HƯỚNG DẪN SỬ DỤNG TIẾNG ANH

Hà Nội, ngày 07 tháng 06 năm 2022

Người đại diện hợp pháp của cơ sở

Xác nhận bằng chữ ký số

GIÁM ĐỐC

M.S.D.N:0305502815-C.T.T.N.H.H
CÔNG TY TNHH KỸ THUẬT NAM PHƯƠNG
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BECKMAN COULTER

ACCESS
Immunoassay Systems

Instructions For Use

Access System Check Solution

REF 81910

FOR PROFESSIONAL USE ONLY

Rx Only

PRINCIPLE

INTENDED USE

For use with the Access Immunoassay Systems in the weekly maintenance System Check Procedure.

REAGENTS

PRODUCT INFORMATION

- Provided ready to use.
- Stable until the expiration date stated on the label when stored at 2 to 8°C.

R4	**Access System Check Solution: 6 x 4.0 mL.** Alkaline phosphatase, 1% bovine serum albumin (BSA), 0.25% ProClin* 300, < 0.1% sodium azide.

*ProClin™ is a trademark of The Dow Chemical Company (“Dow”) or an affiliated company of Dow.

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

SYSTEM CHECK SOLUTION	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

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.

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 Beckman Coulter Ireland Inc., Lismeehan, O'Callaghan's Mills, Co. Clare, Ireland +(353) (0) 65 683 1100

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