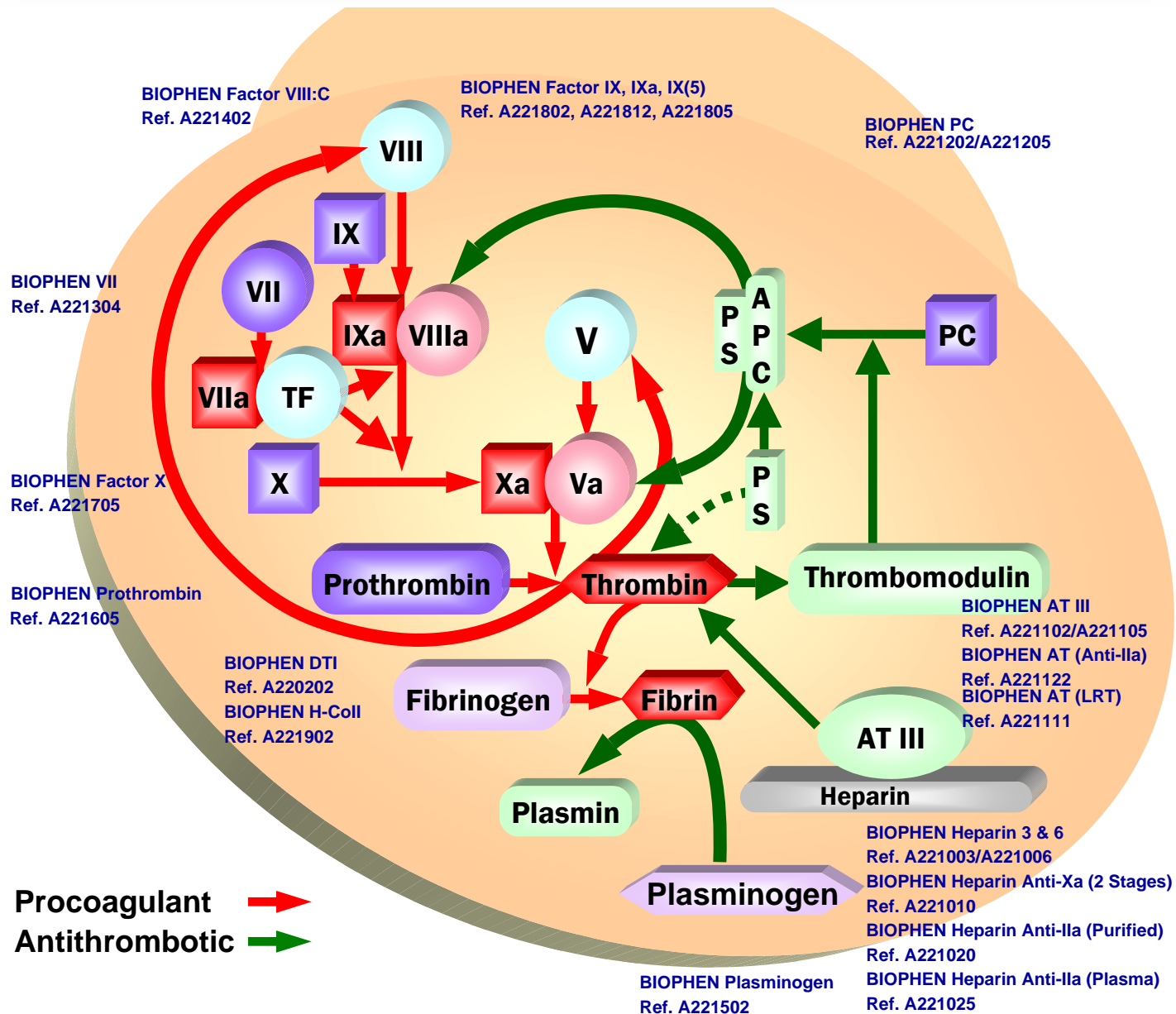


A COMPLETE LINE OF CHROMOGENIC ASSAYS FOR EVALUATING THE HAEMOSTATIC BALANCE



The reagents that you need for your laboratory and which can be adapted to the various automatic instruments

BIOPHEN PC

Improved reactivity and extended dynamic range

Protein C is measured following a specific activation with Protac®, an enzyme extracted from snake venom (Agkistrodon C Contortrix). Activated Protein C (APC) then specifically cleaves the specific substrate SaPC-21, releasing para-nitroaniline (pNA), which colour is measured at 405nm. There is a direct relationship between colour development and Protein C activity in the tested plasma.

