MediRox

CE

Revision: 2016-02-01
Changes: New logotype and text format
Supersedes: 2014-11-10

Multi Calibrator I Art.No: MRX1202

INTENDED USE

For the calibration of fibrinogen Clauss, antithrombin and D-Dimer using MRX Fib Clauss reagent (MRX942B), MRX AT reagent (MRX1200) and MRX D-Dimer reagent (MRX143, MRX147, MRX147B).

SUMMARY AND PRINCIPLE

The calibrator plasma is prepared from citrated human plasma
The calibrator plasma may be used to generate a standard reference curve for fibrinogen, antithrombin and D-dimer determination.

The level of D-dimer in a sample is measured using latex particles coated with a monoclonal antibody (moAb). Unique properties and sensitivity of a unique moAb can cause large variations in both performance and recommended cut-off values for a D-dimer test. It is therefore recommended to always use the same moAb and calibrator in a group where values are compared.
MediRox D-dimer calibrator MRX1202 is for this specific reason designed as a common calibrator for the reagents MRX143, MRX147 and MR147B which all have the same monoclonal antibody, but are intended for different measurement methods.

- MRX143 D-dimer for instruments with wavelength 600-800nm
- MRX147 D-dimer for instruments with wavelength 400-600nm

PRODUCT DESCRIPTION

The calibration plasma MRX1202 consists of 1 x 1mL or 10 x 1 mL lyophilized citrated human plasma with specified levels of fibrinogen, antithrombin and D-dimer.
Calibration values are specified in the lot specific certificate and on the vial label.
Conversion to FEU (D-Dimer)
MediRox D-dimer reagents are developed using D-dimer units (DDU) as reference. For a conversion to Fibrinogen Equivalent Units (FEU) a factor of 2 is generally used[1], although a stoichiometrical calibration would suggest a different theoretical conversion factor[2].
Conversion table (example) :
Calibrator 3.0 mg/L DDU = 3000 ng/mL DDU = 6.0 mg/L FEU = 6000 ng/mL FEU

PRECAUTIONS

Only For *in vitro* Diagnostic Use
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 of 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 before opening and reconstitution. *Dissolve the content of each vial with 1.0 mL of CLSI CLRW type water or equivalent*[3].
Replace the stopper and swirl gently.
Keep the reconstituted calibrator at 15-25°C for 15-30 minutes and mix before use.
Make sure of the complete reconstitution of the product before use.

Note regarding D-Dimer:
Some instruments and methods of analysis may have a lower linearity than assigned calibrator value (approx 3.0 mg/L). The calibrator should then be diluted to a value in the upper part of the linear region, with an equally re-calculated assigned value.

STORAGE CONDITIONS AND STABILITY

Unopened calibrator:
stable until the expiration date shown on the vial when stored at 2-8°C.
Stability after reconstitution: 12 hours at 15-25°C in closed original vial.

INSTRUMENT/TEST PROCEDURE

The user must complete a standard curve for each new lot of reagents and / or if control plasma falls outside the assigned limits. For detailed instructions on performing the tests see insert and application for the specific analyse.

TRACEABILTY OF CALIBRATOR REFERENCE VALUES

Antithrombin and fibrinogen:
The reported values were determined over multiple runs using specific lots of MRX942B and MRX1200 and against SSC/ISTH Secondary Coagulation Standard. SSC/ISTH secondary coagulation standard are traceable to WHO international standards.
D-Dimer:
There is currently no international D-dimer reference standard. The product is calibrated against an In-House standard that is checked against ECAT External Quality Assessment Programme (www.ecat.nl).

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 the 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. Fedde van der Graaf1, Henk van der Borne2, Marion van der Kolk3, PietJ.de Wild1, Ger W.T janssen1,Stan H.M. van Uum4. Exclusion of Deep Venous Trombosis with D-Dimer Testing
2. Bror Edlund, Torbjörn K. Nilsson. A proposed stoichiometrical calibration procedure to achieve transferability of D-Dimer measurements and to Characterize the performance of different methods.
3. Clinical and Laboratory Standards Institute. Preparation and Testing of Reagent Water in the Clinical
4. Laboratory, Fourth Edition, CLSI Document C3-A4; Vol. 26 No. 22.