

### INSTRUCTION FOR USE

## Dia-IMIDAZOL

#### DILUTION BUFFER FOR COAGULATION TESTS



Cat. No.: 21180

12 x 15 ml

#### PRODUCT NAME

Dia-IMIDAZOL dilution buffer.

#### **INTENDED USE**

#### (For In Vitro Diagnostic Use Only)

Dia-IMIDAZOL is a dilution buffer, intended use for diluting control, calibrator and human sample when performing a laboratory, screening test of prothrombin time (PT), fibrinogen (FIB) or special test of D-dimer (Ddi), factors.

#### **ACTIVE INGREDIENTS**

Dia-IMIDAZOL is a buffered solution with preservative.

#### **PRECAUTIONS**

- Hazardous symbol, category, hazard and precautionary statements by the latest CLP regulation:
  - Renro
    - Reproductive toxicant, Category 1B
  - H360: May damage fertility or the unborn child (state specific effect if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard).
  - P201: Obtain special instructions before use.
  - P202: Do not handle until all safety precautions have been read and understood.
  - P281: Use personal protective equipment as required.
  - P308+P313: IF exposed or concerned: Get medical advice/attention.
  - P405: Store locked up.
- P501: Dispose of contents/container to (according to paragraph 13).
- Person installing the Dia-IMIDAZOL solution must be a trained laboratory professional!
- Reagent 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 reagent otherwise erroneous results may occur!
- All reagents, 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 reagent beyond the expiration date printed on the label!

#### **PREPARATION**

Dia-IMIDAZOL solution is ready for use. Wait until the reagent reaches the working temperature!

#### TEST PROCEDURE

Follow as described in the instruction for use of relevant test or calibrator and in the manual of applied coagulometer to measure the required parameter.

#### STORAGE AND STABILITY

Dia-IMIDAZOL solution 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
Week	2	8

# MATERIALS REQUIRED BUT NOT PROVIDED

- PT:
- O Dia-PT (Cat. No.: 81020; 81025; 81050; 81100)
- o Dia-PT LIQUID (Cat. No.: 82012; 82024; 82048; 82096)
- o Dia-PT R (Cat. No.: 83025; 83050; 83100)
- FIB: Dia-FIB (Cat. No.: 61024; 61060)
- Ddi: Dia-D-DIMER (Cat. No.: 32075; 32120)
- Calibrator:
- o Dia-CAL (Cat. No.: 95012)
- o Dia-CAL Spec (Cat. No.: 09605)
- Different levels of control for quality control:
- o Dia-CONT I-II (Cat. No.: 91010, 91020)
- Dia-CONT Ddi I-II (Cat. No.: 93010, 93020)
- o Dia-CONT Spec N (Cat. No.: 09305)
- o Dia-CONT Spec P (Cat. No.: 09405)
- Optical or mechanical coagulation analyser for measuring, Diagon analysers (Coag Line) are recommended.

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SYMBOLS			
	Manufacturer	X	Use-by date
LOT	Batch code	REF	Catalogue number
<b>(Q)</b>	Do not use if package is damaged	Ţ	Fragile, handle with care
<del>*</del>	Keep dry	, F	Temperature limit
$\triangle$	Caution	(i	Consult instruction for use
Σ	Contains sufficient for < <i>n</i> > tests	IVD	In vitro diagnostic medical device
Œ	CE mark	<u> </u>	This side up