MediRox

MRX Fib Clauss Art. No: MRX942B

CE

Revision: 2016-01-01
Changes: New logotype and text format
Supersedes: 2014-11-07

INTENDED USE

For the quantitative determination of fibrinogen, based on the Clauss method, in human citrated plasma.
FOR IN VITRO DIAGNOSTIC USE

SUMMARY AND PRINCIPLE

Fibrinogen is a 340 kDa soluble plasma glycoprotein that is converted by thrombin to fibrin during blood clot formation. In unexplained bleeding cases it can be of clinical importance to quantitate fibrinogen1.
MediRox utilizes the fibrinogen Clauss method where a high concentration of thrombin is added to dilute test plasma2 and the clotting time is measured. In the presence of an excess of thrombin, fibrinogen is transformed into fibrin and clot formation time is inversely proportional to the concentration of fibrinogen in the sample plasma. The test result is compared with a calibration curve prepared by clotting a series of dilutions of a reference plasma sample of known fibrinogen concentration, and a result in g/L is obtained.

PRODUCT DESCRIPTION

The Fib Clauss kit consists of:

- Bovine thrombin: 10 x 5 mL vials of lyophilized bovine thrombin (100 UNIH/mL) with bovine albumin, buffer and preservative.

Precautions:

Bovine thrombin contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.

PREPARATION

Allow each vial of Fib Clauss to equilibrate at 15-25°C for at least 10 minutes before reconstitution. Dissolve the content of each vial with 5 mL of CLSI CLRW type water or equvivalent3.
Swirl gently. Make sure of the complete reconstitution of the product. Keep the reagent at 15-25°C for 30 minutes and invert to mix before use. Do not shake.

STORAGE CONDITIONS AND STABILITY

Unopened reagent is stable until the expiration date shown on the vial when stored at 2-8°C.
Stability after reconstitution: 7 days at 2-25°C in closed original vial.
On board stability 3 days at 15°C (stored on board in open vial during daytime, closed vial at 2-8°C during nighttime)

SPECIMEN COLLECTION AND STORAGE

It is recommended that specimen collection, handling and storage be carried out in accordance with CLSI guideline H21-A5 Vol. 28 No.5 4. Venous blood is collected in 3.2% sodium citrate at a ratio of 9 parts blood to 1 part anticoagulant (1:10 ratio). The ratio is critical. 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/TEST PROCEDURE

Refer to the appropriate instrument manual and application for the complete assay procedure instruction.
Calibration

- Using Sample diluent, prepare dilutions of Fibrinogen calibrator: 1:5, 1:10, 1:20, 1:30 and 1:40
- Perform duplicate determinations on each dilution of the fibrinogen calibrator as follows:
- Incubate 200 µL of diluted calibrator for 2 minutes at 37 °C.
- Add 100 µL of MRX Fib Clauss reagent and immediately start measuring.
- Obtain the clotting times for each of the dilutions of the fibrinogen calibrator.
- Plot the average clotting times obtained versus the respective fibrinogen concentration.

Analyse of patient specimen:

- Dilute the test plasma 1:10 in MRX Sample diluent (MRX184).
- Analyse duplicates of each sample.
- Incubate 200 µL of diluted test plasma for 2 minutes at 37 °C.
- Add 100 µL of Fib Clauss reagent and immediately start measuring.
- Record the clotting time of the plasma samples.

Each laboratory should optimize their own parameter set up on every individual optical/mechanical instrument.

ADDITIONAL REAGENTS AND CONTROL PLASMAS:

- Calibrator plasma — MRX1202, MRX1204
- 3-Level controls — MRX170-MRX183
- 2-Level controls — GHI162-GHI170
- Sample diluent — MRX184

QUALITY CONTROL

In accordance with good laboratory practice it is necessary to run controls to ensure accuracy and reproducibility of the results[5]. It is recommended to use two or three different levels of MediRox controls.

RESULTS

Patient results may be reported in the following units:
g/L or mg/dL
seconds

LIMITATIONS/INTERFERING SUBSTANCES

Degradation products of fibrin(ogen) in the plasma assayed may affect the results of the fibrinogen assay.

No interference up to:
Heparin UFH: 4.0 IU/mL
Triglycerides: 3.75 g/L
Bilirubin: 50 mg/L
Dabigatran: 475 µg/L
Hemolyzed plasma could not be assayed

EXPECTED VALUES

A normal range study was performed using MRX942B Fib Clauss reagent.

System	N	Range (g/L)
ACL TOP	92	1.49 – 3.57

These results were obtained using a specific lot of reagent.
Each laboratory should verify its own normal range.

PERFRMANCE CHARACTERISTICS

Precision:
Within run and total (run to run and day to day) precision was assessed over multiple runs using both normal and abnormal samples.

MRX942B	Mean	CV % within run	CV % between run	CV % Total
Normal control	2,45 g/L	4.0	4.9	6.3
Abnormal control	1,23 g/L	3.2	4.4	5.4

Correlation:

Correlation study was made between MRX942B and HemosIL QFA. Samples from 32 donors were measured. Samples were run in parallel.

Assay	slope	intercept	r	reference method
MRX942B	1.157	- 0.358	0.98	HemosIL QFA

Linearity:

ACL TOP: 0.6 – 8.0 g/L
Due to many variables which may affect results, each laboratory should establish its own linearity range.

REFERENCES.

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