DIAGON
Solutions beyond imagination

INSTRUCTION FOR USE

Dia-CONT Ddi I-II

CONTROL PLASMAS FOR D-DIMER TEST

CE

Cat. No.: 93020 **2 x 10 x 1 ml**
Cat. No.: 93010 **2 x 5 x 1 ml**

PRODUCT NAME

Dia-CONT Ddi I-II control plasmas for D-dimer test.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Dia-CONT I-II two levels control plasmas are intended to control of the following test:

- D-dimer (Ddi).

SUMMARY AND EXPLANATIONS

Dia-CONT Ddi I-II controls are dedicated for internal quality control of D-dimer measuring system. There are instrument and lot specific control ranges in the value sheet for the given reagents.

ACTIVE INGREDIENTS

Dia-CONT Ddi I-II controls are derived from human, anticoagulated, freeze-dried, pooled human plasma from healthy donors with preservative. Furthermore these contain D-dimer antigen from human plasma with enzymatic digestion. Dia-CONT Ddi I-II controls represent two different measuring ranges.

PRECAUTIONS

- Person installing the Dia-CONT Ddi I-II controls must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Dia-CONT Ddi I-II controls, due to its ingredients should be handled with care by observing the precautions recommended for biohazards material!
- Control coming into contact with specimens and other materials should be handled as if capable of transmitting infection and should be disposed of with proper precautions!
- Avoid microbial contamination of the control otherwise erroneous results may occur!
- Each donor unit used in the preparation of this control tested with HBsAg, anti-HIV 1-2, anti-HCV, anti-TP screening tests and found to be non-reactive.
- All controls, waste and utilized disposable laboratory equipment should be considered as hazardous waste! Their handling and disposal should be done according to the valid hazardous material processing regulation.
- Do not use the control beyond the expiration date printed on the label!

PREPARATION

Dia-CONT Ddi I-II controls have to be dissolved with 1ml distilled water. Allow them to stand at room temperature (20-25°C) for at least 30 minutes. The gently horizontal mixing is recommended during the reconstitution. Swirl the vial gently and horizontal again before use, but do not shake!

TEST PROCEDURE

Dia-CONT Ddi I-II controls are to be used as that of patients' plasmas as investigated with D-dimer test.

STORAGE AND STABILITY

Dia-CONT Ddi I-II controls in intact vial is stable until the expiration date given on the vial, when stored at 2-8°C. Stability after opening in the original vial is shown in below table:

T (°C)	20-25	2-8
Hour	8	48

Do not freeze it!

EXPECTED RESULTS

The instrument specific control ranges for each of the parameters may vary from lot to lot. Compare the measured value with the declared one on the value sheet. The obtained results:

- have to be inside of the reference range declared, but the get the exact mean is not obligatory,
- should be considered as a guidance, but every laboratory should determine its own control ranges.

LIMITATIONS

To check the accuracy of the reported result join and perform external quality assurance program in regular intervals.

In case of unexpected control values check all components of the test system are functioning correctly.

MATERIALS REQUIRED BUT NOT PROVIDED

- For controlling of Ddi test:
  - Dia-D-DIMER; Cat. No.: 32120, 32075
- Optical coagulation analyser for measuring, DIAGON analysers (Coag Line) are recommended.

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SYMBOLS			
	Manufacturer		Use-by date
LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged		Fragile, handle with care
	Keep dry		Temperature limit
	Biological risks		Consult instruction for use
	Caution	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <*n*> tests		This side up
CE	CE mark		