

3015060RUO Rev.002 27/05/2020



TECHNOVIEW Argatroban CONT L

TECHNOVIEW Argatroban CONT H - English

INTENDED USE

TECHNOVIEW Argatroban CONT L and TECHNOVIEW Argatroban CONT H are plasmas with different concentrations (low and high) of Argatroban to be used for quality control of argatroban measurements, optimized using TECHNOCLOT DTI assay.

SUMMARY

 $Argatroban \ (Argatra^0, \ Arganova^0, \ Exembol^0, \ Novastan^0) \ is \ a \ parenteral \ anticoagulant, \ acting \ as \ direct \ thrombin inhibitor.$

The REF 5090142 TECHNOVIEW Argatroban CONT L 5 x 1 mL contains:

	Reagent / Content	Description
5 x 1 mL	TECHNOVIEW Argatroban CONT L	Control low, human plasma, lyophilized, ~0.70 μg/mL Argatroban

The REF 5090144 TECHNOVIEW Argatroban CONT H 5 x 1 mL contains:

	Reagent / Content	Description
5 x 1 mL	TECHNOVIEW Argatroban CONT H	Control high, human plasma, lyophilized, ~1.20 µg/mL Argatroban

Please consult the lot specific batch table provided with the controls for the reference range in µg/mL of each control lot.

Material required (not supplied with the kit)

- Distilled water
- Precision pipettes (1000 µL)

- REF 5090140 TECHNOVIEW Argatroban CAL Set 5 x 1mL

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 HbsAg, HIV 1/2 Ab and HCV-Ab-negative as tested by FDA approved or CE marked methods. 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 $^{\circ}\text{C}.$

Stability opened/ in use:

Reagent	1825 °C	28 °C	< -20 °C
TECHNOVIEW Argatroban CONT L	8 hours	6 days	2 weeks
TECHNOVIEW Argatroban CONT H	8 hours	6 days	2 weeks

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 Argatroban CONT 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 Argatroban CONT 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 Argatroban CONT L and TECHNOVIEW Argatroban CONT H are always used in combination with the TECHNOVIEW Argatroban CAL Set and the TECHNOCLOT DTI kit.

The Argatroban 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

STANDARDISATION

The TECHNOVIEW Argatroban CONT L and TECHNOVIEW Argatroban CONT H are directly traceable to an internal reference standard, prepared from argatroban diluted in a normal human plasma pool

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.

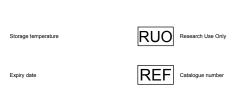








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GTIN Global Trade Item Number

CONT Control

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