EURx® MOLECULAR BIOLOGY PRODUCTS

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Product intended for in vitro diagnostic use only.

CE IVD

SARS-CoV-2 Blue-LAMP Detection KIT

SARS-CoV-2 Blue-LAMP Detection KIT is designed to detect the SARS-CoV-2 coronavirus in samples from patients with symptoms of COVID-19 infection. The purified genetic material of the virus from swab samples taken from the throat, nasopharynx or saliva, etc. is amplified using the LAMP reaction - isothermal amplification of nucleic acids and detected visually by changing the color of the reaction from violet to blue. Virus identification is based on the amplification of a highly conserved region in the ORF1ab gene characteristic of SARS-CoV-2. Additionally, the kit includes a specific control for the human ACTB gene (gene encoding beta-actin), which makes it possible to verify both the correctness of the collected swab and the quality of the purified RNA, and a positive control of the reaction to the Lambda phage sequence, which enables confirming the correctness of the test execution. The kit does not show any cross-reactions with other microorganisms causing respiratory diseases.

The sensitivity of the LAMP amplification method is estimated at 100 copies of RNA molecules. In the case of samples with a lower number of viral RNA copies, it is recommended to use SARS-CoV-2 qRT-PCR Detection KIT (Cat. No. E0430).

Component	**Cat. no. E0460-01** **50 reactions, 25 µl each**	**Cat. no. E0460-02** **500 reactions, 25 µl each**
BlueLAMP Master Mix (2x) brown tube (avoid UV exposure)	625 µl	10 x 625 µl
LAMPCov 10x Primer Mix yellow cap	125 µl	5 x 250 µl
ACTB 10x Primer Mix blue cap	63 µl	5 x 125 µl
Lambda 10x Primer Mix orange cap	35 µl	5 x 70 µl
Lambda 5x Positive Control black cap	63 µl	625 µl
RNase free Water transparent cap	500 µl	5 x 1000 µl

The kit includes:

All kit components should be stored at a temperature of -20°C

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Protocol

Preparation of the sample taken from the patient:

RNA from a swab, saliva or other secretion should be isolated using kits dedicated to viral RNA purification. Follow the instructions recommended by the kit manufacturer although it is highly recommended to use Rnase-free water to elute the sample due to a pH-sensitive dye in Blue-LAMP Master Mix.

Reaction component Master Mix	Negative control N No template	Positive control P Lambda DNA	Sample control A ACTB	Specific reaction C SARS-Cov-2
BlueLAMP Master Mix (2x)	12,5 µl	12,5 µl	12,5 µl	12,5 µl
LAMPCov 10x Primer Mix	2,5 µl	-	-	2,5 µl
ACTB 10x Primer Mix	-	-	2,5 µl	-
Lambda 10x Primer Mix	-	2,5 µl		-
RNase free Water	5 µl	5 µl	5 µl	5 µl
Master Mix volume	20 µl	20 µl	20 µl	20 µl
RNase free Water	5 µl	-	-	-
Lambda 5x Positive Control	-	5 µl	-	-
Sample of purified RNA from a patient	-	-	5 µl	5 µl
Reaction volume	25 µl	25 µl	25 µl	25 µl

Reaction components:

Preparation of LAMP reaction:

1. Determine the number of reactions. In each cycle set:
   - Positive control **P** minimum 1 reaction
   - Negative control **N** minimum 1 reaction
   - Sample control **A** in the number of samples tested
   - Specific reaction **C** in the number of samples tested

   Each patient sample should be tested for the presence of SARS-Cov-2 RNA and the ACTB gene.
2. After thawing, mix all components of the reaction well by pipetting several times. Reactions should be prepared on ice or in a cooling block. Prepare reaction Master Mixes depending on the number of reactions according to the table above. The components of the Master Mix must be mixed by pipetting several times. Do not "vortex" the mixture.
3. Distribute the Master Mix into strip tubes or onto a plate, transferring 20 µl of the solution. Avoid foaming. Remove all the components of the reaction that are no longer needed from the work station, to prevent their contamination.
4. Prepare the reactions in the following order:

   N– Negative control: add 5 µl of water and close the tube to avoid contamination by the patient's RNA.

   P– Positive control: add 5 µl of Lambda 5x Positive Control.

   A– Patient RNA samples: add 5 µl of purified RNA and close the tubes.

   C– Patient RNA samples: add 5 µl of purified RNA and close the tubes.
5. Put the prepared reactions in a thermal cycler heated to 65°C for 40 minutes. It is recommended to use a thermocycler with heated lid to prevent evaporation of the reaction.
6. Cool the samples to room temperature. Do not open the test tubes! The colour change in relation to the negative control can be visually assessed. As the time passes, the colour acquires its maximum intensity.

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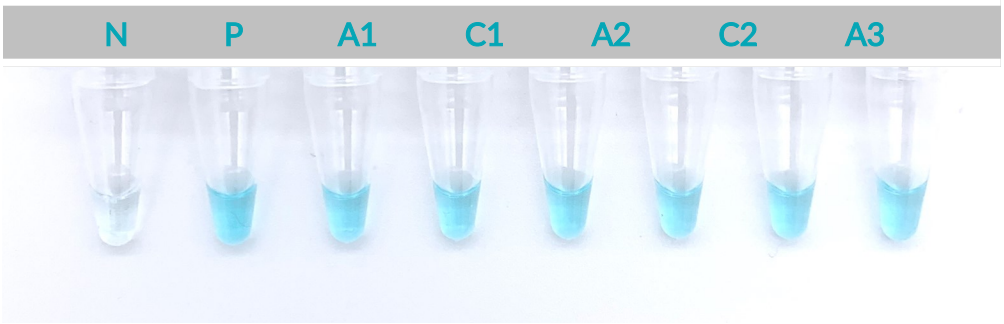
Interpretation of results:

Negative control N	Positive control P	Sample control A	Specific reaction C	Result
-	+	+	+	positive for SARS-CoV-2
-	+	+	-	negative for SARS-CoV-2

BlueLAMP Master Mix is colorless before reacting. To read the correct colour after reaction, cool the samples down to room temperature and wait 15 minutes. The colour becomes more intense over time. Only the result configuration included in the table is considered correct, any other result is incorrect and the test must be repeated. The shades of blue may vary depending on the amount of initial material. The DNA amplification causes reaction to become turbid. This effect is independent of the colour change and is present in all positive (blue) samples. Negative control does not show the turbidity effect and remains clear. Due to the dye's sensitivity to UV light, avoid direct exposure. The result can be read for up to 24 hours after the completion of the reaction.



Description: N – negative control; P – positive control; A1 – sample control, patient 1; C1 – specific reaction, patient 1; A2 – sample control, patient 2; C2 – specific reaction, patient 2; A3 – sample control, patient 3; C3 – specific reaction,