

REF: VT-037 D-Dimer Control Set 1 x 1 mL+1 x 1 mL

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 D-Dimer Control Set are for use in the control of the D-Dimer Turbidimetric assay.

Validity D-Dimer Control Set

REF: VT-037

Package: 1x1 mL+ 1x1 mL **Lyophilized**

For use with;

Validity D-Dimer Turbidimetric reagent

REF: MH-162

SUMMARY AND PRINCIPLE

The use of control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices (GLP).

CONTENTS / MATERIALS PROVIDED

Validity D-Dimer Control Set contain human serum. Sodium Azide (0.09 %) is added as a preservative.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Class A volumetric pipette for delivery of 1.0 mL,
2. Distilled or deionized water meeting specifications equivalent to USP purified water
3. Validity D-Dimer Turbidimetric reagent.

PRECAUTIONS (General and Users)

IVD

For *in Vitro* Diagnostic Use.

Do not use components beyond the expiration date.

Contains sodium azide.

EUH032 Contact with acids liberates very toxic gas.

Do not mix materials from different kit lot numbers.

Human source material.

Controls can contain preservatives (as Sodium Azide or others) which total concentration is lower than the limits mentioned in Directive 67/548/ CEE and 88/379 CEE.

Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA-approved method and found nonreactive for



the presence of HBsAg, HCV, HIV-Ag and antibody to HIV 1/2. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, all human-based products should be handled in accordance with good laboratory practices using appropriate precautions. Safety Data Sheets are available at www.validity.com.tr or contact your local representative. Emergency Phone Number: In emergency situation please contact the National Poison Solidarity Center (Turkey) for information in Turkish:(114) (24 hours/7 days). Please contact with Validity for information in English: +(90) 212 444 0 892 (Turkey) (8:30-18:00/ except Sundays)

STORAGE AND STABILITY

1. Unopened Validity D-Dimer Control Set are stable until the expiration date when stored +2/+8 °C.
2. Opened controls are stable 2 days when stored in a dark place +2 to +8°C.
3. Validity D-Dimer Control Set are stable for 30 days when portioned stored at -20 ° C and protected from light. Freeze and thaw only once.
4. Criterion for the stability data specified by Validity: Recovery values are within $\pm 10\%$ of the initial value.

PREPARATION OF CONTROLS

Lyophilized controls should be reconstituted by adding 1.0 mL of distilled or deionized water.

Close the vial and let stand for 30 minutes. Dissolve the contents of the vial by swirling gently to avoid the formation of foam.

Do not mix by vortex. Don't shake.

INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or microbial growth may indicate deterioration.

REFERENCES

1. 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.
2. Directive 2000/54/EC. Official Journal of the European Communities No. L262 from October 17, 2000.



Archem Sağlık Sanayi ve Tic. A.Ş. (With official contract based manufacturing agreement with Validity Sağlık Hiz. San. 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