

ZINC CALIBRATOR

En

REF: VT-027 Zinc Calibrator Liquid 5 x 3 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

Validity Zinc Calibrator is for calibration of the Zinc Liquid assay.

CONTENTS / MATERIALS PROVIDED

Zinc Calibrator
REF: VT-027
 Package: 5 x 3 mL **Liquid**

For use with:

Validity Zinc Liquid Reagent
 Validity Zinc Control

VT-027 do not contain the human serum.

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 traceability of the method is verified using BCR 637 Zinc Human Serum.

CALIBRATOR STABILITY

Temperature-Conditions	Stability
Unopened at +2/+8°C	Expiry date on the vial.
Opened and stored at +2/+8°C	45 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.validity.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.

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.

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P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal

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

REFERENCES

1. Burtis CA, Ashwood ER, Bruns DE, editors. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. St. Louis , MO, Elsevier Saunders; 2006:2263.
2. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register. July 1, 2001; 17:260–273.
3. Directive 2000/54/EC. Official Journal of the European Communities No. L262 from October 17, 2000.
4. Tietz, N. W. (1983) Clinical guide to Laboratory Tests, p384 W.B. Saunders Co., Philadelphia.



Archem Sağlık Sanayi ve Tic. A.Ş. (With official contract based manufacturing agreement with Validity Sağlık Hiz. Sanayi A.Ş. Company)
 Mahmutbey Mah. Halkalı Cad. No:124 Kat:4
 Bağcılar/İstanbul/Turkey
 Tel: + 90 212 444 08 92
 Fax: +90 212 629 98 89
 info@archem.com.tr www.archem.com.tr
 info@validity.com.tr www.validity.com.tr



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