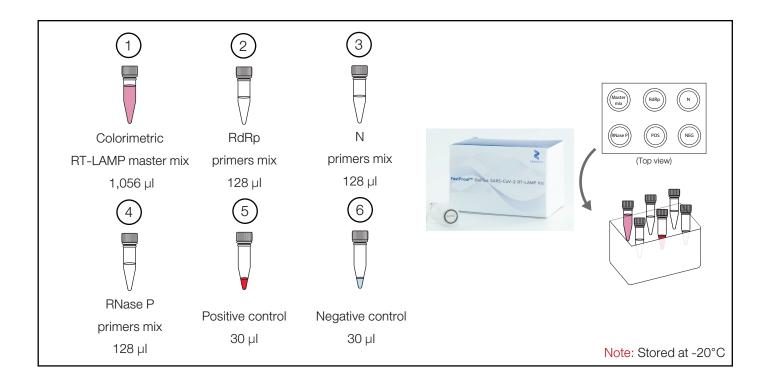
Catalog Number ZE-P10

Publication Number 0001

IVD (In-Vitro Diagnostic)



Product information



Components Included within the Kit

96 tests/kit (32 tests/target gene)

Reagent Name	Volume
Colorimetric RT-LAMP master mix	1,056 µl
2. RdRp primers mix	128 µl
3. N primers mix	128 µl
4. RNase P primers mix	128 µl
5. Positive control	30 µl
6. Negative control	30 µl

RESEARCH AND MANUFACTURED BY

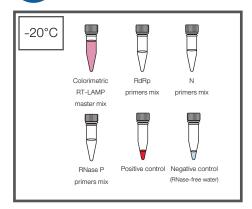
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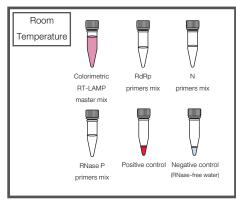
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Fastproof™ GoPlus SARS-CoV-2 RT-LAMP - Instruction Manual

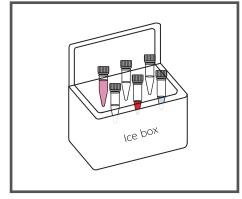
1. Thawing of Solutions



Take the kit, including colorimetric RT-LAMP master mix, primer mix, positive control, and negative control (RNase-free water) out from -20°C.



Thaw all tubes at room temperature.

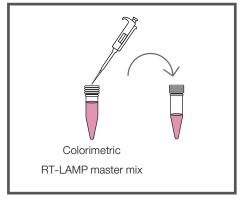


Place all tubes on ice.

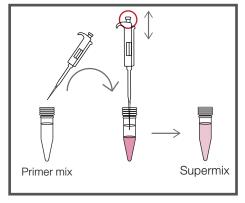
Preparation of RT-LAMP Supermix for RT-LAMP Reactions

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

2.1) Preparation of the RT-LAMP Supermix



Mix the colorimetric RT-LAMP master mix (pink solution) with the primer mix as described in Table 1.

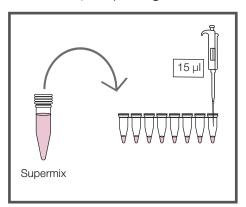


Pipette up and down gently several times to mix the supermix.

Table 1

Volumes for the preparation of the					
RT-LAMP supermix					
	Desired Number of Reaction				
	1	10	20		
	Reaction	Reaction	Reaction		
	(µI)	(µI)	(µI)		
Colorimetric					
RT-LAMP	11	110	220		
master mix					
Primers mix (of each target genes)	4	40	80		
Total	15	150	300		

2.2) Aliquoting of the RT-LAMP Supermix



Aliquot 15 μ I of the RT-LAMP supermix into each of the PCR tubes.

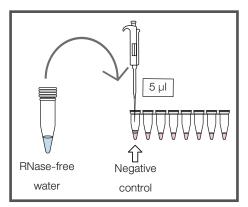
Fastproof™ GoPlus SARS-CoV-2 RT-LAMP - Instruction Manual

2.

