FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

DetechBeads RSV RT-LAMP LyoMix

Instructions for Use (IFU) — Research Reagent

Detechgene

PRODUCT DESIGNATION

This product is supplied for Research Use Only (RUO). It is intended exclusively for laboratory research applications and has no medical or diagnostic purpose. It has not been evaluated for safety or performance for any diagnostic use, and it is not a CE-marked in-vitro diagnostic medical device under Regulation (EU) 2017/746 (IVDR).

The user assumes full responsibility for any validation, qualification, or characterisation required if the product is used for purposes beyond research. **This product must not be used as a basis for clinical decisions or patient management.**

INTENDED RESEARCH USE

The DetechBeads RSV RT-LAMP LyoMix provide a rapid, isothermal method for the laboratory detection of RSV RNA in research settings.

Purified RNA is used as template in an isothermal amplification reaction known as LAMP (Loop Mediated Isothermal Amplification), as an alternative to Polymerase Chain Reaction (PCR). Amplification produces a colorimetric change that indicates the presence of RSV RNA target in the sample.

The product is intended for use with purified RNA samples only. Use with unpurified saliva or swab samples, or with reduced template input, has not been characterised by the manufacturer and would require validation by the user for the intended research application.

PRODUCT DESCRIPTION

The product consists of reverse transcriptase (RT), a LAMP-specific polymerase, and a set of RSV-specific LAMP primers in a lyophilised (“LyoMix”) format. Lyophilisation provides a stable, pre-mixed, low-cost storage format compared with conventional liquid PCR reagents.

CONTENTS

Each pack contains the DetechBeads RSV RT-LAMP LyoMix as 8 PCR strips of 8 tubes each, with one bead per tube (one reaction per bead).

MATERIALS REQUIRED BUT NOT SUPPLIED

- RNase-free water.
- Purified RNA sample (research template).
- Calibrated heat block or thermocycler capable of maintaining 65 °C.
- Appropriate personal protective equipment and RNase-free consumables.

REACTION PROTOCOL

Re-suspend one bead with 23 µL of RNase-free water and 2 µL of purified RNA sample as template (25 µL total reaction volume).

Incubate the reaction mixture at a constant 65 °C for 30 minutes.

Read the colorimetric result at the end of the incubation: yellow indicates a positive amplification result; pink indicates a negative result. Results outside this colour range should be treated as invalid/indeterminate and the reaction repeated.

Note: Lower template input may be possible but has not been validated by the manufacturer; any such use must be validated by the user.

RECOMMENDED RESEARCH CONTROLS

As good laboratory practice for research use, each run should include a positive control and a no-template (negative) control to support interpretation of results and to monitor for reagent performance and contamination. Controls are not supplied with this product.

HANDLING INSTRUCTIONS

- Wear gloves when handling samples and beads.
- Use immediately after opening the packaging.
- Do not use if the package is damaged or has come into contact with any foreign object.
- Single use only.

WARNING — AMPLICON CONTAMINATION

Do not open the reaction tubes after LAMP amplification. LAMP generates very high concentrations of amplicon; opening completed reactions can cause carry-over contamination of the laboratory and subsequent reactions, leading to false results. Maintain physical separation between pre- and post-amplification areas where possible.

SAFETY INFORMATION

Handle all samples and reagents in accordance with good laboratory practice and local biosafety requirements. Samples of biological origin should be treated as potentially infectious and handled at the appropriate biosafety level as determined by local risk assessment.

Consult the Safety Data Sheet (SDS) for full information on reagent composition, hazard classification, and safe handling. Reagent hazard labelling is provided in accordance with Regulation (EC) No 1272/2008 (CLP) where applicable.

STORAGE

Condition	Specification
Room temperature (20 - 25 °C)	Up to 6 months
Refrigerated (4 °C)	Up to 12 months
Avoid	Repeated freeze-thaw cycles; humid storage conditions

Do not use after the expiry date (Use by DD/MM/YYYY) indicated on the packaging.

TRANSPORT

The product is transported at room temperature.

DISPOSAL

Dispose of materials according to local regulations and in accordance with the sample type and associated biosafety classification.

Dispose of LAMP reaction products in accordance with good laboratory practice for amplified nucleic acids.

SYMBOL DEFINITIONS

Product reference / catalogue number

Batch code


Manufactured by


Use-by date (DD/MM/YYYY)


Do not reuse


Consult instructions before use


Storage temperature limits

Note: No CE mark and no IVD symbol are applied, as this product is supplied for Research Use Only and is not an IVD medical device.

MANUFACTURER

Detechgene GmbH

Nattermannallee 1

50829 Cologne,
Germany

info@detechgene.de

www.detechgene.de

Date of Preparation: labelled on the box

IFU Code: labelled on the box