MediRox

MRX PT Quick
Art. No: MRX 943-10

CE

Revision 2015-12-16
Changes: New product
Supersedes N/A

INTENDED USE
For quantitative determination of prothrombin time (PT) in human citrated plasma, according to the Quick method[1].
FOR IN VITRO DIAGNOSTIC USE

SUMMARY AND PRINCIPLE
PT Quick are used for quantitative determination of prothrombin time (PT) in patients administered vitamin K-antagonists and for detection of deficiency in clotting factors in the extrinsic pathway. The PT Quick method is dependent on the activity of K-vitamin dependent clotting factors (FII, FVII and FX) and fibrinogen in the human citrated plasma. In patients treated with vitamin K-antagonists production of the K-vitamin dependent clotting factors will be inhibited and result in a prolonged prothrombin time. Prothrombin time method is based on activation of the extrinsic pathway of factor VII by thromboplastin, in presence of calcium. The activated complex will activate FIX which consequently will activate the conversion of prothrombin (FII) to thrombin and further XIII activate the conversion of fibrinogen to fibrin, detected as a clot.

PRODUCT DESCRIPTION
The PT Quick kit consists of 10 x 10 mL lyophilized rabbit brain thromboplastin, buffer with calcium chloride, stabilizer and 0,05% sodium azide as preservative.
Expected ISI value
Target ISI value: 0.9-1.4
ISI value is lot specific and is specified on the vial label.

MRX943-10 10x10mL

PRECAUTIONS
Only for *in vitro* diagnostic use. Waste is disposed according to local regulations. Wear appropriate clothing. Avoid contact with skin and eyes.

INTERNATIONAL NORMALIZED RATIO AND TRACEBILITY
PT Quick results are expressed in seconds, percent activity or international normalized ratio, INR. The international recommendations of reporting the PT time is INR and refers to the international sensitivity index (ISI) of thromboplastin. MRX943 is calibrated against the international reference of thromboplastin (RBT/05), origin from the first thromboplastin preparation, international reference preparation (IRP 67/40), with an assigned ISI of 1.0.

INR is calculated from the following equation:
$INR = (\text{patient prothrombin time} / \text{mean normal prothrombin time})^{ISI}$
Mean normal prothrombin time (MNPT) = the mean PT of 21 normal plasma donors. Each laboratory are to determine the laboratory specific MNPT due to variance of for each instrument and reagent set-up.
ISI = International Sensitivity Index, specific for each lot of reagent and instrument and reagent system

PREPARATION
- Allow the vial of MRX PT Quick to equilibrate at 15-25 °C for 10-15 minutes before opening and reconstitution.
- Dissolve the content of each vial with 10 mL of CLSI CLRW type water or equvivalent[2].
- Replace the stopper and swirl gently. Keep the reconstituted reagent at 15-25 °C for 60 minutes and mix before use. Make sure of the complete reconstitution of the product before use by mixing thoroughly.
- Continuous stirring or repeated inversion of the reagent is necessary during analysis.

STORAGE CONDITIONS AND STABILITY
Unopened reagent stored at 2-8 °C is stable until the expiration date shown on the vial.
Stability after reconstitution: 5 days at 2-8 °C and at 15-25 °C in closed original vial.
On-board stability 4 days at 15 °C in open vial.

SPECIMENT COLLECTION AND PREPARATION
Specimen collection should be carried out according to CLSI guideline H21-A5 Vol. 28 No.5[3]. Nine parts of freshly drawn plasma are collected into test tube containing 1 part 0.13 M sodium citrate. Correct sampling is crucial for correct determination of prothrombin time. Inverse immediately after sampling. Within 24 hours centrifuge for 15 minutes at 2400*g to obtain plasma. If using commercial vacuum tubes, a full draw must be assured. Trauma or stasis during drawing should be avoided. The presence of a clot in a specimen is cause for rejection.

INSTRUMENT AND TEST PROCEDURE
The measurement procedure is intended for use on manual or automated coagulation system.
Procedure:

- Preincubate the reconstituted reagent at 37°C
- Incubate 100 µL of test plasma at 37 °C for 1 minute.
- Thoroughly mix the pre-incubated PT Quick reagent and add 200 µL of the reagent and immediately start recording the time.
- Record the clotting time in seconds.

EXPECTED VALUES
Determination of PT time is dependent on the instrument and the thromboplastin reagent used and may vary from laboratory to laboratory. The recommendation for each laboratory is to determine the mean normal ratio (MNPT) of each new lot of reagent or new instrument. Expected values were determined on an ACL Top instrument and calculated from the PT from 95 healthy subjects.

MRX943	n	mean (s)	SD	Mean ±2SD
	95	12.6	0.8	11.1-14.1

QUALITY CONTROL
In accordance with good laboratory practice it is necessary to run controls to ensure accuracy and reproducibility of the results. It is recommended to use two or three levels of control from MediRox. Each laboratory is recommended to set up an internal quality control program to ensure evaluation of methods including the current reagent.

- 3-Level controls MRX170-MRX183 or
- 2-Level controls GHI162-GHI170

LIMITATIONS AND INTERFERING SUBSTANCES
The PT results may be affected by insufficient blood sampling with shifted ratio of sodium citrate to patient plasma or by interfering substances such as heparin, EDTA and vitamin K. Deficiency of clotting factor may also affect the PT.
No interference up to:

Heparin UFH: 2 U/mL
Triglycerides: 5 g/L
Bilirubin: 500 mg/L
Hemoglobin 5 g/L

PRECISION
Precision were determined on ACL Top according to the International[4] and European standards [5]. Intra assay precision was determined at one occasion assayed 10 times and inter assay precision at 10 occasions assayed three times, using normal plasma control and abnormal plasma control.

Intra assay precision

MRX943	Mean (s)	CV % within run
Normal plasma control	13.7	0.7
Abnormal plasma control	29.4	2.0

Inter assay precision

MRX943	Mean (s)	CV % between run	CV % total
Normal plasma control	13.8	1.3	1.4
Abnormal plasma control	29.6	2.4	3.1

CORRELATION
Correlation were performed on an ACL Top using MRX943 and two other PT Quick reagents, STA Neoplastine CI plus and RecombiPlasTin 2G. Plasma from 60 healthy donors were analysed in duplicates.

MRX	slope	intercept	r	Reference method
MRX943	1.426	-0.582	0.969	STA Neoplastine CI Plus
MRX943	1.210	-0.231	0.973	RecomiPlasTin 2G

REFERENCES

1. Quick AJ, The Thromboplastin Reagent for the Determination of Prothrombin *Scienæ 1940* vol. 92, No. 2379: pp. 113-114
2. Clinical and Laboratory Standards Institute. Preparation and Testing of Reagent Water in the Clinical Laboratory, Fourth Edition, CLSI Document C3-A4; Vol. 26 No. 22.
3. Clinical and Laboratory Standards Institute. Collection, Transport, and Processing of Blood Specimens for testing Plasma-Based Coagulation and Molecular Hemostasis. Assays; Approved Guideline - Fifth Edition, CLSI Document H21-A5; Vol. 28 No.5.
4. Clinical and Laboratory Standard Institute. User Verification of Performance for Precision and Trueness; Approved Guideline-Second Edition, CLSI Document EP15-A2; Vol.25 No.17.

   Eurachem, a focus for analytical chemistry in Europe. The Fitness for Purpose of Analytical Methods –a laboratory guide to Method Validation and Related Topics.