Instructions for Use

ROTROL N

ROTEM

Tem Innovations GmbH

tem®

Intended Use:

For In Vitro Diagnostic Use only

ROTROL N is a quality control material for monitoring accuracy and precision of tests carried out on the ROTEM® *delta* Thromboelastometry System. For *in vitro* diagnostic use only.

Reagents:

Product Name: ROTROL N
Reference Number: REF 503-24-US
Package size:
5 x 1 vial ROTROL N Lyo
5 x 1 vial ROTROL N Dil (1300 µl) REF 503-23-US
After reconstitution, each vial is sufficient for 4 assays. REF800283-US

Constituents:
ROTROL N control plasma (lyophilized) was made from human plasma collected using sodium citrate as an anticoagulant (3.2%). The plasma was adjusted to yield coagulation values in the ROTEM® approximating the normal range of whole blood (Level 1 control). Stabilizers and buffers were added prior the lyophilisation.

Preparation of the ready-to-use control:
Let the ROTROL N Dil and Lyo vials reach room temperature. Dissolve the contents of the ROTROL N Lyo vial by pouring the contents of the ROTROL N Dil vial into the lyophilisate. A small drop of the diluent remains in the vial. Do not attempt to transfer the diluent with a pipette! Do not use any other diluent than the one supplied. Close the vial with the rubber cap and the screw cap and swirl gently. Take care that the powder is completely dissolved. Then let stand for 10 - 15 minutes in the closed container, to allow the plasma to reconstitute. Before use, bring to 37 °C on the temperature controlled work area for 5 minutes and carefully mix again by swirling gently.

Storage and Stability:
Store at +2 to +8°C (35.6 - 46.4 °F). The unopened ROTROL N reagent is stable until the expiry date indicated on the label.

Stability after Initial Use:
Reconstituted ROTROL N is stable for 8 hours at 2 – 8 °C (35.6 - 46.4 °F). Avoid contamination and always close the vials again (rubber and screw cap) after each use.
Freezing and thawing of ROTROL N is not recommended.

Additional Material:
ROTEM® device; Cup & Pin (measurement cells; REF 200011); pipette tips (REF 400040 / REF 400041), in-tem® reagent (REF 503-02-US) for intrinsic activated thromboelastometry, ex-tem® reagent (REF 503-05-US) for extrinsic activated thromboelastometry, and star-tem® reagent (REF 503-10-US) for recalcification. The reagents are used in accordance with the instructions in the respective package insert.

Method:

Analytical Principle:
The use of controls is a valuable tool to ensure the quality of the coagulation tests. The package insert of ROTROL N shows batch-specific target ranges. The material can therefore not only be used to monitor precision but also the accuracy of the system (device, reagents, user) (2, 3).

Limitation of the Procedure:
All controls are subjected to the limitation of the test system. Variables such as temperature, reagent stability, instrument properties and individual techniques may affect the final result. Always strictly follow the manufacturer's guidelines for the device and reagents.

Target ranges:
Each batch of ROTROL N is supplied with a batch-specific quality certificate with a table of target ranges for the individual tests. When using ROTROL N and the Tem Innovations system reagents, the results for the specified tests should be within these ranges. If other reagents are used, reagent-specific target ranges must be generated by the user.

Measurement Calculation:
The ROTEM® device calculates numerous parameters. These parameters and their mathematical background can be found in the ROTEM® operating manual. The quality certificate for ROTROL N only gives target ranges for the important primary parameters. Most of the other parameters are derived parameters which are derived by conversion from the primary parameters.

Warnings:

Precautions: For In Vitro Diagnostic Use only

Each donor unit used in the preparation of ROTROL N has been tested for antibodies against HIV Type 1 and 2, Hepatitis C-Virus antibodies, Treponema pallidum antibodies as well as Hepatitis B surface-antigen and Hepatitis C genome by PCR. The tests used are all CE certified tests according to list A of the European Directive for IVDs (98/79/EC) and are under supervision by the responsible European governmental authority. The plasmas were found to be negative on the tested parameters. However, since no test can completely rule out the presence of blood borne diseases, these control plasmas have to be handled as potentially infectious material (4).

Procedure (ROTROL N):

Reconstitute each vial ROTROL N Lyo as described under *Preparation of the ready-to-use control.* Use ROTROL N with the dedicated quality control tests available on the ROTEM® system (QCinN for NTEM and QCexN for EXTEM). 300 µl ROTROL P is used per assay in the respective test. The content of one vial ROTROL P is sufficient to check all 4 channels of a ROTEM® system.

