

HƯỚNG DẪN SỬ DỤNG TIẾNG ANH

Hà Nội, ngày 12 tháng 05 năm 2022
Người đại diện hợp pháp của cơ sở
Xác nhận bằng chữ ký số
GIÁM ĐỐC

Trịnh Diệu Hương



ACCESS
Immunoassay Systems

Instructions For Use

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Access Sample Diluent A

REF 81908

FOR PROFESSIONAL USE ONLY

Rx Only

PRINCIPLE

INTENDED USE

The Access Sample Diluent A is intended for use with Access assays to dilute patient samples containing analyte concentrations greater than the analyte specific S5 calibrator.

SUMMARY AND EXPLANATION

The analyte level in patient samples may exceed the level of the specific S5 calibrator. If a quantitative value is required, it will be necessary to dilute the samples in order to determine the analyte concentration.

REAGENTS

PRODUCT INFORMATION

Access Sample Diluent A

Cat. No. 81908: 4 mL/vial

- Provided ready to use.
- Allow the contents to stand for 10 minutes at room temperature.
- Mix gently by inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the vial label when stored at 2 to 10°C.

Diluent	Buffered Bovine Serum Albumin (BSA) matrix with surfactant, < 0.1% sodium azide, 0.5% ProClin* 300.
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*ProClin™ is a trademark of The Dow Chemical Company (“Dow”) or an affiliated company of Dow.

WARNING AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- 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

SAMPLE DILUENT A

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.

Ethoxylated alkyl alcohol 0.1 - 0.5%

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

TESTING PROCEDURE(S)

Samples can be accurately measured within the analytic range of the lower limit of detection and the highest calibrator value of the specific assay. If a sample contains more analyte than the stated value of the highest calibrator, dilute the sample following dilution instruction in the specific assay labeling under "Limitations" section of the assay instructions for use. Refer to the appropriate system manuals and/or Help system for instructions on how to enter a sample dilution in a test request.

PROCEDURAL NOTES

LIMITATIONS

If there is evidence of microbial contamination or excessive turbidity in the reagent, discard the vial.

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.

REVISION HISTORY

Revision L

IFU updated to add Dutch, Finnish, Macedonian, Traditional Chinese, and Estonian

Revision M


New release of IVDR compliant IFU

SYMBOLS KEY

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

EC	REP
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