

5 5-DIAGNOSTICS

HEPA-Remove®

Lyophilized Powder, 1 mg

REF 5D-68179-RUO

RUO FOR IN VITRO USE ONLY. FOR RESEARCH USE ONLY.
NOT FOR USE IN DIAGNOSTIC PROCEDURES.

Store at 2–8 °C

Synthetic peptide for neutralization of Heparin or Heparinlike activity in laboratory samples

DESCRIPTION

HEPA-Remove®, 1 mg, Lyophilized Powder is a synthetic peptide designed to inhibit heparin and heparinlike activity.

MOLECULAR WEIGHT

3.12 kDa

COMPOSITION

Lyophilized Powder

SOLUBILITY

≥ 1mg/mL in distilled water.

INTENDED USE

Given its molecular properties, heparin or heparinlike molecules are known to interfere with many assays including coagulation assays and PCR-based assay. HEPA-Remove® is intended to be used to selectively complex heparins and thereby inhibit the heparin associated assay interference.

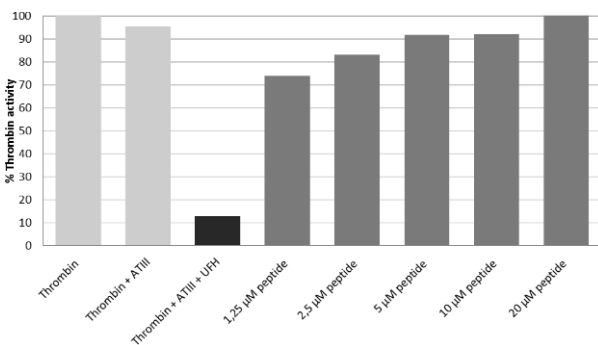


Figure 1: Effect of HEPA-Remove® on thrombin activity.

Thrombin (1.5 nM) is inhibited by addition of 120 nM AT and 0.5 IU/mL UFH, which is restored to 90% and 100% through addition of 5 and 20 µM of the HEPA-Remove® peptide respectively.

INHIBITORY CAPACITY

One vial contains 1 mg or 0.320 mmole and has the capacity to inhibit 4 IU anti-Xa activity of heparin or heparin-like molecules.

Alternatively, the content of a vial can be expressed as 4 Heparin Neutralizing Units (HNU).

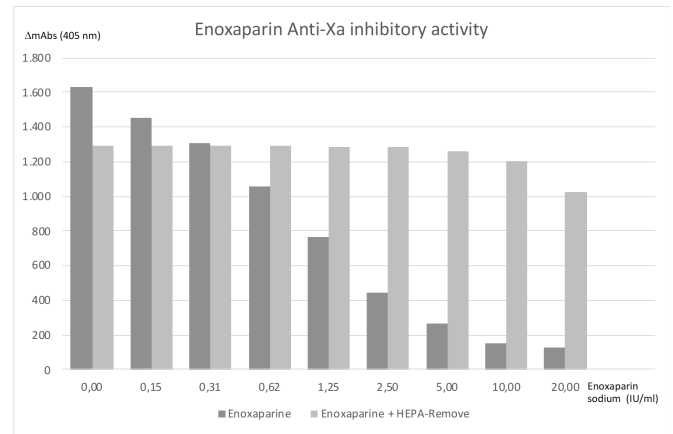


Figure 2: Effect of HEPA-Remove® on anti-Xa activity of Low Molecular weight Heparin.

Normal Pooled Plasma spiked with Enoxaparin sodium at different concentrations was tested with a chromogenic Anti-Xa assay in presence and absence of HEPA-Remove®

INHIBITION OF FXII ACTIVATION

HEPA-Remove® has been found to inhibit FXII activation in aPTT based assays.

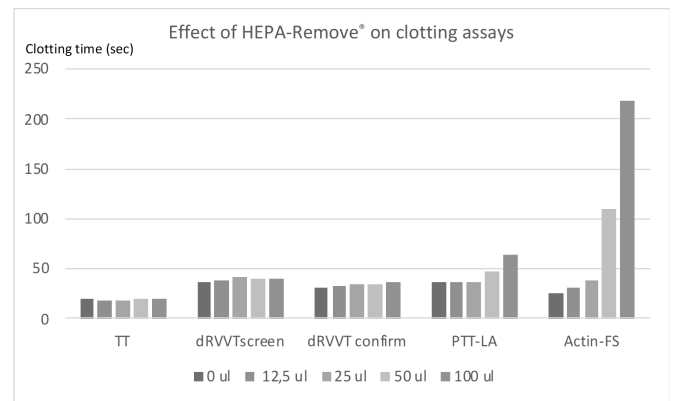


Figure 3: Effect of HEPA-Remove® on coagulation assays.

