MediRox

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FOR IN VITRO DIAGNOSTIC USE
Revision 2016-04-14
Changes: MRX943-2 added as new product volume
Supersedes: 2016-03-08

MRX PT Quick
Art. No: MRX943-10, MRX943-5, MRX943-4, MRX943-2

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
The MRX PT Quick reagent is 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), fibrinogen and FV 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 lyophilized rabbit brain thromboplastin, buffer with calcium chloride, stabilizer and 0.05% sodium azide as preservative.
Expected ISI value: 0.9-1.4
ISI value is lot specific and is specified on the vial label.

MRX943-10	consist of 10 x 10 mL
MRX943-5	consist of 10 x 5 mL
MRX943-4	consist of 10 x 4 mL
MRX943-2	consist of 10 x 2 mL

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

INTERNATIONAL NORMALIZED RATIO AND TRACEABILITY
PT Quick results are expressed in either 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 thromboplastins.

The MRX943 reagent was calibrated against an in-house standard which is traceable to the WHO international standard of rabbit thromboplastin (RTF/05) [2]. The first MediRox MRX943 in-house standard was directly calibrated against RTF/05 in a unique WHO-calibration protocol. RTF/05 is directly traceable to the first International Reference Preparation of Thromboplastin (67/40) with 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 in 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 reconstitution.
- Dissolve the content of each vial in CLSI CLRW type water or equivalent[3]: MRX943-10 in 10 mL, MRX943-5 in 5 mL, MRX943-4 in 4 mL and MRX943-2 in 2 mL.
- 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 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[4]. Correct sampling is crucial for correct determination of prothrombin time. Nine parts of freshly drawn plasma are collected into test tube containing one part 0.13 M sodium citrate. 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 analysis 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 to the test plasma and immediately start recording the time.
- Record the clotting time in seconds.

CALIBRATION AND CALCULATION OF RESULTS
MediRox recommend the use of calibrator plasma for correct comparison of results.

EXPECTED VALUES
Determination of PT time is dependent on the instrument and the thromboplastin reagent used and may vary from laboratory to laboratory. The PT from healthy subjects were determined on ACL Top 700 CTS instrument and expected values were calculated.

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 method evaluation.

- 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.

PT is not affected by substances in concentrations 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 700 CTS according to International[5] and European standards[6]. 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	13.7	0.7
Abnormal plasma	29.4	2.0

Inter assay precision

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

CORRELATION
Correlation were performed on an ACL Top 700 CTS 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 PT Quick	slope	intercept	r	Reference method
MRX943	1.426	-0.582	0.969	STA Neoplastine CI Plus
MRX943	1.210	-0.231	0.973	RecombiPlasTin 2G

REFERENCES

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