CREATININE CALIBRATOR

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REF: A235S	**Creatinine Calibrator Level I**	**1x1.5 mL**
REF: A236S	**Creatinine Calibrator Level II**	**1x1.5 mL**
REF: A217D	**Creatinine Calibrator Set**	**1x3 mL+1x3 mL**
REF: A216D	**Creatinine Calibrator Set**	**3x1 mL+3x1 mL**
REF: A216S	**Creatinine Calibrator**	**1x3 mL**
REF: A217S	**Creatinine Calibrator Level I**	**1x1.5 mL**
REF: A218S	**Creatinine Calibrator Level I**	**1x1.5 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

Archem Creatinine Calibrator is for calibration of the Creatinine Liquid assay.

CONTENTS / MATERIALS PROVIDED

Creatinine Standard Level I-Calibrator
REF: A235S
Package: 1 x 1.5 mL **Liquid**

Creatinine Standard Level II-Calibrator
REF: A236S
Package: 1 x 1.5 mL **Liquid**

Creatinine Calibrator Set
REF: A217D
Package: 1 x 3 mL + 1 x 3 mL **Liquid**

Creatinine Calibrator Set
REF: A216D
Package: 3 x 1 mL + 3 x 1 mL **Liquid**

Creatinine Calibrator
REF: A216S
Package: 1 x 3 mL **Liquid**

Creatinine Calibrator
REF: A217S
Package: 1 x 1.5 mL **Liquid**

Creatinine Calibrator
REF: A218S
Package: 1 x 1.5 mL **Liquid**

For use with:
Archem Creatinine Liquid Reagent
Archem Arcon N (Level I Control) Lyophilized
Archem Arcon P (Level II Control) Lyophilized

A235S / A236S contain the human serum.
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 Archem Creatinine reagent and Certified Reference Material (CRM) NIST SRM 967 as the primary standard.

CALIBRATOR STABILITY

Temperature-Conditions	Stability
Unopened and stored at +15/+25°C	Expiry date on the vial.
Opened and stored at +15/+25°C	30 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.

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

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

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

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