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|-------------------------------|----------------|-----------------------------|-----|
| REF | 5090072 | Technoview UFH CON L | ENG |
| REF | 5090074 | Technoview UFH CON H | |
| 3015207RUO Rev.001 29/06/2021 | | | RUO |

Technoview UFH Controls - English

INTENDED USE

Technoview UFH (Unfractionated Heparin) CON L and CON H are plasmas with different concentrations of UFH (low and high) to be used for quality control measurements of UFH. They are optimized using Technochrom anti-Xa assay.

SUMMARY

Heparin is the most frequently used antithrombotic therapeutic drug. The biological activity of this sulfated glycosaminoglycan resides in its ability to accelerate (up to 2000-fold) the inhibitory effect of antithrombin (AT) on the coagulation proteases.

REAGENTS

The REF 5090072 Technoview UFH CON L contains:

| Reagent | Description |
|----------------|--|
| 5 x 1 mL CON L | Human plasma, lyophilized, ~0.20 IU/mL UFH |

Please consult the lot specific batch table provided with the controls for the exact concentrations in IU/mL of each control.

The REF 5090074 Technoview UFH CON H contains:

| Reagent | Description |
|----------------|--|
| 5 x 1 mL CON H | Human plasma, lyophilized, ~0.50 IU/mL UFH |

Please consult the lot specific batch table provided with the controls for the exact concentrations in IU/mL of each control.

Material required (not supplied with the kit)

- Distilled water
- Precision pipettes (1000 µL)
- Laboratory timer
- REF 5340250 Technochrom anti-Xa
- REF 5090070 Technoview UFH CAL

Warning and precautions

- RUO for research use only.
- This kit is intended for use by personnel trained in laboratory procedures and universal precautions for the use of chemicals and potentially biohazardous substances must be applied.
- All human blood or plasma products as well as test samples must be considered as potentially infectious. They have to be handled with appropriate care and in strict observance of safety regulations. The rules pertaining to disposal are the same as applied to disposing hospital waste.
- Calibrators and control plasmas are made from human blood and any individual plasma involved in the procedure is tested HbsAg, HIV 1/2 Ab and HCV-Ab-negative. However, all human blood products should be handled as potentially infectious material.
- Get a Material Safety Data Sheet for this product from www.technoclone.com.

Stability and storage

The expiry date printed on the labels is only applicable to storage of the unopened containers at 2...8 °C.

Stability opened/ in use:

| Reagent | 18...25 °C (open vial) | 2...8 °C (closed vial) | -20 °C |
|----------------------|------------------------|------------------------|---------|
| Technoview UFH CON L | 48 hours | 7 days | 1 month |
| Technoview UFH CON H | 48 hours | 7 days | 1 month |

Control material can only be frozen once, in its original vial.

TEST PROCEDURE

Preparation of controls

Before starting the test, all the required components are to be brought to room temperature.

When reconstituting plasmas, mixing reagents or buffers avoid foaming.

- *Technoview UFH CON L*: Reconstitute each control vial with 1.0 mL of distilled water. Allow the reconstituted material to stand at room temperature for 30 minutes followed by swirling of the vial before use.
- *Technoview UFH CON H*: Reconstitute each control vial with 1.0 mL of distilled water. Allow the reconstituted material to stand at room temperature for 30 minutes followed by swirling of the vial before use.

Performance of the test

The Technoview UFH CAL is always used in combination with the Technoview UFH CON L, and Technoview UFH CON H and the Technochrom anti-Xa kit.

The UFH concentration of the controls may vary from one lot to another but is clearly indicated in the lot specific batch table provided in the control box.

Technoclone provides instrument specific application sheets, which contain analyser / assay specific handling and performance information.

STANDARDISATION

The Technoview UFH controls are directly traceable to an internal reference standard.

LITERATURE

Please contact Technoclone www.technoclone.com or your local distributor.

EDITORIAL NOTE

This document is available in several languages. The translations have been done using the master document in English. In the event of doubts or discrepancies, the wording in the master document in English shall take precedence.



Consult instructions for use



Global Trade Item Number



Biological risk



Control

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Manufacturer



Lot



Storage temperature



Research Use Only



Expiry date



Catalogue number