REF **5011050 Coagulation Control AK 5 x 1 mL** **ENG**

REF **5011060 Coagulation Control AK 50 x 1 mL**

3015280RUO Rev.013 04/04/2022 RUO

Coagulation Control AK - English

INTENDED USE

Coagulation Control AK can be used for

- Accuracy control of prothrombin time determination in the therapeutic range of oral anticoagulant therapy.
  - in INR
  - in % of normal
- Precision control of prothrombin time in the therapeutic range of oral anticoagulant therapy.
  - in INR
  - in % of normal

SUMMARY

Coagulation Control AK is prepared from plasma of patients stabilized on long-term oral anticoagulant therapy. Therefore the factors of the prothrombin complex (II, VII, IX and X) have the same coagulation activity as plasma from patients on oral anticoagulant therapy. The PIVKA inhibitors (Proteins induced by Vitamin K Absence) are present in Coagulation Control AK as they are in patient's plasma. Coagulation Control AK contains stabilizers but no bactericide additives.

REAGENTS

The REF 5011050 Coagulation Control AK contains:

	Reagent / Content	Description
5 x 1 mL	Coagulation Control AK	Human plasma, lyophilized

The REF 5011060 Coagulation Control AK contains:

	Reagent / Content	Description
50 x 1 mL	Coagulation Control AK	Human plasma, lyophilized

Material required (not supplied with the kit)

- Distilled water
- Precision pipettes
- Laboratory timer

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.
- All human blood or plasma products as well as 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 are 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	2…8 °C	< -20 °C
Coagulation Control AK	4 hours	8 hours	1 month

The vials can be only frozen once.

Upon storage, caps should be screwed tightly.

TEST PROCEDURE

Preparation of Coagulation Control AK

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

When reconstituting plasmas, mixing reagents or buffers avoid foaming.

- *Coagulation Control AK:* Reconstitute each control vial with 1.0 mL of distilled water. Allow the reconstituted material to stand at room temperature for 10 minutes followed by swirling of the vial before use.

  For standardization a reconstitution time of 30 minutes is recommended.

Treat the reconstituted plasma as a citrated sample according to the instructions of the respective test.

LIMITATION OF THE TEST

The figures in the table are only applicable to the indicated lot number of Coagulation Control AK and the method has to adhere strictly as prescribed for the respective reagent.

The guidelines for evaluation given in this leaflet have been established assuming that a constant sensitivity of different batches is guaranteed by the manufactures of each reagent.

INTERPRETATION OF RESULTS

The figures in the table are only applicable to the indicated lot number of Coagulation Control AK and the method has to adhere strictly as prescribed for the respective reagent.

STANDARDISATION

The reported values were determined over multiple runs using a specific lot of reagent and against an Internal Reference Standard which is traceable to the current International Standards, identified in the acceptance range table.

For the tests where International Standards are not available, these parameters have been assigned against an Internal Reference Standard which is traceable to a frozen normal plasma pool of 100 donors.

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.


Expiry date

REF Catalogue number


Consult instructions for

GTIN Global Trade Item Number


Biological risk

Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH, Brunner Str. 67 - 1230 Vienna, Austria


Manufacturer

LOT lot


Storage temperature

RUO Research Use Only