

DetechBeads SARS-CoV-2 RT-LAMP LyoMix

For the rapid detection of Covid-19 in diagnostics

INSTRUCTIONS FOR USE (IFU) – In-vitro Diagnostics

Please read the following instructions thoroughly before using the DetechBeads SARS-CoV-2 RT-LAMP LyoMix.

INTENDED USE

The DetechBeads SARS-CoV-2 RT-LAMP LyoMix offer a sterile, portable and rapid detection method of the SARS-CoV-2 virus in-vitro.

As an alternative to traditional Polymerase Chain Reaction (PCR), purified RNA isolate from a patient is used as template and is subject to an isothermal reaction process of the RNA known as LAMP (Loop Mediated Isothermal Amplification) resulting in a colorimetric change indicating the presence of SARS-CoV-2 in the isolate.

The DetechBeads SARS-CoV-2 RT-LAMP LyoMix are only intended to use for the detection of the SARS-CoV-2 RNA purified samples. Detection of unpurified saliva or swab samples would require local validations.

EXPLANATION OF THE PRODUCT

Detection and diagnosis of the SARS-CoV-2 virus is an essential first step in the treatment of the patient. The DetechBeads SARS-CoV-2 RT-LAMP LyoMix is designed to aid this process in a manner that is faster and cheaper than a PCR, whilst also maintaining a comparable specificity and sensitivity.

The product consists of reverse transcriptase (RT), LAMP specific polymerase and a special set of SARS-CoV-2 specific LAMP primers in a lyophilized format that ensures a stable, pre-mixed and low-cost storage alternative compared to traditional PCR reagents.

The bead is re-suspended with 23µl of RNase-Free water and 2µl of the purified RNA sample as template.

The reaction mixture is then subject to a constant heat of 65°C for 30 minutes to obtain a colorimetric reading of a positive (yellow) or negative (pink) result. Lower template input is possible but should be validated locally.

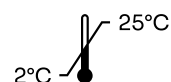
HANDLING INSTRUCTIONS

Use gloves when handling patient samples and the beads.
Use immediately after opening the packaging.
Do not use if package is damaged or comes in contact with any foreign object.
Single use only.

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The DetechBeads SARS-CoV-2 RT-LAMP LyoMix are packaged in a PCR strip consisting of 8 tubes, each containing 1 bead per single reaction.

STORAGE



The optimal conditions for storage of the beads is at room temperature (20°C - 25°C), which can be stored up to 6 months. Storage at 4°C could prolong the shelf life up to a year. Avoid repeated freeze-thaw steps. Avoid humid storage conditions.

WARNING

Do not open the reaction tubes after the LAMP amplification to prevent contamination with LAMP amplicons.

DISPOSAL

Dispose according to local guideline depending on sample type.
Dispose LAMP products in-lieu with good scientific practices.

TRANSPORT

Beads will be transported at room temperature.

SYMBOL DEFINITIONS

REF Product reference **LOT** Batch code

 Manufactured by  Use by DD/MM/YYYY

 Single use  Consult instructions before use

 Temperature range



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Date of Preparation: labeled on the box
IFU Code: labeled on the box