



# IMMAGE Immunochemistry Systems

## Instructions For Use

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**BUF4**  
**Buffer 4**

**REF** 447420

### For *In Vitro* Diagnostic Use

### FOR PROFESSIONAL USE ONLY

Rx Only

## PRINCIPLE

### INTENDED USE

Buffer 4 is intended for use with the IMMAGE Immunochemistry Systems and reagents for the quantitative determinations of components in biological fluids.

## REAGENTS

### CONTENTS

Each kit contains the following items:

KIT COMPONENTS	QUANTITY
IMMAGE Immunochemistry Systems Buffer 4	4
Evaporation Caps	4

### REACTIVE INGREDIENTS

REAGENT CONSTITUENTS	VOLUME
IMMAGE Immunochemistry Systems Buffer 4 (Tris-buffered Saline with Polymer Enhancer)	120 mL
Sodium Azide (used as a preservative)	< 0.1% (w/w)

Also bovine serum albumin and non-reactive chemicals necessary for optimal system performance.

 **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**

Buffer 4

WARNING



H316	Causes mild skin irritation.
H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing and eye/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
	1-(3-Dimethylaminopropyl)-3-Ethylcarbodiimide Hydrochloride 0.1 - 1%
	Tris(hydroxymethyl)- aminomethane 1 - 5%
	Choline Chloride 1 - 5%
	Sodium Trichloroacetate 1 - 10%

SDS

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

**MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT**

IMAGE Immunochemistry Systems  
IMAGE Immunochemistry Systems Reagents

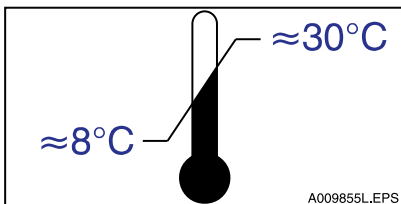
**REAGENT PREPARATION**

1. Mix Buffer 4 thoroughly by inversion.
2. Remove screw cap from container. Check each container for bubbles and remove any bubbles present.

3. Place evaporation cap on container before loading Buffer on the instrument. See Appendices for evaporation cap directions.

## STORAGE AND STABILITY

1. Once opened, BUF4 is stable on the system for 30 days with evaporation cap in place.
2. When unopened, BUF4 is stable until the expiration date on the label if stored at room temperature with the screw cap in place. Room temperature storage is represented by this symbol on the label.



### Buffer storage location:



## ADDITIONAL BUFFER CALIBRATION INFORMATION

Recalibration of affected chemistries may be necessary when buffer lots are changed.

## TESTING PROCEDURE(S)

After setup, load reagents onto the system as directed in the *IMMAGE Operations Manual*.

## ADDITIONAL INFORMATION

For more information, refer to the *IMMAGE Immunochemistry Systems Operations Manual*.

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

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.

## SHIPPING DAMAGE

If damaged product is received, notify your Beckman Coulter Clinical Support Center.

## REVISION HISTORY

### Revision AE

Added new language requirement: Norwegian.

**Revision AF**

Updated corporate address.

**Revision AG**

Added Revision History

**Revision AH**

Added new language requirement: Czech, and Korean.

**Revision AJ**

Added GHS classification and Trademark statement.

**Revision AK**

Added new language requirement: Romanian

**Revision AL**

Updates to comply with requirements per Beckman Coulter Global Labeling Policy.

**Revision AM**

Added new language requirement: Brazilian Portuguese.

**Revision AN**


















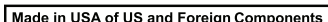

Added new language requirement: Dutch, and Slovak. Additional changes to comply with requirements per Beckman Coulter Global Labeling Policy.

**Revision AP**


Updates to comply with IVDR requirements per Beckman Coulter Global Labeling Policy.

## SYMBOLS KEY

Table 1.0

	Catalogue Number		In Vitro Diagnostic
	Contents		Temperature limit
	Manufacturer		Expiration Date
	Batch code		Safety Data Sheet
	CE Mark		Consult Instructions for Use
	Authorized Representative in the European Community		Date of Manufacture
	Caution		Biological risks
	Buffer 4		Caps
	WARNING		
			

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