Coagulation Control N

For research use only

GB

REF	5020040	Coagulation Control N	5 x 1 mL
REF	5020050	Coagulation Control N	50 x 1 mL

Symbols key			
	Manufacturer		Expiry date
	Storage temperature		Consult instructions for use
RUO	For resarch use only		Determinations
AQUA	Distilled water	LOT	Lot
BUF	Reaction buffer / Reaktionspuffer	MTP	Microtiter plate
CAL	Calibrator	REF	Catalogue number
CONJ	Conjugate	RTU	Ready to use
CONT	Control	STOP	Stop solution
DIL	Dilute or dissolve	SUB	Substrate
INC	Incubation buffer	WASH	Washing solution concentrate

Technoclone Herstellung von
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Coagulation Control N

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PRODUCT DESCRIPTION

INTENDEND USE

For use as accuracy control of screening tests (PT/aPTT/TT/Fibrinogen) and determination of various coagulation factors within normal coagulation activity.

Precision control, i.e. the recording of the day to day variation, is an important procedure in coagulation testing; checking the accuracy of the test system is particularly important.

Coagulation Control N can be used for:

- Accuracy control of all screening tests, i.e. prothrombin time (PT), partial thromboplastin time (aPTT), thrombin time (TT), fibrinogen determination (Clauss), and of various coagulation factors in the normal coagulation activity.
- Precision control of all parameters listed in the table.

COMPOSITION

Coagulation Control N 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 Control N contains stabilizers but no bactericide additives.

MATERIAL REQUIRED (not supplied with the kit)

- Pipettes
- Distilled water

WARNING AND PRECAUTIONS

- RUO for *research* use only
- 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 and must be disposed of in the same way as hospital waste.
- Each single donor plasma and each lot of Coagulation Control N are tested and found negative for Hb_SAg, HIV 1/2 Ab and HCV Ab. However, universal precautions (treating all human source materials as if potentially infectious) should be exercised.

STABILITY AND STORAGE

The expiry date printed on the labels applies to storage of the unopened bottles at +2…8 °C.

Stability after reconstitution:

RT*	+2…8 °C	-20 °C
4 hours	8 hours	1 month

The vials can be only frozen once.

Upon storage, caps should be screwed tightly.

*=room temperature [1]

TEST PROCEDURE

PREPARATION AND PERFORMANCE OF THE TEST

- Open the vial carefully and reconstitute the contents in 1 mL of distilled water by carefully rotating the vial until the product is completely reconstituted (avoid frothing).
- Allow the reconstituted Coagulation Control N to stand for 10 minutes at room temperature before use [2]. Invert to mix before use (avoid foaming).
- Treat the reconstituted plasma as a citrated sample according to the instructions of the respective test.

ANALYSES RESULTS

EVALUATION OF THE RESULTS

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

STANDARDIZATION AND TRACEABILITY

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.

LIMITATION OF THE TEST

The figures in the table are only applicable to the indicated lot number of Coagulation Control N 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.

LITERATURE

Please contact Technoclone or your local distributor.

[1] Use the reconstituted plasma in single factor determinations within 2 hours stored at room temperature.
[2] For standardization a reconstitution time of 30 minutes is recommended.