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Technoview Argatroban CAL - English

INTENDED USE

Technoview Argatroban CAL is a set of 5 calibration plasmas to be used for calibration of Argatroban measurements,

SUMMARY

Argatroban (Argatra, Arganova, Exembol, Novastan) is a parenteral anticoagulant, acting as direct thrombin inhibitor. REAGENTS

The Technoview Argatroban CAL contains:

	Reagent	Description
1 x 1 mL	Technoview Argatroban CAL 1	Calibrator 1, human plasma, lyophilized, no Argatroban
1 x 1 mL	Technoview Argatroban CAL 2	Calibrator 2, human plasma, lyophilized, ~0.50 μg/mL Argatroban
1 x 1 mL	Technoview Argatroban CAL 3	Calibrator 3, human plasma, lyophilized, ~1.0 µg/mL Argatroban
1 x 1 mL	Technoview Argatroban CAL 4	Calibrator 4, human plasma, lyophilized, ~1.5 µg/mL Argatroban
1 x 1 mL	Technoview Argatroban CAL 5	Calibrator 5, human plasma, lyophilized, ~2.0 µg/mL Argatroban

Please consult the lot specific batch table provided with the calibrators for the exact concentrations in µg/mL of each

Material required (not supplied with the kit)

- Distilled water Precision pipettes (1000 µL)

- Laboratory timer
 REF 5100025 Technoclot DTI
 REF 5090142 Technoview Argatroban CON L
 REF 5090144 Technoview Argatroban CON H

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 $^{\circ}$ C.

Stability opened / in use:

Reagent	1825 °C
Technoview Argatroban CAL 1	4 hours
Technoview Argatroban CAL 2	4 hours
Technoview Argatroban CAL 3	4 hours
Technoview Argatroban CAL 4	4 hours
Technoview Argatroban CAL 5	4 hours

TEST PROCEDURE

Preparation of calibrators

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 Argatroban CAL 1 - CAL 5: Reconstitute each calibrator 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 Argatroban Calibrator Set is always used in combination with the Technoview Argatroban CON L, Technoview Argatroban CON H and the Technoclot DTI kit.

The Argatroban concentrations of calibrators 1 - 5 may vary from one lot to another but are clearly indicated in the lot specific batch table provided in the calibration set.

Calibrator 1, calibrator 2, calibrator 3, calibrator 4 and calibrator 5 are used to establish a calibration curve. Results below the lower limit of quantification (instrument specific) should be declared as <LLoQ. Samples found with a concentration above calibrator 5 should be re-tested in an appropriate dilution.

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

STANDARDISATION

The Technoview Argatroban CAL is directly traceable to an internal reference standard, prepared from Argatroban

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









REF Catalogue number



Consult instructions for use

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GTIN Global Trade Item Number





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