

610345-03E * Date of revision November 1,2023(Revision 4)

Wash Solution A

Product list

| Catalogue No. | Product name |
|---------------|-----------------|
| 912587 | Wash Solution A |

Manufactured by:

Alfresa Pharma Corporation

2-2-9 Kokumachi, Chuo-ku, Osaka 540-8575, Japan For any incidents: incident-ivdr@alfresa-pharma.co.jp For technical support: technical-support@alfresa-pharma.co.jp

Refer to the following URL for the package inserts in languages other than English:

https://alfresa-pharma-global.com/fit/products/



FOR IN VITRO DIAGNOSTIC USE ONLY

1.0 INTENDED USE

Wash Solution A is used for cleaning reaction cuvette, sampling probe, reagent probes and mixing bar of the Discrete Clinical Chemistry Analyzers dedicated to our reagents only.

2.0 COMPONENTS

A pack of Wash Solution A includes two bottles of 500 mL stock solution (10X). Wash Solution A contains:

Polyoxyethylene alkyl ether 5 % Sodium hydroxide 3 % Sodium metaxylene sulfonate 2 %

Safety Data Sheet is available upon request by users.

Hazard statements:

· May be corrosive to metals



- · Causes severe skin burns and eye damage
- Causes serious eye damage
- · Causes damage to respiratory organs

3.0 ADDITIONAL REQUIRED EQUIPMENT

3.1 Analyze

Discrete Clinical Chemistry Analyzer NS-Prime

Discrete Clinical Chemistry Analyzer AA01

Note: Please contact us, if you want use with other analyzers dedicated to our reagents.

3.2 Others

Purified water (distilled or deionized (DI) water) Graduated cylinder

4.0 REAGENT PREPARATION

Dilute Wash Solution A 10-fold with purified water and mix well before use. Do not use Wash Solution A as it is. Do not use at a dilution ratio other than 10-fold. Use diluted wash solution (1X) in analyzer's "Washing Bottle" within two years after dilution

Caution: In handling it, wear rubber gloves and protective glasses.

5.0 STORAGE AND SHELF LIFE AFTER FIRST OPENING

5.1 Storage

Store at 1–30 $^{\circ}$ C. Use Wash Solution A within label expiry date. Keep out of direct sunlight.

5.2 Storage and shelf life after first opening

Tightly keep the lid on and store at 1-30 ℃ after opening Wash Solution A.

6.0 WARNINGS AND PRECAUTIONS

6.1 General precautions

For in vitro diagnostic use

Only experienced laboratory personnel should use this; the test using our reagents should be used in a manner consistent with Good Laboratory Practice. If you become aware of a serious incident related to this product, be sure to report it to the manufacturer and the competent authorities.

6.2 Safety precautions

- 1. Do not pipet by mouth.
- Do not smoke, eat, or apply cosmetics in areas where patients' specimens or kit reagents are handled.
- Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
- Take care to avoid self-inoculation, splashing to the mucous membrane, or generation of aerosols.
- Wear laboratory gloves while handling patients' specimens or disposing of solid or liquid wastes.
- Upon disposal of reagents or other materials, comply with relevant legal provisions.

- 7. All human specimens should be considered potentially infectious. Handle all specimens as if capable of transmitting HBV, HCV, HIV, or other microbes. Decontaminate and dispose of specimens and all potentially contaminated materials as if they contain infectious agents.
- 8. Wash Solution A is strongly alkaline. In handling it, wear rubber gloves and protective glasses. Upon exposure to the eye or skin, take emergency measures such as washing with plenty of water. Consult a doctor if necessary. Upon accidental ingestion, seek medical attention immediately.

6.3 Limitations

- 1. Do not use Wash Solution A bottles for purposes other than those stated.
- 2. Do not use Wash Solution A as it is, be sure to dilute 10-fold before using
- Use of reagents, disposables, or spare parts other than those supplied by the authorized distributor may produce incorrect results.

7.0 SYMBOLS USED IN PRODUCT INSERTS AND ON LABELS

| Symbols | Meanings of the symbols | |
|---------|--|--|
| CE | CE marking | |
| | Use-by date (Expiry date) | |
| LOT | Batch code | |
| REF | Catalogue number | |
| *** | Manufacturer | |
| EC REP | Authorized representative in the European Community (Authorized European representative) | |
| IVD | In vitro diagnostic medical device (In vitro diagnostic) | |
| 1 | Temperature limit (for store) Consult instructions for use | |
| []i | | |
| | May be corrosive to metals Causes severe skin burns and eye damage Causes serious eye damage | |
| | Causes damage to respiratory organs | |

* 8.0 INFORMATION ON PACKAGING MATERIALS

Outer bag

The following materials are used in the packaging of this product (accordance with Directive 94/62/EC on packaging and packaging waste).

| Outer bag HDPE 2 | Outer bag label PAP 22 | | |
|---------------------|---------------------------|------------------------|--|
| Product bottle | | | |
| Bottle HDPE 2 | Cap PP 5 | Bottle label PAP 22 | |

| Others | |
|----------------------|--|
| Instructions for use | |
| | |