BECKMAN COULTER

ACCESS
Immunoassay Systems

Instructions For Use

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ACCESS BNP CALIBRATORS
B-type natriuretic peptide (BNP)

REF 98202

FOR PROFESSIONAL USE ONLY

For *in vitro* diagnostic use

Rx Only

PRINCIPLE

INTENDED USE

The Access BNP Calibrators are intended to calibrate the Access BNP test for the quantitative determination of BNP levels in human EDTA plasma using the Beckman Coulter Access Family of Immunoassay Systems.

SUMMARY AND EXPLANATION

Quantitative assay calibration is the process by which samples with known analyte concentrations (i.e., assay calibrators) are tested like patient samples to measure the response. The mathematical relationship between the measured responses and the known analyte concentrations establishes the calibration curve. This mathematical relationship, or calibration curve, is used to convert Relative Light Unit (RLU) measurements of samples to specific quantitative analyte concentrations.

TRACEABILITY

The measurand (analyte) in the Access BNP Calibrators is traceable to the manufacturer's working calibrators. Traceability process is based on EN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the Access reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

REAGENTS

CONTENTS

Access BNP Calibrators

Ref. No. 98202: S0–S5, 1.5 mL/vial

- Provided ready to use.
- Store upright and freeze at -20°C or colder in a non-defrosting freezer away from the freezer door.
- Stable until the expiration date stated on the label when stored at -20°C or colder.
- Vial is stable at 2 to 10°C for 30 days after initial use or when removed from frozen storage.
- Signs of possible deterioration are quality control values out of range.
- Refer to calibration card for exact concentrations.

S0:	Buffered bovine serum albumin (BSA) matrix with surfactant < 0.1% sodium azide, and 0.1% ProClin* 300.
S1, S2, S3, S4, S5:	Recombinant human BNP complex at levels of approximately 25, 100, 500, 2,500 and 5,000 pg/mL in buffered BSA matrix with surfactant, < 0.1% sodium azide, and 0.1% ProClin 300.
Calibration Card:	1

*ProClin is a trademark of LANXESS Corp.

WARNING AND PRECAUTIONS

- For *in vitro* diagnostic use.
- 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,[1] 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 section: 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

BNP Calibrator S0	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%
BNP Calibrators S1 - S5	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.
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SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

CALIBRATION

CALIBRATION INFORMATION

The Access BNP Calibrators are provided at 6 levels – zero and 25, 100, 500, 2,500 and 5,000 pg/mL. Assay calibration data are valid up to 28 days.

Run the calibrators in duplicate.

TESTING PROCEDURE(S)

PROCEDURE

Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

PROCEDURAL NOTES

LIMITATIONS

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

ADDITIONAL INFORMATION

Beckman Coulter, the stylized logo, and the Beckman Coulter product and service marks mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries.

May be covered by one or more pat. -see www.beckmancoulter.com/patents.

REVISION HISTORY

Revision A

New release.

Revision B

Updated EC REP Address

Revision C

Added new languages

Revision D

Added new languages

Revision E

Remove CE Mark and EC REP Address. Update Additional Information Section.

Revision F

Updated ProClin trademark statement.

SYMBOLS KEY

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

REFERENCES

1. Approved Guideline - Protection of Laboratory Workers From Occupationally Acquired Infections, M29-A4, 4th Edition, May 2014. Clinical and Laboratory Standards Institute.

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