BECKMAN COULTER

ACCESS
Immunoassay Systems

Instructions For Use

ACCESS IL-6 QC
Interleukin-6

REF A30946

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 QC is intended for monitoring system performance of the Access IL-6 assay.

SUMMARY AND EXPLANATION

Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of the Access IL-6 immunoassay. In addition, they are an integral part of good laboratory practices.[1,2,3,4,5,6] When performing assays with Access reagents for IL-6, include quality control materials to validate the integrity of the assays. The assayed values should fall within the acceptable range if the test system is working properly.

TRACEABILITY

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

Cat. No. A30946: 2.5 mL/vial, 2 vials each level

- Provided ready to use.
- Store upright and frozen at -20°C.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the label when stored at -20°C.
- After thawing, controls are stable for 14 days at 2 to 10°C.
- Signs of possible deterioration are control values out of range.
- Refer to the QC value card for mean values and standard deviations (SD).

QC 1:	Buffered PBS matrix with porcine serum, recombinant human IL-6, at a level of approximately 8 pg/mL, < 0.1% NaN_3, 0.15% ProClin* 300.
QC 2:	Buffered PBS matrix with porcine serum, recombinant human IL-6, at a level of approximately 300 pg/mL, < 0.1% NaN_3, 0.15% ProClin 300.
QC 3:	Buffered PBS matrix with porcine serum, recombinant human IL-6, at a level of approximately 800 pg/mL, < 0.1% NaN_3, 0.15% ProClin 300.
QC Value 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 QC: QC1, QC2, QC3	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

TESTING PROCEDURE(S)

PROCEDURE

Determine the concentration of IL-6 in the Access IL-6 QC materials using the Access Immunoassay System in the same manner as a patient sample. Because samples can be processed at any time in a "random access" format rather than a "batch" format, quality control materials should be included in each 24-hour time period.[1] More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws. Refer to the appropriate system manuals and/or Help system for information on quality control theory, configuring controls, quality control sample test request entry, and reviewing quality control data.

REPORTING RESULTS

EXPECTED RESULTS

For the value assignment of the Access IL-6 QC material, a number of samples, representative of the entire lot, are selected and assayed to provide a reliable estimate of the mean value. The mean values and standard deviations are listed on the QC value card. Variations, such as in technique, equipment, or reagents may result in values different from those listed. Therefore, each laboratory should establish its own mean values and standard deviations (SD).

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.**

REVISION HISTORY

Revision F

Release EUA IFU

SYMBOLS KEY

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

REFERENCES

1. Cembrowski GS, Carey RN. Laboratory quality management: QC ⇌ QA. ASCP Press, Chicago, IL, 1989.

2. Broome HE, Cembrowski GS, Kahn SN, Martin PL, Patrick CA. Implementation and use of a manual multi-rule quality control procedure. Lab Med 1985; 16: 533-537.

3. Westgard JO, Barry PL, Hunt MR, Groth T. A multi-rule Shewhart chart for quality control in clinical chemistry. Clin Chem 1981; 27: 493-501.

4. Koch DD, Oryall JJ, Quam EF, Feldbruegger DH, et al. Selection of medically useful QC procedures for individual tests done in a multitest analytical system. Clin Chem 1990; 36: 230-233.

5. Mugan K, Carlson IH, Westgard JO. Planning QC procedures for immunoassays. J Clin Immunoassay 1994; 17:216-222.

6. Approved Guideline - Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions, C24-A3. June 2006. Clinical and Laboratory Standards Institute.

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