

# HƯỚNG DẪN SỬ DỤNG TIẾNG ANH

Hà Nội, ngày 30 tháng 05 năm 2022  
**Người đại diện hợp pháp của cơ sở**  
*Xác nhận bằng chữ ký số*  
**GIÁM ĐỐC**

**Nguyễn Thị Kim Chi**

**FOR PROFESSIONAL USE ONLY****PRINCIPLE****CAUTION**

For U.S.A. only, Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician.

**INTENDED USE**

UniCel DxI Access Immunoassay Systems Wash Buffer II is intended for use with the Access Immunoassay Systems and specific Access immunoassay reagents.

**REAGENTS****PRODUCT INFORMATION**

- Provided ready to use.
- Stable until the expiration date stated on the label when stored at room temperature (15 to 30°C). An increase in substrate background measurements or increased relative light units for the zero calibrators in "sandwich"-type assays may indicate instability.

<b>R3</b>	Wash Buffer II: 1 x 10 L TRIS buffered saline, surfactant, < 0.1% sodium azide, and < 0.05% Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one (3:1).
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**WARNING AND PRECAUTIONS**

- For *in vitro* diagnostic use.
- For hazards presented by the product refer to the following sections: REACTIVE INGREDIENTS and GHS HAZARD CLASSIFICATION.

**REACTIVE INGREDIENTS** **CAUTION**

**Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.**

## GHS HAZARD CLASSIFICATION

Wash Buffer II

WARNING



H317

May cause an allergic skin reaction.

H412

Harmful to aquatic life with long lasting effects.

P273

Avoid release to the environment.

P280

Wear protective gloves, protective clothing and eye/face protection.

P333+P313

If skin irritation or rash occurs: Get medical advice/attention.

P362+P364

Take off contaminated clothing and wash it before use.

reaction mass of:

5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SDS

Safety Data Sheet is available at [beckmancoulter.com/techdocs](http://beckmancoulter.com/techdocs)

## TESTING PROCEDURE(S)

**DIRECTIONS FOR USE** Refer to the appropriate system manuals and/or Help system for detailed instructions.

## ADDITIONAL INFORMATION

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

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May be covered by one or more pat. -see [www.beckmancoulter.com/patents](http://www.beckmancoulter.com/patents).

## REVISION HISTORY

### Revision N

New release of IVDR compliant IFU


## SYMBOLS KEY

Glossary of Symbols is available at [beckmancoulter.com/techdocs](http://beckmancoulter.com/techdocs) (document number C02724).

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EC	REP
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