

REF	5090042	Technoview LMWH CON L	ENG
REF	5090044	Technoview LMWH CON M	
REF	5090046	Technoview LMWH CON H	
3015210RUO Rev.001 29/06/2021			RUO

Technoview LMWH Controls - English

INTENDED USE

Technoview LMWH (Low Molecular weight Heparin) CON L, CON M and CON H are plasmas with different concentrations of LMWH (low, medium and high) to be used for quality control measurements of LMWH. 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** 5090042 Technoview LMWH CON L contains:

	Reagent	Description
5 x 1 mL	CON L	Human plasma, lyophilized, ~0.35 IU/mL LMWH

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

The **REF** 5090044 Technoview LMWH CON M contains:

	Reagent	Description
5 x 1 mL	CON M	Human plasma, lyophilized, ~0.70 IU/mL LMWH

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

The **REF** 5090046 Technoview LMWH CON H contains:

	Reagent	Description
5 x 1 mL	CON H	Human plasma, lyophilized, ~1.10 IU/mL LMWH

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** 5090040 Technoview LMWH 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 LMWH CON L	48 hours	7 days	1 month
Technoview LMWH CON M	48 hours	7 days	1 month
Technoview LMWH 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 LMWH 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 LMWH CON M*: 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 LMWH 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 LMWH CAL is always used in combination with the Technoview LMWH CON L, Technoview CON M and Technoview LMWH CON H and the Technochrom anti-Xa kit.

The LMWH 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 LMWH 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.



Manufacturer



Storage temperature



Expiry date



Consult instructions for use



Biological risk

LOT

Lot

RUO

Research Use Only

REF

Catalogue number

GTIN

Global Trade Item Number

CONT

Control

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