

Wash buffer concentrate • Instructions for use





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 concentrate is a 20.4 % solution of SDS (sodium dodecyl sulfate) solution in distilled water. SDS is a detergent that is known to denature proteins.

Diluted to a 0.4 % solution it is used in the basophile histamine release assay (BHRA)/ HR-Test methods as an incubation buffer to reduce protein interference.

For in vitro diagnostic use.

Intended user

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

Composition

Sodium dodecyl sulfate in distilled H₂O

204.0 g/L

Variants

| Product name | Article no | UDI code | Volume | Pack size |
|-------------------------------|------------|----------------|--------|-----------|
| Wash buffer concentrate 10 mL | RLR007S.10 | 05744003280179 | 10 mL | 1 |
| Wash buffer concentrate 50 mL | RLR007S.50 | 05744003280186 | 50 mL | 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.

Mix well before use.

Material required but not provided

Distilled H₂O, 500 mL Distilled H₂O, 5000 mL Standard laboratory equipment

Reagent preparation

Dilute the wash buffer concentrate to prepare the Wash Buffer:

| Preparation of: | Article no | Vials | Distilled H₂O | well | Storage & Stability | |
|---------------------|------------|-------|---------------|------|---------------------|-------------------|
| | | | | | +2 - +8 °C | RT (+15 - +30 °C) |
| Wash buffer 510 mL | RLR007S.10 | 1 | 500 mL | ΑĬ× | 3 months | 1 month |
| Wash buffer 5100 mL | RLR007S.50 | 2 | 5000 mL | | 3 months | 1 month |



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Test principle

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

Warnings and 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.

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



DANGER

Contains sodium dodecyl sulphate

H315: Causes skin irritation.

H318: Causes serious eye damage.

P280: Wear protective gloves/eye protection/face protection.

P305+P351+P338+P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.

P332+P313: If skin irritation occurs: Get medical advice/attention.

Waste disposal

Disposal should be according to local, state, or national legislation.

When diluted to 0.4 % solution, the mixture is not considered as hazardous waste.

Manufacturer

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Wash buffer concentrate • Instructions for use • IVD





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Symbols

| CE | CE mark | | |
|--------|------------------------------|--|--|
| IVD | For in vitro diagnostic use | | |
| REF | Catalog number | | |
| LOT | Batch code | | |
| UDI | Unique device identifier | | |
| \Box | Expiry date | | |
| 1 | Storage temperature | | |
| | Consult instructions for use | | |
| | Manufacturer | | |