

Name:	PACKAGE INSERT for 5x TBS WASH BUFFER
Purpose:	This solution is intended to wash-off excess acridinium ester conjugate, non-bound components and background molecules during a chemiluminescence immunoassay reaction in the KleeYa® analyzer.
Catalog number:	10111002
Reference number:	TWB56
Product size:	4 x 2 L (5x concentrated)

1 INTENDED USE

INFO

For in vitro diagnostic use only.

For professional use.

The product is intended as a wash buffer for the chemiluminescence reaction in the fully automated chemiluminescence immunoassay analyzer KleeYa®.

The 5x TBS Wash Buffer is designed for the flash system, which implies the usage of an acridinium-labeled conjugate.

The 5x TBS Wash Buffer is used to wash-off excess conjugate and background molecules during the immunoassay reaction.

Please refer to the KleeYa® instrument's Instruction for Use for further information.

2 INGREDIENTS

The 5x Wash Buffer is supplied as a 2 L concentrated Tris-buffered saline solution (5x) being sufficient for preparing 10 L of working solution.

Brand name	Ingredients
5x TBS Wash Buffer	• Tris base < 4 % • NaCl < 5% • Preservatives < 0.2 % • Surfactants < 0.5 %

3 SAFETY INSTRUCTIONS



WARNING

H317
P280, P302+P352,
P333+P313, P362+P364

- For hazard and precautionary statements, please refer to the Safety Data Sheet (SDS). This instruction is provided for your safety and gives important instructions for the handling of the solution.
- Read Safety Data Sheet!
- May cause an allergic skin reaction.
- Improper handling of solution can cause skin, eye irritations.
- Avoid contact with eyes, skin and clothing.
- In case of eye or skin contact flush eyes with copious amounts of water for several minutes or wash skin area with water.
- Wear laboratory gloves, lab coat and eye protection when handling the reagent.
- Follow Good Laboratory Practices (GLP) when handling the reagents.
- Keep the reagent container closed when not in use.
- Do not use solution if direct packaging is damaged!
- Strictly follow the local and national provisions, legislation and laboratory regulations.

4 REAGENT PREPARATION AND USE

Prior to dilution, allow the 5x TBS Wash Buffer to reach room temperature (20-25 °C).

Fill the full bottle of 5x TBS Wash Buffer (2 L) into the 10 L container of the fully automated chemiluminescence immunoassay analyzer KleeYa® and add 8 L of DI water (until the indication line on the 10 L tank) in order to get 10 L of 1x TBS Wash Buffer. Always add the 5x TBS Wash Buffer before the DI water in order to ensure optimal blending of reagents. Precaution should be taken to minimize foaming. Avoid vigorous agitation by adding the DI water slowly.

After completion of the wash buffer preparation, the cap must be placed lightly on the container to allow proper degassing of the wash buffer solution. Wait 2 hours for the microbubbles to disappear from the solution before use.

Avoid any dust or microbial contamination of the 10 L container, 5x TBS Wash Buffer and DI water.

Do not mix the remains of 1x TBS Wash Buffer from different 10 L containers.

Do not use 5x TBS Wash Buffer once frozen.

Do not use the 5x TBS Wash Buffer after expiry.

If the solution remains in the tank after the end of onboard stability the solution shall be discarded, the tank shall be cleaned according to the Instructions for Use.

NOTE: In case you observe increased foam formation in the liquid waste container, please refer to the instructions provided by the manufacturer.

5 ENVIRONMENTAL CONDITIONS

Storage Conditions	
Temperature:	Operating/After opening: +15 °C to +30 °C (59 °F to 86 °F) Storage: +4 °C to +32 °C (40 °F to 89 °F) Transport: +4 °C to +32 °C (40 °F to 89 °F)
Shelf life:	2 years after the date of manufacture.
In-use stability:	30 days (in diluted, ready to use form)

Appropriate precautions and good laboratory practices must be followed during storage, handling and disposal of the 5x TBS Wash Buffer. Refer to the SDS associated with the 5x TBS Wash Buffer.

6 DISPOSAL AND DECONTAMINATION

DANGER

Hazardous waste

Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 91/689/EEC.

NOTICE

Disposal of non-contaminated parts

Material out of use (e.g. packaging material) should be properly disposed.

Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any local, State and Federal authority requirements / regulations.

Dispose of surplus and nonrecyclable products via a licensed waste disposal contractor.

7 MANUFACTURER

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