

OPA disc • Instructions for use •

REF: RLR013, RLA708, RLA708X

Intended purpose & product description

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

Summary and explanation

The OPA disc is a filter disc, coated with o-phthaldialdehyde*, that in combination with the diluent (Art. no. RLR009 and RLA702) is used to prepare the coupling reagent, which is included in the test completion of the assay.

*) o-phthalaldehyde is a benzene dicarbaldehyde with the formula $C_6H_4(CHO)_2$ used as a reagent in the analysis of amino acids.

For in vitro diagnostic use.

Intended user

The OPA disc is for professional (health care) use only.

Composition & variants

Product name	Article no	Vial size	UDI code	Pack size
OPA disc, 5 mg	RLR013	10 discs	05744003280216	1 vial
OPA disc, 25 mg	RLA708	20 discs	05744003280193	1 vial
OPA disc, 25 mg	RLA708X	100 discs	05744003280209	1 vial

Reagent preparation

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

Prepare a volume that corresponds the number of plates and panels in the test set up (10 mL coupling reagent per plate / panel)

Article	Amount		Article	Amount
RLR013 (OPA disc, 5 mg)	1 disc	+	RLR009 (diluent)	10 mL
RLR708, RLA708X (OPA disc, 25 mg)	1 disc	+	RLA702 (diluent)	50 mL
<p>Soak for 60 min & mix by gentle inverting. <i>Note: The enclosed disc is coated with o-phthaldialdehyde. The disc is not designed to dissolve into the diluent</i></p>				
Stability	Note date/time of preparation. The coupling reagent is stable for 8 hrs at RT			
Pool vials	It is recommended to pool coupling reagent vials in a larger suitable beaker			
No of test	10 mL coupling reagent is sufficient for one BHRA (96-well) plate/panel			

Storage and handling conditions

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

Prepared coupling reagent is stable for 8 hours

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Material & Equipment required but not provided

Beaker(s) for preparation / pooling of coupling reagent.
RLA702 / RLR009 Diluent
RLA703 / RLR011 Stop reagent

Test procedure

1. Pipet 75 µL Coupling reagent into each well.
2. Reaction time: 10 min NOTE: it is important to time the reaction precisely.
3. Pipet 75 µL Stop reagent into each well.
4. 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 and precautions

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.



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.

Prepared coupling reagent

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

Waste disposal

The OPA disc and the coupling reagent 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)

Manufacturer

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Symbols

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