

Washing Buffer (20x concentrated)

WASH | BUF | 20x

CE

**Only for in-vitro diagnostic use
For professional use only**

Instructions for use

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REF

W0000, W0000DB

1. INTENDED USE

WASH BUF 20x is a buffered solution with detergent for use with products of the NovaLisa® and Novagnost® line as well as other ELISA products of Gold Standard Diagnostics Frankfurt GmbH, which are combined as a kit with this reagent. The solution is used to remove unbound reagent or sample material from the wells of the microtiterplate during the washing steps.

The reagent is supplied in a 20-fold concentration and must be diluted with distilled (or demineralised) water before use to obtain the working solution **WASH BUF 1x** (see instructions for use of the respective NovaLisa®, Novagnost® or other Gold Standard Diagnostics Frankfurt GmbH ELISA product).

2. PRINCIPLE OF FUNCTION

WASH BUF 20x contains pH stabilisers, salts and detergents to remove excess unbound material from the wells of the microtiterplate without interfering with the specific ELISA binding reactions. The composition of the reagent ensures that the appropriate buffer environment is maintained, reducing non-specific background noise, and enhancing the specific signal.

3. MATERIAL

Flask with 20-fold concentrated phosphate buffer (0.2 M) for washing the wells; pH 7.2 ± 0.2

REF	W0000	W0000DB (Novagnost)
Volume	50 mL	50 mL
Cap Colour	white	naturally coloured

The reagent contains 0.2 % (w/v) 5-bromo-5-nitro-1,3-dioxane for preservation. Therefore, the following hazard and safety statements apply.

Warning



H315	Causes skin irritation.
H319	Causes serious eye irritation.
P280	Wear protective gloves, eye protection, face protection.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.

Before use, observe the information in the associated Safety Data Sheet (SDS).

SDS available at: clinical.goldstandarddiagnostics.com

3.1. Material required but not supplied

- Distilled or demineralised water
- Measuring cylinder
- Manual or automatic equipment for rinsing microtiterplates ("washer")

4. STABILITY AND STORAGE

Store **WASH BUF 20x** at 2 - 8 °C. Once opened the reagent is usable until the expiry date stated on the labels if stored at 2 - 8 °C.

5. PREPARATION OF THE REAGENT

Before use, bring the reagent to room temperature (20 - 25 °C) and mix well by inverting several times!

Dilute **WASH BUF 20x** 1+19; e.g. 10 mL **WASH BUF 20x** + 190 mL distilled (or demineralised) water. The diluted buffer (**WASH BUF 1x**) is stable for 5 days at room temperature (20 - 25 °C). If crystals appear in the concentrate, warm up the solution to 37 °C e.g., in a water bath. Mix well before dilution.

6. WASHING PROCEDURE

The washing procedure is carried out according to the information in the respective instructions for use of the NovaLisa®, Novagnost® or other Gold Standard Diagnostics Frankfurt GmbH ELISA products.

Attention: To avoid microbial contamination, the following points must be observed:

- use only clean pipette tips, dispensers, and laboratory materials
- do not return any residual liquid to the original bottle
- do not exchange lids
- reseal bottles immediately after opening and removal
- Check reagents for contamination when using them again.

7. QUALITY CONTROL

In accordance with the manufacturer's ISO-certified quality management system, each batch of the **WASH BUF 20x** is tested against predetermined specifications to ensure consistent product quality.

8. LIMITATIONS

WASH BUF 20x is only suitable for use in combination with products that belong to the NovaLisa® or Novagnost® line or that belong to another Gold Standard Diagnostics Frankfurt GmbH product line that provides for the use of **WASH BUF 20x**.

WASH BUF 20x is not suitable for use in NovaLisa® or Novagnost® products that must be processed without or with a wash buffer other than **WASH BUF 20x**.

WASH BUF 1x can be used in automated ELISA washers depending on the salt tolerance of the washer. Please be sure to observe the respective manufacturer's specifications!

9. SAFETY MEASURES AND WARNINGS

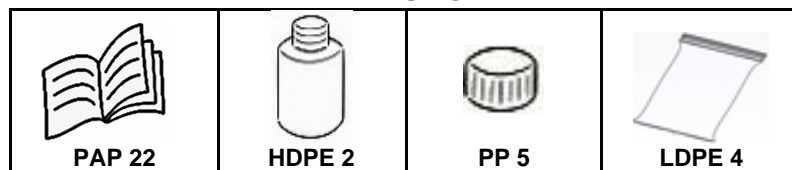
- In vitro diagnostic device for professional use.
- The information, safety measures and warnings in the instructions for use must be strictly followed. In case of deviation, the user is liable for any incorrect results.
- Wearing a lab coat, disposable gloves and protective goggles is recommended during use. Should contact with reagents nevertheless occur, the relevant Safety Data Sheet (SDS) must be consulted.
- All materials of human or animal origin should be considered potentially infectious and handled accordingly.
- Do not use after the expiry date.
- **Note:** any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

10. DISPOSAL CONSIDERATIONS

10.1. Reagent

Chemicals and preparations, as well as their containers, are generally hazardous waste. Their disposal is subject to national waste legislation and regulations. The competent authority provides information on the disposal of hazardous waste.

10.2. Information on Packaging Materials















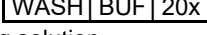
11. REVISION HISTORY

Revision	Chapter	Change
rev01	9	Note added
rev02	several	Name change of the manufacturer, contact information updated

12. ORDERING INFORMATION

REF	W0000	WASH BUF 20x	Washing Buffer (20x concentrated)	50 mL
	W0000DB	WASH BUF 20x	Washing Buffer (20x concentrated)	50 mL

13. SYMBOLS KEY

	Manufactured by
	In-vitro-Diagnostic device
	Batch designation
	Expiry date
	Storage temperature
	CE marking
	Unique Device Identifier
	Product number
	Consult Instructions for Use
	“Washing Buffer 20x Concentrate”;  W0000 Washing Buffer (20x concentrated)
	20-fold dilution of  Working solution



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