BECKMAN COULTER

CE 2797

ACCESS
Immunoassay Systems

Instructions For Use

Access Intact PTH Calibrators
Parathyroid Hormone, Intact

REF A16953

FOR PROFESSIONAL USE ONLY

Rx Only

Routine Mode (~30 minutes)
Intraoperative Mode (~15 minutes)

PRINCIPLE

INTENDED USE

The Access Intact PTH Calibrators are intended to calibrate the Access Intact PTH assay for the quantitative determination of intact parathyroid hormone (parathyrin, PTH) levels in human serum and plasma using the Access 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 RLU (Relative Light Unit) measurements of patient samples to specific quantitative analyte concentrations.

TRACEABILITY

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

The average recovery of WHO standard preparation 79/500 diluted in Access Sample Diluent A (Ref. No. 81908) is 57% for the Routine Mode and 53% for the Intraoperative Mode over the full range of the assay.

REAGENTS

PRODUCT INFORMATION

Access Intact PTH Calibrators

Ref. No. A16953: PTH Reconstitution Buffer (RB), 2 vials, 4.0 mL/vial; S0-S5, 1.0 mL/vial

- Used for both the Routine and Intraoperative modes.
- Calibrators and Reconstitution Buffer are **single use only**.
- S0-S5 calibrators are provided lyophilized.
- Reconstitute each calibrator vial volumetrically with 1.0 mL **PTH Reconstitution Buffer**. Allow 30 minutes for dissolution. Mix gently before use.
- Use reconstituted calibrators within 2 hours if stored at 18-25°C.

- Use reconstituted calibrators within 10 hours if stored at 2-10°C.
- Lyophilized calibrators and PTH Reconstitution Buffer are stable until the expiration date stated on the label when stored at 2 to 10°C.
- Signs of possible deterioration are control values out of range or failure of calibrators to completely reconstitute.
- Refer to calibration card for exact concentrations.

RB:	Buffered protein (bovine) matrix, 0.5% ProClin* 300.
S0:	PBS buffer, bovine serum albumin (BSA), surfactant, < 0.1% sodium azide.
S1, S2, S3, S4, S5:	Approximately 10, 60, 300, 1,500 and 3,500 pg/mL (1.1, 6.4, 31.8, 159.0 and 371.0 pmol/L) PTH (synthetic antigen), respectively in PBS buffer with BSA, surfactant, < 0.1% sodium azide.
Calibration Cards:	4

*ProClin is a trademark of LANXESS Corp.

- **Calibration Cards:** For the Access Intact PTH assay, one set of calibration cards are provided for use on Access 2 and UniCel DxI 600/800, and another set is provided for use on the DxI 9000 instrument for the Routine Mode or Intraoperative Mode.

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

Calibrators	H402	Harmful to aquatic life.
	P273	Avoid release to the environment.
		Ethoxylated alkyl alcohol 0.1 - 0.5%
Reconstitution Buffer	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

CALIBRATION

CALIBRATION INFORMATION

The Access Intact PTH Calibrators are provided at six levels - zero and approximately 10, 60, 300, 1,500 and 3,500 pg/mL (1.1, 6.4, 31.8, 159.0 and 371.0 pmol/L). Assay calibration data are valid up to 28 days.

Calibrators run 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.

Separate calibration cards are required to run the Routine and Intraoperative modes of the Access Intact PTH assay. Each mode has a separate calibration card and must be calibrated accordingly. The same calibrator set is used for both modes.

PROCEDURAL NOTES

LIMITATIONS

If there is evidence of microbial contamination or excessive turbidity in a 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.

REVISION HISTORY

Revision J

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

Revision K

New release of IVDR compliant IFU.

Revision L

Updated "Product Information" section.

Revision M

Updated "Product Information" section.

Revision N

Added Translations.

Revision P

Updated ProClin trademark statement.

Revision R

Added Translations.

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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