REF 5184004 FXI Deficient Plasma, native, 5 x1 mL
For research use only

3015202US Rev. 001 [01] 06/2018

FXI Deficient Plasma - English

INTENDED USE

Faktor XI deficient plasma is used for the determination of the Factor XI by the one-stage clotting method based on the activated partial thromboplastin time (aPTT).

SUMMARY

Factor XI Deficient Plasma is a lyophilized human plasma, produced from native sample plasma, deficient in Factor XI plasma, containing buffer and stabilizers. The residual coagulation activity of Factor XI is < 3 %, a ll other coagulation factors have normal levels.

REAGENTS

The REF 5184004 Factor XI Deficient Plasma, native contains:

mL	Reagent	Description
5 x 1	FXI Deficient Plasma	Human plasma, lyophilized, native factor XI deficient plasma

Material required (not supplied with the kit)

- Pipettes
- Distilled water

REF 5410010 Imidazole buffer 50 mL

REF 5277015 $CaCl_2$ 25mmol/l Solution 100 mL

- aPTT reagent (only one required)

REF 5035105 Siron LS 2 x 4 mL

REF 5035060 Dapttin TC 5 x 2 mLCalibrator and controls

REF 5220110 Coagulation Reference 5 x 1 mL

REF 5020040 Coagulation Control N 5 x 1 mL

REF 5021055 Coagulation Control A 5 x 1 mL

Other package sizes of the respective product might be available.

Warning and precautions

For research use only

This lot of reagents prepared from human blood and each single plasma used for this lot are HBsAg, HIV 1/2 Ab negative and HCV Ab positive.

All bood and plasma samples and products have to be regarded as potentially infectious and handeled with appropriate care and in compliance with the biosafety regulations in force. Dispose the same way as hospital waste.

A Material Safety Data Sheet for this product is available from www.technoclone.com

Stability and storage

The expiry date printed on the labels is only applicable to storage of the unopened containers at 2…8°C. Stability after reconstitution:

Reagent	18...25°C	< -20°C
FXI Deficient Plasma	2 hours	1 month

Reagent can only be frozen once and in its original vial.

TEST PROCEDURE

Preparation of plasma samples

Mix 9 parts of venous blood and 1 part of Sodium Citrate solution (0.11 mol/L) and centrifuge for 15 min at a RCF of at least 2500 (corresponding to DIN 58905). Store the plasma at room temperature (up to 4 hours).

Preparation of reagents

Reconstitute each vial of the lyophilized Factor XI Deficient Plasma with 1 mL of distilled water. The distilled water and reagent have to r each room temperature before mixing. Replace the s topper and s wirl gently. Make sure of the complete reconstitution of the reagent. Keep the reconstituted reagent for 30 minutes at room temperature. Invert to mix before use. Do not shake. Avoid foam formation.

Instrument test procedures

Technoclone provides instrument specific application sheets for Ceveron® Instruments and an alyzers from other manufacturers which contain analyser/assay specific handling and performance informations.

Quality control

In order to verify the accuracy of the results, Coagulation Control N and A should always be tested in the same way as the sample plasma. Controls should be analyzed at least once every 8 hours shift in accordance with good laboratory practice. Refer to the respective instrument's manual for additional information.

LIMITATION OF THE TEST

Incorrect sample handling can lead to partial activation of the coagulation factors and to falsely elevated single factor determinations.

Lupus anticoagulant can affect the apparent factor activity in single factor determination and must be ruled out.

Samples with excessive hemolysis, icterus, or lipemia, should not be used.

A new calibration is required for each lot of reagent (both aPTT and FXI Deficient Plasma) and following a major service of either instrument or equipment.

INTERPRETATION OF RESULTS

Sample results may be expressed in % activity or IU/mL (100 % equals 1.00 IU/mL)

Reference Range

Factor XI: 65-150% (0.65-1.50 IU/mL)

Due to many variables which may affect clotting times (including the population age), each laboratory should establish its own normal range.

PERFORMANCE CHARACTERISTICS

Performance data are given below. Results obtained in individual laboratories may differ.

Precision

Reproducibility was determined with samples in the normal and abnormal range (in series and day to day) on Ceveron® alpha with Siron LS. The following results were obtained.

Sample	Mean FXI (%)	Within run CV (%)	Between run CV (%)
1	109.6	4.90	4.50
2	45.4	4.10	4.50

LITERATURE

Please contact Technoclone www.technoclone.com or your local distributor.


manufacturer

RUO For research use only


storage temperature

LOT lot


expiry date

REF catalogue number


consult instructions for use

GTIN Global Trade Item Number


Biological risk

Technoclone Herstellung von Dignostika und Arzneimitteln GmbH, Brunner Strasse 67, 1230 Vienna, Austria

EN/GE/ER ; A3-40-60g/m² zalka druck ;Pantone 2717c schwarz