

Diluent • Instructions for use • IVD (€

REF: RLR009, RLA702

Intended purpose & product description

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

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 pfthaldialdehyde (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

Please refer to the Insctructions for use for the the OPA disc (Art. no. RLR013, RLA708 and RLA708X) for preparation of the coupling reagent

Test principle

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

Storage and handling conditions

Store at +2 - +8 °C until labelled expiry.

The reagent should reach room temperature before use.

Warnings

The diluent is a non-hazardous reagent



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Waste disposal

Non-hazardous waste

Manufacturer

RefLab ApS Copenhagen Bioscience Park 'COBIS' Ole Maaloes Vej 3 DK 2200 Copenhagen N Denmark

Symbols

CE	CE mark		
IVD	For in vitro diagnostic use		
REF	Catalog number		
LOT	Batch code		
GTIN	GTIN code		
\subseteq	Expiry date		
1	Storage temperature		
[]i	Consult instructions for use		
	Manufacturer		