



ACCESS
Immunoassay Systems

Instructions For Use

© 2020 Beckman Coulter, Inc. All rights reserved.

Access IL-6 Calibrators Interleukin-6

REF A30944

For Use Under the Emergency Use Authorization (EUA) Only

For in vitro diagnostic use

Rx Only

FOR USE ON ACCESS FAMILY OF IMMUNOASSAY SYSTEMS

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

The Access IL-6 Calibrators are intended to calibrate the Access IL-6 assay for the quantitative determination of IL-6 levels in human serum and plasma (heparin) using the 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 RLU (Relative Light Unit) measurements of patient samples to specific quantitative analyte concentrations.

TRACEABILITY

The measurand (analyte) in the Access IL-6 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.

The NIBSC/WHO International Standard for IL-6 (89/548) which was intended as a potency standard, was evaluated in the kit. The NIBSC/WHO standard is a CHO cell-derived recombinant human IL-6. The dose response curve of the International Standard (89/548) parallels the Access IL-6 calibration curve. To convert sample values obtained with the Access IL-6 kit to equivalent NIBSC 89/548 units, use the equation below.

$$\text{NIBSC (89/548) equivalent value (IU/mL)} = 0.107 \times \text{Access IL-6 value (pg/mL)}$$

REAGENTS

PRODUCT INFORMATION

Access IL-6 Calibrators

Cat. No. A30944: S0, 4.0 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% NaN ₃ , 0.15% ProClin* 300.
S1, S2, S3, S4, S5:	Buffered BSA matrix, recombinant human IL-6, < 0.1% NaN ₃ , 0.15% ProClin 300.
Calibration Card:	1

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

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

IL-6 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%

IL-6 CALIBRATORS S1, S2,
S3, S4, 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.

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 IL-6 Calibrators are provided at six levels – zero and approximately 2.5, 25, 250, 750 and 1,500 pg/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

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

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.

** 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 F

Release EUA IFU

SYMBOLS KEY

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



Manufactured for: Beckman Coulter, Inc. 250 S. Kraemer Blvd. Brea, CA 92821 U.S.A
www.beckmancoulter.com