BECKMAN COULTER

CE 2797

ACCESS
Immunoassay Systems

Instructions For Use

© 2025 Beckman Coulter, Inc. All rights reserved.

Access Ostase QC
Bone Specific Alkaline Phosphatase

REF 37309

FOR PROFESSIONAL USE ONLY

Rx Only

PRINCIPLE

INTENDED USE

The Access Ostase QC is intended for monitoring system performance of the Access Ostase assay.

SUMMARY AND EXPLANATION

Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of the Access Ostase 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 bone alkaline phosphatase (BAP), 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 Ostase 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 Ostase QC

Cat. No. 37309: 4.0 mL/vial, 1 vial each level

- 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.
- 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:	Human BAP at a level of approximately 11 µg/L in a buffered bovine serum albumin (BSA) matrix with surfactant, < 0.1% sodium azide, and 0.5% Proclin* 300.
QC 2:	Human BAP at a level of approximately 45 µg/L in a BSA matrix with surfactant, < 0.1% sodium azide, and 0.5% ProClin 300.
QC Value Card:	1

*ProClin is a trademark of LANXESS Corp.

WARNING AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Human source material used in the preparation of the reagent has been tested and found negative or non-reactive for Hepatitis B, Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease.[7]
- 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

Ostase QC, QC1 and QC2 — 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 human BAP in the Access Ostase 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 Ostase 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, and 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

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.

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 J

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

Revision K

New release of IVDR compliant IFU.

Revision L

Added Translations.

Revision M

Added Translations.

Revision N

Updated ProClin trademark statement.

Revision P

Added Translations.

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. Tentative Guideline - Internal quality control: Principles and definitions, C24-T. 1987. Clinical and Laboratory Standards Institute.

7. HHS Publication, 5th ed., December 2009. Biosafety in Microbiological and Biomedical Laboratories.

EC REP Beckman Coulter Ireland Inc., Lismeehan, O'Callaghan's Mills, Co. Clare, Ireland +(353) (0) 65 683 1100

Beckman Coulter, Inc., 250 S. Kraemer Blvd., Brea, CA 92821 U.S.A.
+(1) 800-854-3633
www.beckmancoulter.com