NAPTT REAGENT

Synthetic Phospholipid Platelet Substitute

Ref. 5D-51426

5-DIAGNOSTICS
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For Research Only. Not for Use in Diagnostic Procedures.
For *in vitro* use only

Intended Use:

NAPTT Reagent is a synthetic phospholipid platelet substitute intended for use with the European Pharmacopeia (EP) method for the detection of activated coagulation factors in therapeutic products[1]. Also, **NAPTT Reagent** can be used in non-activated partial thromboplastin time (NaPTT) testing for the study of contact activation and hypercoagulability[2] in human plasma samples.

Contents:

NAPTT Reagent, 10 mL **5 vials**
Contains proprietary synthetic phospholipid blend and sodium azide (<0.02%) as preservative. Ready to use, pale blue solution.

Stability after opening: 2 weeks at 2-8°C.

Storage:

Unopened reagents must be stored at **2-8°C** in original packaging box. They are then stable until the expiration date printed on the box.

Reagents Required But Not Provided:

- EP Buffer: 0.09 M NaCl, 0.06 M Tris, pH 7.5.
- PNP: Platelet-Poor Pooled Normal Plasma (5D-40401A, 10x2 mL and 5D-40401B, 8x5 mL).
- Controls, NAPPT Control-1 with 10 mIU FIXa (5D-44206A) and NAPTT Control-2. 20 mIU FIXa (5D-44206B).
- M/40 Calcium Chloride: 0.025 M $CaCl_2 \cdot 2H_2O$.

Samples:

Therapeutic compounds should be diluted in EP Buffer. Plasma samples should be prepared from 3.2% citrate anticoagulated blood by centrifugation for 10 min. at 2000g according to CLSI guidelines[3].

EP Method for Therapeutic Products:

Prepare 1:10 and 1:100 dilutions of the preparation to be tested in EP buffer (0.09 M NaCl, 0.06 M Tris, pH 7.5). Pre-warm samples and carry out tests in 37°C water bath. Tests should be carried out either by tilt-tube technique in polystyrene tubes or in any clot-testing instrument using plastic or non-contact activating surfaces. Mix 0.1 mL of **NAPTT Reagent** with 0.1 mL of platelet-poor plasma (PNP) prepared from pooled normal plasma and pre-warm for 1 minute at 37°C. Add 0.1 mL of the pre-warmed sample, then add 0.1 mL M/40 calcium chloride (0.025 M) and time to a clotting endpoint.

For results to be considered valid, a control test using buffer as blank sample must be between 200-350 seconds. Duplicate tests are advised.

NaPTT Method for Plasma:

For detecting activated clotting factors in plasma, use **NAPTT Reagent** in place of an aPTT reagent. For example, mix 0.1 mL of test sample with 0.1 mL **NAPTT Reagent** at 37°C, then add 0.1 mL pre-warmed M/40 calcium chloride and time to a clotting endpoint at 37°C. (No pre-incubation is required unless the user wishes to study the kinetics of factor activation or inactivation).

A normal NaPTT result is usually 200-350 seconds but is shortened by contact activation, tissue factor and other enzyme procoagulants. If results are short the nature of any unknown procoagulant can be probed using specific inhibitors or antibodies.

The results obtained should be for research use only and not for patient diagnosis or treatment.

Cautions:

- Avoid unintentional contact activation of samples from glass or other negatively charges surfaces by using inert plastic materials throughout.
- Results may vary across different instruments and methods depending on exposure of samples to surface contact.
- Contact activation products and other enzyme procoagulants may gradually disappear from samples in a time and temperature-dependent manner.

Note: NaPTT test results are typically quite prolonged compared with regular clotting tests and may be quite variable (+/- 10%) due to exogenous variables such as surface contamination.

References:

1. European Pharmacopeia 8.0: 2.6.22. Activated Coagulation Factors.
2. Langdell RD, Wagner RH, Brinkhouse KM. J Lab Clin Med. 1953; 41; 637-647.
3. CLSI guidelines on collection, transport and processing of blood specimens. 2008; H21-A5.

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