

Wash buffer • Instructions for use • IVD

REF: RLR007W.200, RLR007W.5

Intended purpose

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

Summary and explanation

Wash buffer is a 0.4 % solution of SDS (sodium dodecyl sulfate) in distilled water. SDS is a detergent that is known to denature proteins. In the basophile histamine release assay (BHRA)/ HR-Test methods it is use as an incubation buffer to reduce protein interference.

For in vitro diagnostic use.

Intended user

Wash buffer is for professional (health care) use only.

Composition

Sodium dodecyl sulfate in distilled H₂O

4.0 g /L

Variants

Product name	Article no	UDI code	Volume	Pack size
Wash buffer 200 mL	RLR007W.200	05744003280155	200 mL	1
Wash buffer 5 L	RLR007W.5	05744003280162	5 L	1

Storage and handling conditions

Store at +2 - +8 °C until labeled expiry Please note that the reagent, when cold, appears cloudy with precipitates. The reagent must reach room temperature before use. When stored at RT: 1 month from manufacturing date. Mix well before use.

Reagent preparation

The wash buffer is ready to use

Test principle

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

Warnings and precautions

The wash buffer is a non-hazardous reagent

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.

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



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Waste disposal

Non-hazardous waste

Manufacturer

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Symbols

CE	CE mark	
IVD	For in vitro diagnostic use	
REF	Catalog number	
LOT	Batch code	
UDI	Unique device identifier	
	Expiry date	
	Storage temperature	
ĺĺĺ	Consult instructions for use	
	Manufacturer	