25-Hydroxyvitamin D (25-OH-VD) Control Set

REF: VT-057	**25-Hydroxyvitamin D (25-OH-VD) Control Set**	**2 x 1 mL**

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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

25-Hydroxyvitamin D (25-OH-VD) Control is for quality control of the 25-Hydroxyvitamin D (25-OH-VD) Liquid assay.

CONTENTS / MATERIALS PROVIDED

25-Hydroxyvitamin D (25-OH-VD) Control Set
REF: VT-057
Package: 2 x 1 mL **Liquid**

For use with:
25-Hydroxyvitamin D (25-OH-VD) Liquid Reagent
25-Hydroxyvitamin D (25-OH-VD) Calibrator

VT-057 does 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.

CONTROL STABILITY

Temperature-Conditions	Stability
Unopened at +2/+8°C	Expiry date on the vial.
Opened and stored at +2/+8°C	30 days

PREPARATION OF CONTROL

Control 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.

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. Burtis CA, Ashwood ER, Bruns DE, editors. Tiets 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.

TRADEMARKS

25-Hydroxyvitamin D (25-OH-VD) Control Set 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
CONTROL	Control
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