BIOPHEN Antithrombin

Highly sensitive assay; Variant method available for abnormal ATIII with decreased heparin binding affinity

Kinetics method based on the inhibition of Factor Xa, which is at a constant concentration and in excess, by Antithrombin in presence of heparin. The remaining Factor Xa is then measured by its amygdolitic activity on a Factor Xa specific chromogenic substrate, which releases pNA. The amount of pNA generated is inversely proportional to the Antithrombin concentration present in the tested plasma.

BIOPHEN Prothrombin

Measurement of Prothrombin concentrations associated with the G20210A mutation

Prothrombin is measured following its specific activation with Ecarin®, an enzyme extracted from snake venom (Echis Carinatus). Meizothrombin is formed and then it specifically cleaves the specific substrate SIIa-01, releasing para-nitroaniline (pNA), which colour is measured at 405nm. There is a direct relationship between colour development and Prothrombin activity in the tested plasma.

BIOPHEN VII

Highly sensitive assay for Factor VII in plasma and concentrates

Factor VII forms an enzymatic complex with Tissue Factor, provided by rabbit Thromboplastin. It then activates Factor X, present in the assay at a constant concentration and in excess, to Factor Xa, which concentration is exactly measured by its activity on a specific Factor Xa chromogenic substrate (SXa-11). Factor Xa cleaves the substrate and generates pNA. The amount of pNA generated is directly proportional to the Factor Xa activity. There is a direct relationship between the amount of Factor VII in the assayed sample and the Factor Xa activity generated.

Calibrators and Controls

Established against the International Standards (NIBSC) when available

BIOPHEN Normal and Abnormal Control Plasma and BIOPHEN Plasma Calibrator contain 12 vials of normal citrated human plasma proposed for the calibration and the quality control of some coagulation factors. The various parameters measured are Factor VII+X, Protein C, Antithrombin III and Lupus Anticoagulant. The BIOPHEN Normal and Abnormal Control Plasma are tested for the absence of Lupus Anticoagulant.

BIOPHEN Factor IX New!

In presence of thrombin, phospholipids and calcium, first Factor XIa, supplied in the assay at a constant concentration and in excess, activates FIX, present in the tested sample, into FIXa, which forms an enzymatic complex with thrombin activated factor VIII:C, also supplied in the assay at a constant concentration and in excess, phospholipids (PLPs) and Calcium, that activates Factor X, present in the assay system, into Factor Xa. This activity is directly related to the amount of Factor IX, which is the limiting factor. Generated Factor Xa is then exactly measured by its specific activity on Factor Xa chromogenic substrate (SXa-11). Factor Xa cleaves the substrate and releases pNA. The amount of pNA generated is directly proportional to the Factor IXa activity. Finally, there is a direct relationship between the amount of Factor IX in the assayed sample and the Factor Xa activity generated, measured by the amount of pNA released, determined by colour development at 405nm.

BIOPHEN Heparin

Homogeneous reactivity with UFH and LMWH. Single calibration curve

Kinetics method based on the inhibition of a constant amount of factor Xa, by the tested heparin in presence of endogenous antithrombin, and hydrolysis of a Factor Xa specific chromogenic substrate (SXa-11), by the factor Xa in excess. pNA is then released from the substrate. The amount of pNA released is then a relation of the residual factor Xa activity. There is an inverse relationship between the concentration of heparin and color development, measured at 405 nm.

BIOPHEN AT (LRT)

Reagents are all in a stable liquid presentation

Kinetics method based on the inhibition of Factor Xa, which is at a constant concentration and in excess, by Antithrombin in presence of heparin. The remaining Factor Xa is then measured by its amygdolitic activity on a Factor Xa specific chromogenic substrate, which releases pNA. The amount of pNA generated is inversely proportional to the Antithrombin concentration present in the tested plasma. Due to the assay's insensitivity to heparin, plasmas from patients on heparin therapy may be tested.