Recommended External Control Procedure:

- Conducting a quality control serves as verification of the whole system; device, pipette, reagent, user. It is recommended to run a control test (QCinN for INTEM and QCexN for EXTEM) prior to assays of patient samples. Control tests should also be run:
  1. After preventive maintenance is performed on the instrument.
  2. Whenever a new shipment or lot number of reagent is received and prior to use on the ROTEM® system.
  3. Whenever a value from the ROTEM® Service Menu is out of range (Phase shift, Variance, Center, Amplitude, or Temperature) and it cannot be corrected (see ROTEM® *delta* operating manual chapter 5.5.1).
- If a result is outside the target range, the test should be repeated in accordance with the test-specific instructions on the same channel and on a further second channel.
- If both measurements are within the target range, it is likely that there has been procedural error during the first measurement.
- If both measurements are outside the target range, it is possible that a reagent has deteriorated or there is a systematic user error. If the control is also outside the target range with fresh reagents, a defective control is likely. If the result is repeated with a freshly reconstituted control, it is likely that there is a device failure, in which case, you should contact your technical service provider.
- If the first result on the original channel is confirmed and the result on the second channel is OK, it can be assumed that there is a channel-specific problem or a calibration problem. Do not use this channel for any further measurements. In this event, proceed as recommended in the ROTEM® user manual or contact your technical service provider.

Recommended External Control Interval:

Manufacturer recommendation: minimum every week (e.g. QCinN on channel 1 - 2 and QCexN on channel 3 - 4 with ROTROL N the first week and QCinP and QCexP with ROTROL P the following week).

CLIA recommendation: minimum daily and/or within every 8 hours that a patient test is resulted. Additionally testing should be performed if required. External quality control should be performed at 2 levels (e.g. QCinN on channel 1, QCexN on channel 2 with ROTROL N; QCinP on channel 3, QCexP on channel 4 with ROTROL P).

CLIA equivalent QC testing, option 2 (QSA.02.04.01): Internal quality control (see ROTEM® *delta* operating manual chapter 5.5.1) should be checked at a minimum daily and external quality controls should be run at a minimum weekly using 2 levels of controls (e.g. QCinN on channel 1, QCexN on channel 2 with ROTROL N; QCinP on channel 3, QCexP on channel 4 with ROTROL P).

Performance data:

Precision:

INTEM / QCinN	CT CV[%]	α-angle CV[%]	A20 CV[%]
Within-run [1]	1.4	0.6	8.1
Between Operator [2]	2.7	0.6	5.4

EXTEM / QCexN	CT CV[%]	α-angle CV[%]	A20 CV[%]
Within-run [1]	3.1	0.6	11
Between Operator [2]	7.9	0.3	5.5

[1] .5 runs on each of the 4 channels of one instrument using ROTROL N
[2] 5 operators run ROTROL N in duplicates

Bibliography:

(1) NCCLS Document H21-A2. Collection, transport, and processing of blood specimens for coagulation testing and performance of coagulation assays. 3rd ed. Approved Guideline 1998
(2) Blutgerinnungsstudien mit der Thrombelastographie, einem neuen Untersuchungsverfahren. Hartert, H.: Klin. Wochenschrift 1948; 26: 577-583
(3) Thromboelastographic Coagulation Monitoring during Cardiovascular Surgery with the ROTEG Coagulation Analyzer, Calatzis, A. et. al.: Management of Bleeding in Cardiovascular Surgery edited by Roque Pifarre'; Hanley & Belfus, Inc. Philadelphia, PA, 2000
(4) Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Washington 1993 (HHS publication No. (CD) 93-8395)

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???	Symbols on labels	Symboles sur les étiquettes	Simbolos en las etiquetas
LOT	lot	Lot	Lote
REF	reference or order number	Référence ou numéro de commande	Referencia o número de pedido
	store between x and y degree celsius	A conserver entre x et y °C	Conservar entre "x" y "y" grados Celcios
CE	CE marking according to IVD guideline 98/79 EC	Marquage CE conforme aux directives IVD 98/79 EC	Marca CE según directiva IVD 98/79 CE
	expiry date	Date d'expiration	Fecha de caducidad
CERT	certificate (standard curve and evaluation table)	Certificat (courbe standard et tableau d'évaluation)	Certificado (curva estándar y tabla de evaluación)
	instructions for use	Mode d'emploi	Instrucciones de uso
IVD	in-vitro diagnostic use	Diagnostic in vitro	Para uso en diagnóstico in vitro
	single use only	A usage unique	Úsese solo una vez
SN	serial number	Numéro de série	Número de serie
	manufacturing date	Date de fabrication	Fecha de fabricación
	name and address of the manufacturer	Nom et adresse du fabricant	Nombre y dirección del fabricante
10 x 7	number of tests (n) in the kit (e.g. 10 x 7 tests)	Quantité de tests (n) dans le kit (ex. 10 x 7 tests)	Cantidad de tests (n) contenidos en el kit (ej. 10 x 7 tests)
	biohazard	Risque biologique	Riesgo biológico
RCNS	reconstitute with...	À reconstituer avec...	Reconstituir con...
Reagenz	name of the reagent (e.g. Aqua = distilled water)	Nom du réactif (ex. Aqua = eau distillée)	Nombre del reactivo (ej. Aqua = agua destilada)
200 µl	volume of the diluent	Volume du diluent	Volumen del diluente