

Reagent kit • Instructions for use • IVD CE

REF: RLA700

Intended purpose

The device is a consumable, which is used for performing the basophil histamine release assay (BHRA). 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
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
Tweezer				1
Coupling reagent label				10

Storage and handling conditions

Store at +2 - +8 °C

The reagent must reach room temperature before use.

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. Use the tweezer for transfer of OPA disc(s) into the diluent vial(s).

Article	Amount		Article	Amount
RLR013 (OPA disc)	1 disc	+	RLR009 (diluent)	1 vial (10 mL)
Soak for 60 min & mix by gentle inverting.				
<i>Note: The enclosed disc is coated with o-pfthaldialdehyde. 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 in a suitable beaker			

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No. of test	1 vial (10 mL) of coupling reagent is sufficient for one BHRA (96-well) plate/panel
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Test procedure

1. Pipet 150 µL wash buffer into each well.
2. Incubate for 30-45 min at 37 °C (36-38 °C).
3. Tap the wash buffer out (into waste / sink)
4. Wash the plate with distilled water 3 times. If washing manually (multi-channel pipette) gently tap the plate upside down after each wash.
5. Gently tap the plate free of any residual water on highly absorbent paper towel after finishing the washing procedure.
6. Pipet 75 µL coupling reagent into each well.
7. Reaction time: 10 min
NOTE: it is important to time the reaction precisely.
8. Pipet 75 µL stop reagent into each well.
9. Follow separate IFU for fluorometric detection in the Histareader™ 501/501-1

Test principle

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

Warnings

OPA disc, 5 mg - RLR013



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.

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Prepared coupling reagent

The coupling reagent is an environmentally hazardous reagent (See waste disposal information below)

Wash buffer - RLR007W.200

The wash buffer is a non-hazardous reagent.

Diluent - RLR009

The diluent is a non-hazardous reagent.

Stop reagent - RLR011

The stop reagent is a non-hazardous reagent.

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)

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Wash buffer - RLR007W.200

Non-hazardous waste.

Diluent - RLR009

Non-hazardous waste.

Stop reagent - RLR011

Non-hazardous waste.












Manufacturer

RefLab ApS
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Denmark

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Symbols

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