BECKMAN COULTER

ACCESS
Immunoassay Systems

# Instructions For Use

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# Access EPO Calibrators
# Erythropoietin

REF A16365

**FOR PROFESSIONAL USE ONLY**

**Rx Only**

**ANNUAL REVIEW**

| Reviewed by | Date | Reviewed by | Date |
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## PRINCIPLE

### INTENDED USE

The Access EPO Calibrators are intended to calibrate the Access EPO assay for the quantitative determination of EPO levels in human serum and plasma (heparin) 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 EPO Calibrators is traceable to the WHO Second IRP (67/343) a urine-derived form of human erythropoietin. 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

### PRODUCT INFORMATION

**Access EPO Calibrators**

**Cat. No. A16365: S0, 10 mL/vial; S1–S5, 2.5 mL/vial**

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Vial is stable at 2 to 10°C for 90 days after initial use.
- Signs of possible deterioration are control values out of range.
- Refer to calibration card for exact concentrations.

| | |
|---|---|
| **S0:** | Buffered BSA matrix, < 0.1% sodium azide and 0.15% ProClin* 300. |
| **S1, S2, S3, S4, S5:** | Recombinant human EPO, buffered BSA matrix, < 0.1% sodium azide and 0.1% sodium Omadine.** |
| **Calibration Card:** | 1 |

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

**Omadine is a trademark of Olin Corporation.

## 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

| | | |
|---|---|---|
| EPO Calibrators<br>S1, S2, S3, S4, S5 | WARNING | |
| |  | |
| | H317 | May cause an allergic skin reaction. |
| | 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% |
| EPO Calibrator S0 | WARNING | |
| |  | |
| | H317 | May cause an allergic skin reaction. |
| | 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% |

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|---|---|
| SDS | Safety Data Sheet is available at techdocs.beckmancoulter.com |

# CALIBRATION

### CALIBRATION INFORMATION

The Access EPO Calibrators are provided at six levels – zero and approximately 5, 25, 125, 375 and 750 mIU/mL. 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.

# PROCEDURAL NOTES

### LIMITATIONS

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

# ADDITIONAL INFORMATION

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Developed and manufactured in collaboration with R&D Systems, a Bio-Techne brand.***

*** R&D Systems is a registered trademark of Bio-Techne Corporation.

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

### REVISION HISTORY

**Revision J**

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

### SYMBOLS KEY

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

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