

PT 6-Level Calibrator Art.No: MRX1205

INTENDED USE

For calibration of MRX PT Quick reagent (MRX943) by determination of a local ISI.

SUMMARY AND PRINCIPLE

The calibrator plasma is used to generate a calibration curve for determination of International Sensitivity Index (ISI) and Mean Normal Prothrombin Time (MNPT) for calculation of INR in patient sample. The international recommendation of reporting prothrombin time (PT) is in unit INR and refers to the International Sensitivity Index (ISI) of thromboplastins. INR is calculated from the following equation¹:

$$\text{INR} = (\text{PT}/\text{MNPT})^{\text{ISI}}$$

PT = Prothrombin Time of the patient plasma

MNPT = Mean Normal Prothrombin Time, the mean PT of 21 normal plasma donors

ISI = International Sensitivity Index, specific for each lot of reagent and instrument/reagent system

PRODUCT DESCRIPTION

The PT 6-Level Calibrator MRX1205, consists of, 6 x 1mL, lyophilised citrated human plasma (MRX1205 L1; MRX1205 L2; MRX1205 L3; MRX1205 L4; MRX1205 L5 and MRX1205 L6). The calibrator level range from PT INR 0,9 to 7,0.

Calibration values are specified in the lot specific certificate and on the vial label.

PRECAUTIONS

For *in vitro* Diagnostic Use Only.

The product contains material of human origin. The plasma used in the production is tested and found non-reactive for hepatitis B surface antigen (HBsAg), for human hepatitis C virus (Anti-HCV) and for human immunodeficiency viruses (HIV-1 and HIV-2). No test can however completely exclude the presence of infected material and the product should be treated as potentially infectious. Waste is disposed according to local regulations. Wear appropriate laboratory clothing, avoid contact with skin and eyes.

PREPARATION

- Allow the vials with calibrator levels to equilibrate at 15-25 °C for 10-15 minutes.
- Reconstitute the content of each vial with 1.0 mL of CLSI CLRW type water or equivalent².
- Replace the stopper and swirl gently. Keep the reconstituted calibrators at 15-25 °C for 15-30 minutes and mix thoroughly before use. Prior to use make sure of complete reconstitution of the calibrators.

STORAGE CONDITIONS AND STABILITY

Unopened vial: stable until the expiration date shown on the vial when stored at 2-8 °C

Stability after reconstitution: 8 hours at 15-25 °C in closed original vial

CALIBRATION AND REFERENCE VALUES

Determination of International Sensitivity Index (ISI) and Mean Normal Clotting Time (MNPT)

For calculation of ISI and MNPT, please download *Form For Calibration of MRX1205* on MediRox homepage (www.medirox.se/downloads/product/coagulationcalibrators/formforcalibrationofMRX1205).

The clotting time for PT (seconds) are determined in duplicates for each calibrator level (L1-L6). The logarithmic value of mean PT of each calibrator level is plotted on the y-axis and the logarithmic INR value, (stated in the lot specific certificate of analysis of for the calibrator kit), on the x-axis. An orthogonal regression gives a fitted straight line from equation mentioned above, where the ISI correspond to the 1/slope and MNPT to the intercept on the y-axis:

$$\text{ISI} = 1/\text{slope}$$

$$\text{MNPT} = 10^{\text{y-intercept}}$$

Manual determination of International Normalized Ratio (INR) using calibration curve

The PT clotting time (seconds) are determined in duplicates for each calibrator level (L1-L6). A calibration curve is generated by calculation of the mean PT value, plotted on a logarithmic scale against the logarithmic INR value (stated in the lot specific certificate of analysis) on the x-axis. The INR value of the sample from the patient is determined manually from the logarithmic scale.

TRACEABILITY OF CALIBRATOR REFERENCE VALUES

Recommendation from the World Health Organization (WHO) states that thromboplastins used in clinical prothrombin time tests, as control of oral anticoagulant therapy, must be calibrated against international standards of thromboplastins.

The specified INR Levels for calibrator MRX1205, is traceable to the international standard of thromboplastin through assignment of INR values with MRX943. The MRX943 reagent was calibrated against an in-house standard which is traceable to the WHO international standard of rabbit thromboplastin (RTF/05)³. 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. Traceability of MRX1205 to the international standards is valid for results expressed in the unit INR.

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 different levels of MediRox controls:

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

LIMITATIONS

This product is designed for calibration of MRX943 MRX PT Quick. The calibration plasma is subjected to the limitations of the assay system. Deviations may indicate possible problems with one or more components in the test system.

REFERENCES

1. Guidelines for thromboplastins and plasma used to control oral anticoagulant therapy, Annex 3, World Health Organization, WHO Technical Report Series, No.889, 1999
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, 2012
3. International collaborative study for the calibration of a proposed international standard for thromboplastin, rabbit plain, Expert Committee on Biological Standardization, World Health Organization, 2005