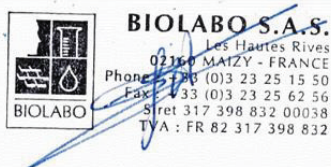




BIOLABO REAGENTS
www.biolabo.fr

MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives,
02160, Maizy, France



Factor XI Deficient Plasma

Immuno-depleted plasma for the determination of Factor XI activity
in citrated human plasma

REF 13311 R1 6 x 1 mL



Made In France

TECHNICAL SUPPORT AND ORDERS

Tel: (33) 03 23 25 15 50

support@biolabo.fr

Latest revision: www.biolabo.fr

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (automated or semi-automated method). It allows the quantitative determination of Factor XI activity in citrated human plasma.

This test is realized with reagents BIOLABO as follows:

REF 13660 and 13670: BIO-SIL (APTT Silica)

REF 13560 and 13570: BIO-CK (APTT Kaolin)

REF 13565 : CaCl₂ Solution 0.025 M

REF 13883: Owren Köller buffer to dilute reference, control and patient's plasmas.

GENERALITIES (2)

Factor XI is involved in the process of endogenous coagulation. The deficit in factor XI described by Rosenthal in 1953, appears following tooth avulsion or surgery. These can be seen by phenomenon of hemorrhagic syndrome of variable intensity.

PRINCIPLE (1)

The assay consists in the measurement of the clotting time, in presence of cephalin and activator, of a system in which all the factors are present in excess except of factor XI which is derived from the sample being tested.

REAGENTS

R1 F-XI Deficient Plasma

Human Origin

Freeze dried citrated plasma without Factor XI (removed by selective immune adsorption).

SAFETY CAUTIONS

- Material Safety Data Sheet is available upon request.
- Each donor unit used to manufacture this product was tested and found non-reactive for HbsAg, antibody to Hepatitis C and antibody to HIV-1/HIV-2.
- However, no test method can offer complete assurance that infectious agents are absent. All specimens or reagents from biological origin should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions.
- Waste disposal: Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

- Open the vial carefully and add exactly 1 mL of demineralized water.
- Recap and let stand for 15 minutes at room temperature.
- Before use, gently agitate to avoid the formation of foam.

STABILITY AND STORAGE

Stored away from light, well capped in the original vial at 2-8°C, when stored and used as described, reagents are stable:

Unopened:

- Until expiry date stated on the label of the kit.

Once opened:

- R1 must be reconstituted immediately,
- Once reconstituted; plasma is stable: 8 hours at 2-25°C.

SPECIMEN COLLECTION AND HANDLING (4) (5)

Citrated Plasma: Mix freshly drawn blood (9 Volumes) with buffered tri-sodium citrate solution 3.2% (1 volume).

Centrifuge for 10 min at 3000 g and extract supernatant.

Storage in plastic tube: 4h at 2-25°C

If quickly frozen: 15 days at -20°C, 1 month at -80°C (Thaw frozen plasmas at 37°C until complete thawing).

LIMITES (3) (6)

Heparins and Thrombin inhibitors (e.i. hirudin, argatroban ...) present in the specimen to be tested may lead to under-estimation of the factor XI activity in the specimen.

The presence of Lupus anticoagulants may lead to an under-estimation of Factor XI activity in the specimen.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Automated or semi-automated coagulation analyzer

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with

CALIBRATION

- **REF** 13970: BIO CAL, reference plasma for calibration of coagulation tests

Calibration frequency depends on proper instrument functions and on the preservation of reagent.

QUALITY CONTROL

- **REF** 13971: COATROL1 Level 1
- **REF** 13972: COATROL 2 Level 2

- External quality control program.

It is recommended to control in the following cases:

- At least once a run
- At least once within 24 hours
- When changing vial of reagent
- After maintenance operations on the instrument

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
 2. If control is still out of range, use a new vial of fresh calibrator
 3. If control is still out of range, use a new vial of reagent and re-assay
- If control is still out of range, please contact BIOLABO technical support or your local Agent.

