

UIBC CALIBRATOR

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REF: A301S	UIBC Calibrator	1 x 5 mL
REF: A302S	UIBC Calibrator	5 x 5 mL
REF: A301D	UIBC Calibrator	3 x 1 mL
REF: ZA107	UIBC Calibrator	250 mL

Changes made in the instructions for use are marked as grey.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package.

INTENDED USE

UIBC Calibrator is for calibration of the UIBC Liquid assay.

CONTENTS / MATERIALS PROVIDED

UIBC Calibrator
REF: A301S
 Package: 1 x 5 mL **Liquid**

UIBC Calibrator
REF: A302S
 Package: 5 x 5 mL **Liquid**

UIBC Calibrator
REF: A301D
 Package: 3 x 1 mL **Liquid**

UIBC Calibrator
REF: ZA107
 Package: 250 mL **Liquid**

For use with:

Archem UIBC Liquid Reagent
 Archem Arcon N (Level I Control) Lyophilized
 Archem Arcon P (Level II Control) Lyophilized

Sodium Azide (0,09 %) is added as preservative.

Materials Required But Not Provided:

1. Class A volumetric pipette for liquid transfer
2. Distilled or deionized water meeting the specifications equivalent to USP (United States Pharmacopeial Convention) purified water.

STANDARDIZATION

The calibrator values were obtained by using Archem UIBC reagent and Certified Reference Material (CRM) NIST SRM 3126 as the primary standard.

CALIBRATOR STABILITY

Temperature-Conditions	Stability
Unopened at +2/+8°C	Expiry date on the vial.
Opened and stored at +2/+8°C	60 days

PREPARATION OF CALIBRATOR

Calibrator is ready for use.

INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or microbial growth may indicate deterioration.

PRECAUTIONS



Human source material. Treat as potentially infectious material. Each plasma donor used in the preparation of this product has been tested by an FDA-approved method and found negative for the presence of HIV 1/2 HBsAg, HCV, HIV-Ag antibodies. However, none of the known testing methods can offer complete assurance that the hepatitis B virus, Human Immunodeficiency Virus (HIV) or infectious agents are not present. All human-based products should be handled in accordance with Good Laboratory Practice (GLP) principles using appropriate precautions. Safety data sheets are available at www.archem.com.tr or you may contact your local representative.

WARNINGS

IVD: For in Vitro Diagnostic use only.
 Do not use expired reagents.
 Reagents with two different lot numbers should not be interchanged.
 For professional use.
 Follow Good Laboratory Practice (GLP) guidelines.
 Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

H317 :May cause allergic skin reaction.

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Precaution

- P280 :Use protective gloves / clothes / glasses / mask.
- P264 :Wash your hands properly after using.
- P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention

- P302+P352 :Wash with plenty of water and soap if it contacts with skin.
- P333+P313 :Seek medical help if it irritates your skin or develops rash.
- P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal

- P501 :Dispose the vials and contents according to the local regulations.

REFERENCES

1. Council Directive (2000/54/EC). Official Journal of the European Communities No. L262 from Oct. 17, 2000.
2. EU-Dir 1999/11 Commission Directive of 8 March 1999 adapting to technical progress the principles of Good Laboratory Practice as specified in Council Directive 87/18/EEC
3. Clinical and Laboratory Standards Institute, H26-A2, Validation, verification, and quality assurance of automated hematology analyzers; Approved Guideline - Second Edition.
4. Gabbay, K.H., Hasty, K., Breslow, J.L., Ellison, R.C., Bunn, H.F., and Gallop, P.M., J. Clin. Endocrinol. Metab. 44, 859 (1977).
5. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens.

TRADEMARKS

UIBC Calibrator is a trademark of ARCHEM Sağlık Sanayi ve Tic. A.Ş. in various jurisdictions.



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SYMBOLS

IVD

In Vitro Diagnostic Medical Device

LOT

Lot Number

CAL

Calibrator

GTIN

Global Trade Item Number

REF

Reference Number

FOR USE WITH

Identifies Products to Be Used Together

PRODUCT OF TURKEY

Product of Turkey



Manufacturer



Expiration Date



Temperature Limits



Consult Instructions for Use



Caution



Number of Tests

