

Diluent • Instructions for use • IVD CE

REF: RLR009, RLA702

Intended purpose

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

Summary and explanation

The diluent is used in combination with the OPA disc (Art. no. RLR013, RLA708 and RLA708X) to prepare the coupling reagent, which is included in the test completion of the assay.

The coupling reagent facilitates the solid phase-bound histamine molecules to be presented in a liquid phase and when coupled to the pftaldialdehyde (OPA) it can be fluorometrically detected.

For in vitro diagnostic use.

Intended user

The diluent is for professional (health care) use only.

Composition

Sodium hydroxide 0.05 mol/L

Variants

Product name	Article no	UDI code	Volume	Pack size
Diluent, 1 L	RLA702	05744003280230	1 L	1
Diluent, 10 mL	RLR009	05744003280223	10 mL	10 (as part of the RLA700 Reagent Kit)

Reagent preparation

The reagent is ready for use

Test principle

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

Storage and handling conditions

Store at +2 - +25 °C until labelled expiry.

The reagent should reach room temperature before use.

Warnings and precautions

The Diluent is a non-hazardous reagent.

Safety data sheets (MSDS/SDS) available on www.reflab.dk

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.

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Waste disposal










Non-hazardous waste

Manufacturer

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

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Symbols

	CE mark
	For in vitro diagnostic use
	Catalog number
	Batch code
	Unique device identifier
	Expiry date
	Storage temperature
	Consult instructions for use
	Manufacturer