Preparation of RT-LAMP Supermix for RT-LAMP Reactions

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

2.3) Preparation of the Negative Control

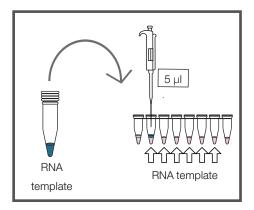


Add 5 μ I of the provided RNase-free water to one of the reaction PCR tubes.

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.

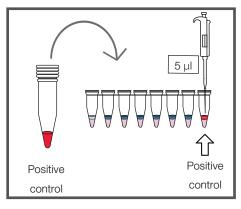
Note: To prevent cross contamination, finish aliquoting the RT-LAMP supermix into the reaction tubes and preparing the negative control prior to touching the RNA templates for testing. Also, the work area for the preparation of the RT-LAMP supermix (always clean) and the work area for all activities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

3. Addition of the Extracted RNA Sample to the Reaction PCR Tube

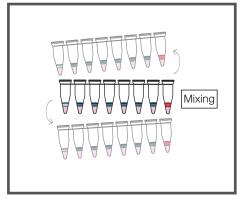


Add 5 μ I of the extracted RNA sample to the reaction PCR tube prepared in step 2.2 Mix well by pipetting up and down gently.

4. Preparation of the Positive Control



Add 5 μ I of the provided positive control to the reaction PCR tube. One tube of the positive control per 1 round of testing is suggested.

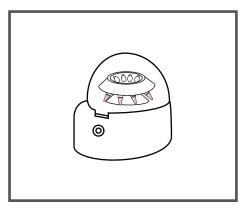


Mix all reaction tubes well.

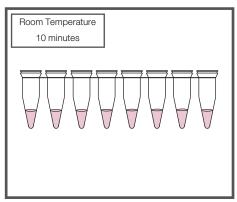
Note: This step of adding the RNA positive control into the supermix should be the last to perform.

Fastproof™ GoPlus SARS-CoV-2 RT-LAMP - Instruction Manual

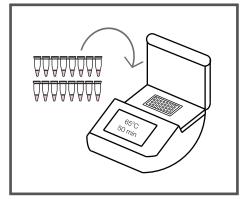
5. Running the RT-LAMP Reaction



Spin down the reaction PCR tubes.



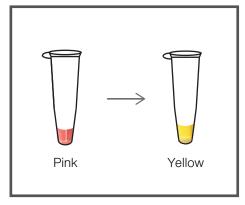
Incubate the reactions at room temperature for 10 minutes or incubate at 37°C for 10 minutes in a Heating block.

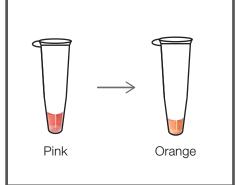


Incubate the reaction PCR tubes at 65°C for 50 minutes in a Heating block.

Result Interpretation of the Fastproof™ GoPlus SARS-CoV-2 RT-LAMP

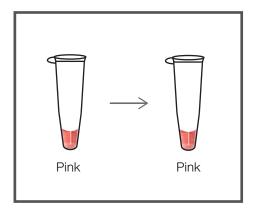
1. COVID-19 is "Positive" (Detected)





If the reaction solution turns yellow or orange. "Positive"

2. COVID-19 is "Negative" (Not detected)



If the reaction solution remains pink "Negative"

Interpretation of results

RdRp	N	RNase P (Internal control)	Results
+	+	+	SARS-CoV-2 Positive
+	-	+	SARS-CoV-2 Positive
-	+	+	SARS-CoV-2 Positive
-	-	+	SARS-CoV-2 Negative
+/-	+/-	-	Invalid

Warnings and Precautions

- Open the lid of the RT-LAMP supermix only as needed in order to prevent the oxidation and contamination that might affect to the color change and the result interpretation.
- In order to prevent the contamination, the reaction tubes after amplification must be tightly closed.
- LAMP amplicons and other wastes should be tightly collected in the bioharzard bag and subsequently treated according to the standard biosafety guildelines.

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.