TECO DIAGNOSTICS
1268 N. Lakeview Ave.
Anaheim, CA 92807
1-800-222-9880

D-Dimer
CONTROL SET

INTENDED USE
Teco D-Dimer Control set are for use in the control of the D-Dimer Turbidimetric assay.

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

Materials Required but not Provided:
1. 1 mL Class A volumetric pipette.
2. Distilled or deionized water meeting the specifications equivalent to USP (United States Pharmacopeial Convention) purified water.
3. Teco D-Dimer Turbidimetric reagent.

PRECAUTIONS
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.
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 nonreactive for the presence of HBsAg, HCV, HIV-Ag and antibodies to HIV 1/2. 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.

STORAGE AND STABILITY
1. Unopened Teco D-Dimer Control Set are stable until the expiration date when stored 2-8 ˚C.
2. Open controls are stable for 2 days when stored in a dark place 2-8°C.
3. Teco D-Dimer Control Set is stable for 30 days when stored at -20 ° C and protected from light. Freeze and thaw only once.
4. Criterion for the stability data specified by Teco: Recovery values are within ± 10% of the initial value.

PREPARATION OF CONTROLS
1. Lyophilized controls should be reconstituted by adding 1.0 mL of distilled or deionized water.
2. Close the vial and let stand for 30 minutes. Dissolve the contents of the vial by swirling gently to avoid the formation of foam.
3. Do not mix by vortex. Do not shake.

INDICATIONS OF INSTABILITY OR DETERIORATION
The presence of extreme turbidity or microbial growth may indicate deterioration.

REFERENCE
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

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Manufactured by:

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