

REF	5220110	Coagulation Reference 5 x 1 mL	ENG
REF	5220120	Coagulation Reference 50 x 1 mL	
3015265RUO Rev.013 27/12/2021			RUO

Coagulation Reference - English

INTENDED USE

Calibration plasma for all screening tests and coagulation factors.

Coagulation Reference can be used for:

- Establishing calibration curves for screening tests.
- Establishing calibration curves for all coagulation factors given in the table.
- Accuracy control for all screening tests, i.e. prothrombin time (PT), partial thromboplastin time (aPTT), thrombin time (TT) and determination of fibrinogen (Clauss) within the normal range.
- Precision control of all parameters listed in the table.

SUMMARY

Coagulation Reference is prepared from selected citrated plasma donations of healthy donors. The clotting activity is normally distributed. Thereby the "average" presence of all coagulation factors and inhibitors is secured. Coagulation Reference contains stabilizers but no bactericide additives.

REAGENTS

The **REF** 5220110 Coagulation Reference contains:

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

The **REF** 5220120 Coagulation Reference contains:

	Reagent / Content	Description
50 x 1 mL	Coagulation Reference	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
Coagulation Reference	2 hours

TEST PROCEDURE

Preparation of Coagulation Reference

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 Reference:** Reconstitute each calibrator 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.

Freezing of the reconstituted reagent is not recommended due to possible loss of activity.

LIMITATION OF THE TEST

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

STANDARDISATION

The expected values in the batch table are determined according to the manufacturers instructions. Calibration according to WHO by Technoclone.

The Coagulation Reference is calibrated against the respective WHO International Standard or an internal house standard, where no international standard is available. Consult the batch table.

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.



Consult instructions for use



Global Trade Item Number



Biological risk

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



Manufacturer



lot



Storage temperature



Research Use Only



Expiry date



Catalogue number