

Stop reagent • Instructions for use • IVD





REF: RLR011, RLA703

Intended purpose & product description

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

Summary and explanation

The Stop reagent is included the assay test completion, and serves as a stabilizer in the coupling procedure by lowering the pH.

For in vitro diagnostic use.

Intended user

The stop reagent is for professional (health care) use only.

Composition

Perchloric acid

0.59 % w/v (0.059 mol/L)

Variants

Product name	Article no	UDI code	Volume	Pack size
Stop reagent, 1 L	RLA703	05744003280254	1 L	1
Stop reagent, 100 mL	RLR011	05744003280247	100 mL	1 (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 Stop reagent 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.

Waste disposal



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Non-hazardous waste

Manufacturer

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Denmark

Symbols

ϵ	CE mark		
IVD	For in vitro diagnostic use		
REF	Catalog number		
LOT	Batch code		
UDI	Unique device identifier		
\geq	Expiry date		
*	Storage temperature		
[]i	Consult instructions for use		
	Manufacturer		