BIOPHEN Plasminogen

The assay of choice for measuring plasminogen without interference of the plasma factors

Plasminogen is measured following its specific activation by addition of streptokinase and plasminogen-free fibrinogen in excess. The complex formed between plasminogen and streptokinase possesses a "plasmin-like" activity, which then specifically cleaves the plasmin-specific substrate SPm41, releasing para-nitroaniline (pNA), which colour is measured at 405nm. There is a direct relationship between colour development and Plasminogen activity in the tested plasma.

BIOPHEN FVIII:C

Two optimized protocols for measuring Factor VIII:C in the very low range (Haemophilia A) or in concentrates

In presence of a constant amount of Factor IXa, Phospholipids (PLPs) and Calcium, thrombin activated Factor VIII:C forms an enzymatic complex, which activates Factor X, supplied in the assay at a constant concentration and in excess, to Factor Xa. This activity is directly related to the amount of Factor VIII:C, which is the limiting factor. Generated Factor Xa is then measured by its activity on a specific Factor Xa chromogenic substrate (SXa-11). Factor Xa cleaves the substrate and releases pNA. The amount of pNA generated is directly proportional to the Factor Xa activity. There is a direct relationship between the amount of Factor VIII:C in the assayed sample and the Factor Xa activity generated.

BIOPHEN Factor X

A rapid a single specific measurement of Factor X activity

Factor X is measured following a specific activation with RVV, an enzyme extracted from snake venom (Russell's viper venom). Activated Factor X (FXa) then specifically cleaves the specific substrate SXa-11, releasing para-nitroaniline (pNA), which colour is measured at 405nm. There is a direct relationship between colour development and Factor X activity in the tested plasma.

References

Protein C:

- BIOPHEN PC 2.5 (Ref. A221202) 75 tests IVD
- BIOPHEN PC 5 (Ref. A221205) 200 tests IVD

Heparin using an anti-Xa method:

- BIOPHEN Heparin 3 (Ref. A221003) 90 tests IVD
- BIOPHEN Heparin 6 (Ref. A221006) 240 tests IVD
- BIOPHEN Heparin Anti-Xa (2 Stages) (Ref. A221010) 100 tests IVD
- BIOPHEN Heparin Anti-IIa (Purified) (Ref. A221020) 500 tests IVD
- BIOPHEN Heparin Anti-IIa (Plasma) (Ref. A221025) 100 tests IVD

Antithrombin using an anti-Xa method:

- BIOPHEN Antithrombin 2.5 (Ref. A221102) 50 tests IVD
- BIOPHEN Antithrombin 5 (Ref. A221105) 200 tests IVD

Quantitative determination of the heparin cofactor activity of Antithrombin (AT) using an anti-Xa method :

- BIOPHEN AT (LRT) (Ref. A221111) 220 tests RUO
- BIOPHEN AT (Anti-IIa) (Ref. A221122) 100 tests RUO

IVD = In Vitro Diagnostic Use = CE marked products

RUO = Research Use Only

Plasminogen using a chromogenic method:

- BIOPHEN Plasminogen (Ref. A221505) 100 tests RUO

Prothrombin using a chromogenic method:

- BIOPHEN Prothrombin (Ref. A221605) 100 tests RUO

FVII activity using a chromogenic method:

- BIOPHEN VII (Ref. A221304) 160 tests RUO

FVIII:C activity using a chromogenic method:

- BIOPHEN FVIII:C (Ref. A221402) 100 tests IVD

Factor IX using a chromogenic method:

- BIOPHEN Factor IX (Ref. A221802) 100 tests RUO
- BIOPHEN Factor IX (5) (Ref. A221805) 200 tests RUO
- BIOPHEN Factor IXa (Ref. A221812) 100 tests RUO

Factor X using a chromogenic method:

- BIOPHEN Factor X (Ref. A221705) 100 tests RUO

Standards and controls:

- BIOPHEN Plasma Calibrator (Ref. A222101) 12x1 mL IVD
- BIOPHEN Normal Control Plasma (Ref. A223201) 12x1 mL IVD
- BIOPHEN Abnormal Control Plasma (Ref. A223301) 12x1 mL IVD