

REF 5090140 TECHNOVIEW® Argatroban CAL Set 5x1mL

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For research use only**TECHNOVIEW® Argatroban CAL Set 5x1mL- English****INTENDED USE**

TECHNOVIEW® Argatroban CAL Set is a set of 5 calibration plasmas to be used for calibration of argatroban measurements, optimized using TECHNOCLOT® DTI assay.

SUMMARY

Argatroban (Argatra®, Arganova®, Novastan®) is an oral anticoagulant drug which acts as a direct thrombin inhibitor.

REAGENTS

The TECHNOVIEW® Argatroban CAL Set 5x1 mL contains:

mL	Reagent	Description
1 x 1	TECHNOVIEW® Argatroban CAL 1	Calibrator 1, human plasma, lyophilized, no argatroban
1 x 1	TECHNOVIEW® Argatroban CAL 2	Calibrator 2, human plasma, lyophilized, -0.50 µg/mL argatroban
1 x 1	TECHNOVIEW® Argatroban CAL 3	Calibrator 3, human plasma, lyophilized, -1.0 µg/mL argatroban
1 x 1	TECHNOVIEW® Argatroban CAL 4	Calibrator 4, human plasma, lyophilized, -1.5 µg/mL argatroban
1 x 1	TECHNOVIEW® Argatroban CAL 5	Calibrator 5, human plasma, lyophilized, -2.0 µg/mL argatroban

Please consult the batch table provided with the calibrator set for the exact concentrations in µg/mL of each calibrator.

Material required (not supplied with the kit)

- Pipettes
- Distilled water

REF 5100025 TECHNOCLOT® DTI Kit 2 x 20.T

REF 5090142 TECHNOVIEW® Argatroban CONT L 5x1 mL

REF 5090144 TECHNOVIEW® Argatroban CONT H 5x1 mL

Warning and precautions

For research use only.

Every single donor plasma and every lot of the calibrators included is tested and found negative for HbSAg, HIV 1/2 antibodies and HCV antibodies. However, general precautions should be taken by handling all human source materials as potentially infectious.

All blood and plasma samples and products have to be regarded as potentially infectious and handled with appropriate care and in compliance with the biosafety regulations in force. Dispose the same way as hospital waste.

A material safety data sheet for this product is available 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 after reconstitution:

Reagent	18...25 °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 reagents**

Vials with lyophilized calibrators and distilled water used for reconstitution need to reach room temperature (18...25 °C) before reconstitution. Reconstitute each vial (calibrator 1-5) with 1 mL of distilled water. Allow the reconstituted material to stand at room temperature for 30 minutes followed by swirling of the vial before use. Avoid foaming.

Performance of the test

The TECHNOVIEW® Argatroban Calibrator Set is always used in combination with the TECHNOVIEW® Argatroban CONT L and TECHNOVIEW® Argatroban CONT H and the TECHNOCLOT® DTI kit.

The argatroban concentration of calibrator 1-5 may vary from one lot to another but is 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 limit of quantification (instrument specific) should be declared as <LoQ. 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 Set is directly traceable to an internal reference standard, prepared from argatroban diluted in a normal human plasma pool.

LITERATURE

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

*Argatra®, Arganova® and Novastan® are registered trademarks of Mitsubishi Pharma.



Manufacturer

RUO

For research use only



Storage temperature

LOT

Lot



Expiry date

REF

Catalogue number



Consult instructions for use

GTIN

Global Trade Item Number



Biological risk

CAL

Calibrator



Control