MediRox

CE

Revision: 2016-08-04

Multi Calibrator II Art.No: MRX1203, MRX1203-10

INTENDED USE

For calibration of antithrombin, fibrinogen Clauss, and PT Quick using MRX AT reagent (MRX1200), MRX Fib Clauss reagent (MRX942, MRX942B), and MRX PT Quick reagent (MRX943).
For *in vitro* Diagnostic Use Only.

SUMMARY AND PRINCIPLE

The calibrator plasma is used to generate a reference curve for antithrombin, fibrinogen and prothrombin time determination in PT %.

PRODUCT DESCRIPTION

The calibrator plasma is prepared from citrated lyophilized human plasma with specified levels of antithrombin (IU/mL), fibrinogen (g/L) and prothrombin time (PT %).

MRX1203 consist of 1*1 mL
MRX1203-10 consist of 10*1 mL
Target values of the calibrator are specified in the lot specific certificate and on the vial label.

PRECAUTIONS

The product contains material of human origin. The plasma used in the production is tested and found nonreactive for Hepatitis B surface antigen (HBsAg), Anti-HCV and HIV antibodies. 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 clothing. Avoid contact with skin and eyes.

PREPARATION

- Allow the vial of calibrator to equilibrate at 15-25 °C for 10-15 minutes
- Dissolve the content of each vial in 1.0 mL GHI154 Diluent or of CLSI CLRW type water or equivalent[1]
- Replace the stopper and swirl gently. Keep the reconstituted calibrator at 15-25 °C for 15-30 minutes. Mix well and make sure of the complete reconstitution of the product before use, if needed use a vortex mixer.

STORAGE CONDITIONS AND STABILITY

Unopened vial:
stable until the expiration date shown on the vial when stored at 2-8 °C.
Stability after reconstitution:
Antithrombin and fibrinogen calibration: 12 hours at 15-25 °C in closed original vial.
PT Quick calibration: 6 hours at 15-25 °C in closed original vial.

INSTRUMENT/TEST PROCEDURE

For detailed instructions of calibration procedures see respectively reagent inserts and instrument specific application. The user must complete a reference curve for each new lot of reagents and/or if control plasma falls outside the assigned limits.

Calibration of Antithrombin

- Three dilutions of MRX1203 are recommended. (Approximately: 0.25 – 0.50 – 1.00 IU/mL). Dilute the calibrator in Sample Diluent (MRX184)
- Perform duplicate determinations on each dilution of the calibrator

Calibration of Fibrinogen Clauss

- Five dilutions of MRX1203 are recommended. Dilute the calibrator in Sample Diluent (MRX184): 1:5, 1:10, 1:20, 1:30 and 1:40
- Perform duplicate determinations on each dilution of the calibrator

Calibration of PT Quick

- Four dilutions of MRX1203 are recommended. Dilute the calibrator in Sample Diluent (MRX184): 100 %, 75 %, 50 %, and 25 %
- Perform duplicate determinations on each dilution of the calibrator

TRACEABILTY OF CALIBRATOR REFERENCE VALUES

Antithrombin and fibrinogen:
The reported values were determined over multiple runs using specific lots of MRX1200, MRX942, and MRX942B calibrated against SSC/ISTH Secondary Coagulation Standard traceable to WHO international standards. For AT, 1 % AT activity is defined as 0.01 IU of AT activity in 1 mL plasma.
PT Quick:
The reported values were determined on ACL Top 700 CTS over multiple runs using specific lots of MRX943 calibrated against an in-house standard, traceable to the WHO international standard of rabbit thromboplastin (RTF/05). The first in-house standard was directly calibrated 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[2].

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

LIMITATIONS

This product is designed for calibration of coagulation assays. 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. 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
2. International collaborative study for the calibration of a proposed international standard for thromboplastin, rabbit plain, Expert Committee on Biological Standardization, Word Health Organization, 2005