

# ANIARA

Manufactured By: HYPHEN BioMed

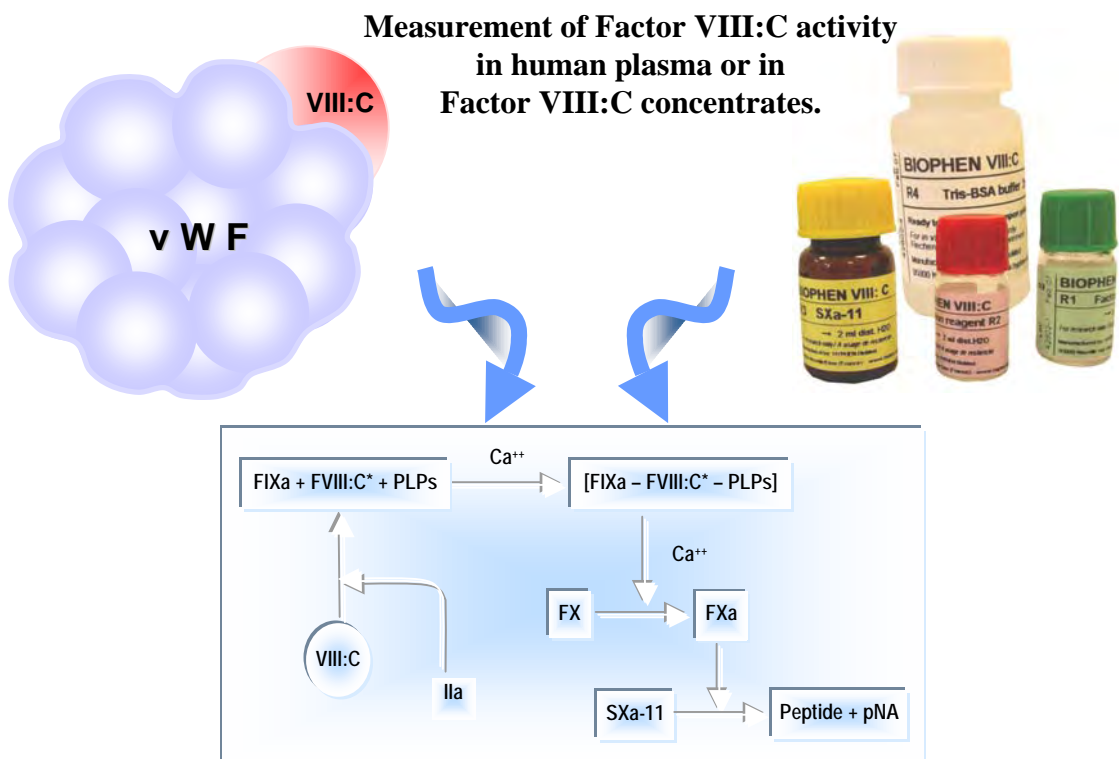
# CE

## BIOPHEN VIII:C

### Factor VIII:C Chromogenic assay

Ref. A221402

**A reference method, which can be used with manual or automated techniques.**



- A fully homogeneous assay, using only highly purified human proteins.
- Designed with highly characterized synthetic phospholipids.
- Complies with European Pharmacopea Recommendations.
- Large excess of Factor X (< 40 % converted to Xa during the assay time).
- Offers a high (concentrates and high factor VIII:C concentrations in plasma) and a low working range ( Von Willebrand disease and haemophilia A).

Form AH18  
4-2007

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May 2006/REF 007



# BIOPHEN VIII:C

## (Ref. A221402)

Chromogenic assay of Factor VIII:C activity in plasma or concentrates

### Assay principle

- BIOPHEN Factor VIII:C is a chromogenic assay for testing the cofactor activity of Factor VIII:C.
- When activated by thrombin, Factor VIII:C forms an enzymatic complex with Factor IXa, phospholipids and Calcium, which activates Factor X to Factor Xa.
- 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 in presence of a constant and in excess amount of Factor IXa. Generated Factor Xa is then exactly 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.
- Finally, there is a direct relationship between the amount of Factor VIII:C in the assayed sample and the Factor Xa activity generated, measured by the amount of pNA released, determined by colour development at 405nm.

### Kit presentation

#### R1: Reagent 1: Human Factor X

Human Factor X, lyophilised in presence of a fibrin polymerisation inhibitor; 2 vials.

#### R2: Reagent 2: Activation Reagent

Factor IXa (human), containing human thrombin, calcium and synthetic phospholipids, lyophilised; 2 vials.

#### R3: Reagent 3: SXa-11

Chomogenic substrate, specific for Factor Xa (SXA-11), lyophilised. 2 vials containing SXa-11 with a thrombin inhibitor.

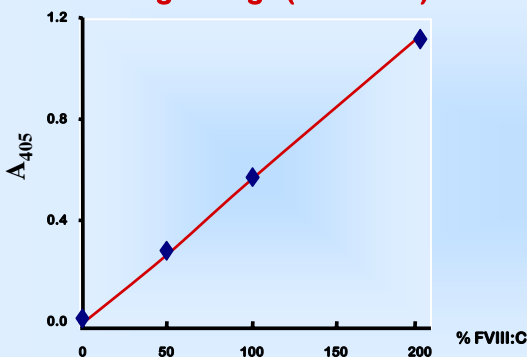
#### R4 : Reagent 4: Tris-BSA Buffer

Tris-BSA Buffer, ready to use, containing sodium azide (NaN<sub>3</sub>). 4 vials of 25 mL.

### Procedure

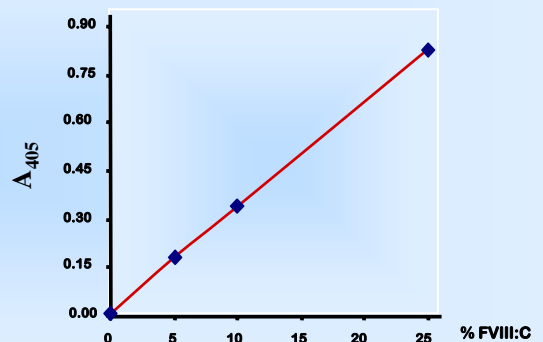
- Specimen: citrated human plasma, or factor VIII:C concentrates.
- Plasma Dilution: High range → 1:40; Low range → 1:10.
- Concentrates' Dilution: predilution to 50 – 200 %, then → 1 : 40.
- Calibration: factor VIII:C calibrator or standard.
- End-point method or kinetics protocols.

#### High Range (0 to 200%)



### Calibration Curves

#### Low Range (0 to 25%)



### Assay Characteristics

- Total assay time : **10 minutes** or below
- Assay range : **0 to 200 %** for high range  
**0 to 25 %** for low range
- Reproducibility: **< 2 %**
- Detection limit : **about 0.5 %** for low range
- Specificity : Factor VIII: C deficient plasma **< 1 %**
- Adaptations to automatic instruments available
- Can be used with microplate methods

IVD = In Vitro Diagnostic Use = CE RUO = Research Use Only

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### Other related

### Products

- Factor VIII deficient plasma (# ADP040A) - RUO
- vWf deficient plasma (# ADP150A) - RUO
- ZYMUTEST vWF (# ARK030A) - IVD

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