

Reagent kit • Instructions for use •

REF: RLA700

Intended purpose

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

Summary and explanation

The RLA700 *Reagent kit* consists of reagents for the test completion of the BHRA methods that involves fluorometric detection of histamine.

For in vitro diagnostic use.

Intended user

Reagent kit is for professional (health care) use only.

Composition

Product name	Article no	UDI code	Volume	Amount
Reagent kit	RLA700	05744003280117		
Consists of the following articles:				
Wash buffer	RLR007W.200	05744003280179	200 mL	1
OPA disc , 5 mg	RLR013	05744003280186	10 discs	1
Diluent	RLR009	05744003280223	10 mL	10
Stop reagent	RLR011	05744003280247	100 mL	1
Tweezers				1
Coupling reagent label				10

Material & Equipment required but not provided

Standard laboratory material & equipment

Distilled H₂O

Incubator (37 °C)

Plate washer or multi-channel pipette

Histareader™501 or Histareader™501-1

Reagent preparation

Allow the reagents to reach room temperature before use. Prepare *Coupling reagent* during tempering.

RLR007W.200 Wash buffer is ready for use.

RLR011 Stop reagent is ready for use.

RLR013 & RLR009 is used to prepare the coupling reagent: (Use the tweezer of OPA disc transfer)

Article	Amount		Article	Amount
RLR013 <i>OPA disc</i>	1 disc	+	RLR009 <i>Diluent</i>	1 vial (10 mL)
Soak for 60 min & mix by gentle inverting.				
<i>Note: The enclosed disc is coated with o-pftaldialdehyde. The disc is not designed to dissolve into the diluent.</i>				
Label	Note date/time on the label provided and affix to vial(s)			
Stability	Coupling reagent is stable for 8 hrs from preparation			
Pool vials	It is recommended to pool coupling reagent vials into a suitable beaker			
No. of test	1 vial (10 mL) of coupling reagent is sufficient for one BHRA (96-well) plate/panel			

Reagent kit • Instructions for use • IVD CE

REF: RLA700

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 must reach room temperature before use.

Warnings & precautions

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.

OPA disc, 5 mg – RLR013

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



DANGER

Contains o-phthaldialdehyde:

- H301: Toxic if swallowed.
- H314: Causes severe skin burns and eye damage.
- H317: May cause an allergic skin reaction.
- H335: May cause respiratory irritation.
- H410: Very toxic to aquatic life with long lasting effects.
- P260: Do not breathe dusts or mists.
- P273: Avoid release to the environment.
- P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
- P304+P340+P310: IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor.
- P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Reagent kit • Instructions for use •

REF: RLA700

Wash buffer - RLR007W.200

The wash buffer is a non-hazardous reagent.
Safety data sheets (MSDS/SDS) available on www.reflab.dk

Diluent - RLR009

The diluent is a non-hazardous reagent.
Safety data sheets (MSDS/SDS) available on www.reflab.dk

Stop reagent - RLR011

The stop reagent is a non-hazardous reagent.
Safety data sheets (MSDS/SDS) available on www.reflab.dk

Waste disposal

OPA disc, 5 mg - RLR013

The mixture is to be considered as hazardous waste. Disposal should be according to local, state or national legislation. Dispose of through authority facilities or pass to chemical disposal company.

EWC-code: 16 05 08 (mixture itself)
 15 02 02 (paper towel, inert material etc. contaminated with the mixture)

Prepared coupling reagent

The mixture is to be considered as hazardous waste. Disposal should be according to local, state or national legislation. Dispose of through authority facilities or pass to chemical disposal company.

EWC-code: 16 05 08 (mixture itself)
 15 02 02 (paper towel, inert material etc. contaminated with the mixture)

Wash buffer - RLR007W.200

Non-hazardous waste.

Diluent - RLR009

Non-hazardous waste.

Stop reagent - RLR011

Non-hazardous waste.

Manufacturer












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Reagent kit • Instructions for use •

REF: RLA700

Symbols

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