Different volumes of HEPA-Remove® (320 µM) were added to normal pooled plasma and analyzed in routine CaCl₂ triggered clotting assays.

If full FXII activation is required for the correct interpretation of the results, HEPA-Remove® can be added to the assay after the FXII activation, for example in combination with the CaCl₂ reagent in clotting assays.

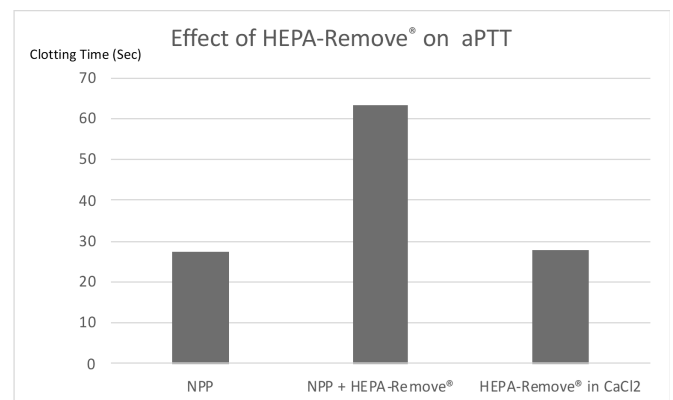


Figure 4: Effect of HEPA-Remove® on aPTT assays.

HEPA-Remove® added to Normal Pooled Plasma (NPP) prolongs the aPTT (Actin FS) due to its inhibitory activity on FXII activation. When added after full activation of FXII, together with the CaCl₂, the clotting times are not influenced.

REAGENT PREPARATION

Gently remove the freeze-drying stopper to avoid loss of product when opening the vial.

1. For CaCl₂ triggered assays

The vial contains 1 mg of reagent and can be restored with 1 mL CaCl₂ (0.025M) to obtain a stock solution of about 1 mg/mL or 4 HNU/mL.

Dilute further in CaCl₂ (0.025M) to the desired final concentration based on the Heparin Neutralizing capacity needed.

Use this CaCl₂ with HEPA-Remove® solution to activate your assay.

This application is mandatory for aPTT based assays where incomplete activation of FXII may lead to false results.

2. For other assays

The vial contains 1 mg and can be restored with 1 mL distilled water or assay buffer to obtain a stock solution at about 1 mg/mL or 4 HNU/mL. Dilute further in distilled water or buffer to the desired concentration to inhibit the expected heparin concentration in the sample.

EXAMPLE

For a chromogenic assay with a sample volume of 100 µL of a 1:10 plasma dilution in buffer and an expected max concentration of heparin of 2 IU/mL:

- the plasma (10 µL) contains max 0.02 IU of Heparin
- 90 µL buffer should contain 0.02 HNU of HEPA-Remove® to counter the heparin concentration.
- Reconstitute a vial of 4 HNU HEPA-Remove® with 20 mL of assay buffer

STORAGE AND STABILITY

Lyophilized HEPA-Remove®:

Stable at 2-8°C up to the expiration date printed on the label;

Reagent stability after reconstitution, free from any contamination or evaporation:

- 8 hours at room temperature (18-25°C).
- 1 week in the refrigerator at 2-8°C.
- 6 months frozen at -20°C or less. Thaw as quickly as possible at 37°C and use immediately. Avoid repeated freeze-thaw cycles.

HEPA-Remove®:

Contamination by microorganisms must be avoided.

NOTE: HEPA-Remove® contains no preservatives; after reconstitution it must be used rapidly or stored frozen. Alternatively, a preservative (for example sodium azide at 0.9 mg/mL) can be added.

WARNINGS AND PRECAUTIONS

For Laboratory Use Only. Not for use in human or direct animal applications. Not for use in diagnostic procedures.











Waste should be disposed in accordance with local regulations.

REFERENCES

1. Unpublished data.

SYMBOL DEFINITION

Symbols used and signs listed in the ISO 15223-1 standard.

	CE Mark / CE-Kennzeichnung / Marquage CE		Temperature limitation / Temperaturbegrenzung / Temperatures limites de
	In-vitro diagnostic medical device / In-vitro Diagnostikum		See instructions for use / Gebrauchsanweisung beachten / Lire le mode d'emploi
	Catalog number / Bestellnummer / Référence catalogue		Contains sufficient for <n> tests / Genügend für <n> Tests / Suffisant pour <n> tests
	Batch code / Chargenbezeichnung / Désignation du lot		Manufacturer / Hersteller / Fabricant
	Use by / Verwendbar bis / Utilisable jusqu'à		For research use only / Nur für Forschungszwecke / usage de recherche uniquement



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