IL-3 and Preparation vial • Instructions for use • IVD CE

REF: RLR004, RLR041, RLA500

Intended purpose

The device is a consumable, which is used for performing the basophil histamine release assay (BHRA).

Summary and explanation

IL-3 is an interleukin that stimuliates the histamine release from basophils via the IL-3 receptor. IL-3 activates the calcium signaling and positively affects growth and survival of the cells.

For in vitro diagnostic use.

Intended user

IL-3 and Preparation vials are for professional (health care) use only.

Composition

RLR004	Lyophilized IL-3 in 0.036 % HSA	0.1 µg IL-3 per vial
RLR041	Lyophilized IL-3 in 0.036 % HSA	6.0 ng IL-3 per vial
RLA500	Lyophilized IL-3 in 0.036 % HSA (5 vials)	6.0 ng IL-3 per vial

Variants

Product name	Article no	UDI code	Volume	Pack size
Preparation vial (IL-3)	RLR041	05744003280308	6 ng/vial	1
Preparation vial (IL-3), box of 5	RLA500	05744003280315	6 ng/vial	5
IL-3, 0.1 µg	RLR004	05744003280292	0.1 µg/vial	1

Reagent preparation

The IL-3 / Preparation vials are ready for use
Refer to separately provided BHRA / HR-Test method-specific work instructions for details of sample preparation.

Test principle

Refer to separately provided BHRA / HR-Test method-specific work instructions.

Storage and handling conditions

Store at 5-8 °C until labelled expiry.

Warnings and precautions

IL-3 products are non-hazardous reagents.
Virus safety applies to the 0.036 % HSA content:

When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded, and the testing of each donation and pools of plasma for signs of virus/infections. Manufacturers of these products also include steps in the processing of the blood or plasma that can inactivate or remove viruses. Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.
There are no reports of virus infections with albumin manufactured to European Pharmacopoeia specifications by established processes.

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For in vitro diagnostic use only
For laboratory professional use

Contact the manufacturer if discoloration or other signs of contamination appear.
According to the EU regulation 2017/746, users shall report any serious incident related to device to the manufacturer and the competent authority of the EU Member State in which the user is established.

Waste disposal

Non-hazardous waste

Manufacturer

RefLab ApS
Kanalholmen 1, 2 th.
DK 2650 Hvidovre
Denmark

Phone: +45 7070 2345
info@reflab.dk
www.reflab.dk

Symbols

CE	CE mark
IVD	For in vitro diagnostic use
REF	Catalog number
LOT	Batch code
UDI	GTIN code
	Expiry date
1M	Expiry after opening
	Storage temperature
	Consult instructions for use
	Manufacturer