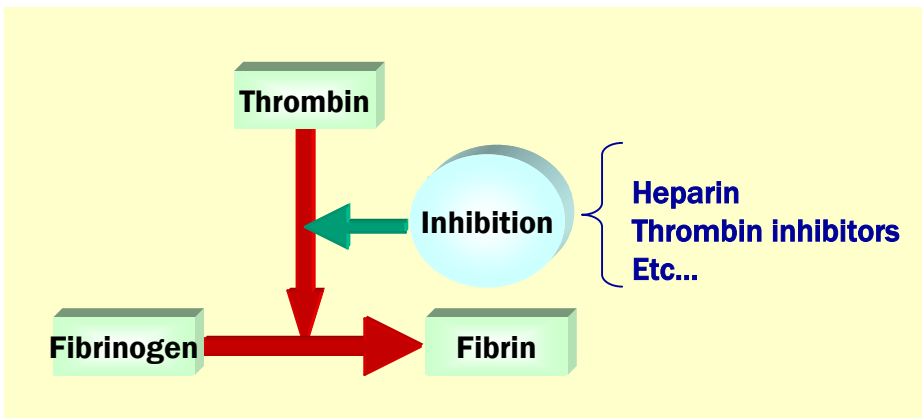




Manufactured By: HYPHEN BioMed

THE REAGENT OF CHOICE FOR ALL YOUR THROMBIN TIME APPLICATIONS

HEMOCLOT Thrombin Time (T.T.) ACK011K / ACK011L



High sensitivity to heparin (UFH, LMWH) and all direct thrombin inhibitors (hirudin and new anti-thrombin drugs)

Clotting assay for the determination of trombin time in human citrated plasma

kit designed with highly purified bovine thrombin, highly stable following reconstitution and highly sensitive to low concentrations of thrombin inhibiting substances

Sep 2006
REF 025

Form AH08
11-2007



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HEMOCLOT Thrombin Time (T.T.)

Assay principle

Hemoclot T.T. is an in vitro clotting assay developed for the determination of the Thrombin Time induced by bovine thrombin (Thrombin Time, T.T.), in presence of calcium, on human citrated plasma, and exploration of the anti-thrombin activities.

Excellent sensitivity to low concentrations of heparin in plasma (from 0.05 to 0.10 IU/ml Unfractionated Heparin (UFH), and from 0.20 IU/ml Low Molecular Weight Heparin (LMWH), in plasma).

Very sensitive to hirudin in plasma from concentration > 20 ng/ml.

Manual, semi-automatic or automatic clotting method .

Assay characteristics

- Assay optimized to offer an excellent sensitivity to low concentrations of Unfractionated Heparin (UFH) (from 0.05 to 0.10 IU/ml in plasma), of Low Molecular Weight Heparin (LMWH) (from 0.20 IU/ml in plasma), and of hirudin (>20 ng/ml).
- Total assay time : 1 min. or below
- Intra assay reproducibility: CV ≤ 2-6 % (for a normal plasma clotting time, using KC10 instrument)
- Inter assay reproducibility: CV ≤ 3-8 % (for a normal plasma clotting time, using KC10 instrument).
- Can be used with: manual, semi-automated or automated methods.

Procedure:

Specimen: citrated human plasma, undiluted

Intended use: IVD

Measurement of the clotting time induced by thrombin, in presence of calcium, on plasma, and exploration of the anti-thrombin activities, especially for evidencing presence of low concentrations of heparin in plasma, and of hirudin (qualitative detection) or other thrombin inhibitors.

Kit presentations

- HEMOCLOT Thrombin Time (T.T.) (Ref. ACK011K) 6x2 ml (6x20 tests using KC10 or manual method)
- HEMOCLOT Thrombin Time (T.T.) (Ref. ACK011L) 6x8 ml (6x80 tests using KC10 or manual method)

Reagent (R1): Bovine thrombin, lyophilised in the presence of calcium, and stabilized.

Performances

- Excellent homogeneity within a same manufacturing lot is ensured, as well as between the successive manufacturing lots.
- Excellent preservation of performances of reconstituted reagents, stored at 2-8°C for 7 days or at RT for 48 hours, compared with those of freshly reconstituted vials.
- Excellent sensitivity to low concentrations of UFH (from 0.05 to 0.10 IU/ml), of LMWH (from 0.20 IU/ml) and of hirudin (> 20 ng/ml), in plasma.

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