REFERENCE INTERVALS (7)(8)

Plasma (adult) Usually 60-150%

Factor XI is lower in new-born (30% to 50% of the adult values). Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES CHARACTERISTICS

On automatic analyser SOLEA 100 at 37°C:

Precision:

Intra-Assay N = 20	level 1	level 2	Inter-Assay N = 20	level 1	level 2
Mean %	129	50	Mean %	125	59
S.D. %	5.1	1.9	S.D. %	7.8	3.7
C.V. %	4.0	3.7	C.V. %	6.3	6.3

Detection limit: 8% of Factor XI

Measuring Range: from 15% (QL) to 240%

Interferences APTT Silica (sec):

Turbidity	No interference up to 0.404 abs
Bilirubin	Positive interference from 133 µmol/L
Hemoglobin	No interference up to 261 µmol/L

Other substances may interfere with the results (see § Limits)

Onboard stability: Deficient plasma is stable 4 hours

Calibration Stability: Re-calibrate each day

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

PROCEDURE

Manual procedure on semi-automate BIO SOLEA 2, BIO SOLEA 4:

Prepare dilutions 1/10, 1/20, 1/40, 1/80 of **REF** 13970 BIO-CAL

Reference Plasma in Owren Köller buffer

Pre-incubate PT Reagent at least 15 min at 37°C and mix gently.

Measure and record the clotting time for each dilution as follows:

Reference plasma diluted 1/10 to 1/80	0,1 mL
Deficient plasma	0,1 mL
APTT Reagent :	0,1mL
Incubate 3 minutes at 37°C.	
CaCl ₂ 0,025 M :	0,1mL
The automatic countdown timer will start immediately after CaCl ₂ addition and stop when the clot is formed.	

Do the same for controls and specimens to be tested (pre-diluted 1/10 in Owren Köller buffer):

Controls and specimens (diluted 1/10)	0,1 mL
Deficient Plasma	0,1 mL
APTT Reagent :	0,1mL
Incubate 3 minutes at 37°C.	
CaCl ₂ 0,025 M :	0,1mL

Automated procedure : Full detailed application available on request

- Performances and stability data have been validated on SOLEA 100 and Thrombolyzer Compact X (available on request).
- With manual procedure and on other automated coagulation analyser, performances and stability data must be validated by user.
- Other validated applications or proposal are available on request.

CALCULATION

Manual procedure:

Plot a Standard Curve using results obtained with dilutions 1/10 to 1/80 of reference plasma

Concentration % = f (Clotting Time)

Read the concentration of controls and samples reporting clotting time on the graph.

Automated and semi-automated procedure:

Patients results (seconds) will be automatically converted in % of Deficient Factor according to calibration curve.

REFERENCES

- (1) NOSSEL, H.L. NIEMETZ J., MIBASHAN R.S., SCHULZE W.G. : Measurement of factor XI (plasma thrombin antecedent). « *Diagnosis and therapy of the congenital deficiency state* ». Br. J. Haematol., **12**, 133-144, 1966
- (2) SAMPOL, J., ARNOUX D., BOUTIERE B. : « *Manuel d'Hémostase* » Paris : Editions scientifiques et médicales Elsevier, **48**, 359-361, 1995
- (3) BRANDT J.T., TRIPLETT D.A., ROCK W.A., BOVILL E.G., ARKIN C.F. : « *Effect of lupus anticoagulant on the activated partial thromboplastin time* » Arch. Pathol. Lab. Med., **115**, 109-114, 1991
- (4) WOODHAMS B., GIRARDOT O., BLANCO M.J., COLESSE G., GOURMELIN Y. : « *Stability of coagulation proteins in frozen plasma* » Blood Coag. Fibrinolysis, **12**, 229-236, 2001
- (5) CLSI Document H21-A5: "Collection, transport, and processing of blood specimens for testing plasma-based coagulation assays and molecular haemostasis assays; approved guideline". Fifth edition, **28**, 5, 2008
- (6) YOUNG D.S., *Effect of Drugs on Clinical laboratory Tests*, 4th Ed. (1995) p.3-254 à 3-257
- (7) CAEN J., LARRIEU M.J., SAMAMA M. : « *L'hémostase. Méthodes d'exploration et diagnostic pratique* ». Paris : L'expansion scientifique, 1975.
- (8) ANDREW M., PAES B., MILNER R., JOHNSTON M., MITCHELL L., TOLLEFSEN D.M., POWERS P. : « *Development of the human coagulation system in the full-term infant* ». Blood, **70**, 1, 165-172, 1987