ANIARA DIAGNOSTICA LLC

Please note that the uses described in the following page(s) have not been approved or cleared by FDA, with respect to the described assay or test.

In the US, the product is intended **For Research Use Only. Not for Use in Diagnostic Procedures.**

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ANIARA

Manufactured By: HYPHEN BioMed

BIOPHEN FVIII:C technical file (#A221402) (A221406 in progress)

Intended use and applications

IVD: ☒ CE ☐ 510(k) in progress ☐ RUO

Diagnosis of congenital or acquired FVIII:C deficiencies (Haemophilia A); Assay of FVIII:C activity in citrated human plasma or therapeutic concentrates; Follow-up of FVIII:C recovery in treated patients.

Principle

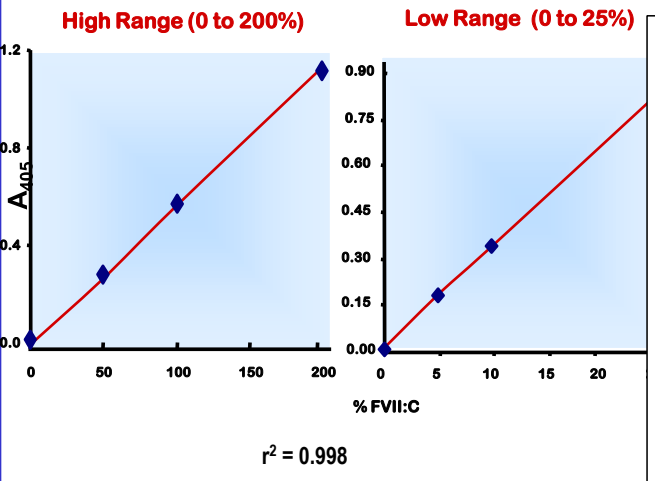
Quantitative determination of FVIII:C activity in human citrated plasma or in concentrates, using a chromogenic method, manual or automated.

R1: Human FX, lyophilised in presence of a fibrin polymerisation inhibitor.
R2: Activation Reagent ((h)FIXa, (h)thrombin, calcium and synthetic PLPs) lyophilised.
R3: FXa specific chromogenic substrate (SXa-11), lyophilised with a thrombin inhibitor.
R4+ : Special Tris-BSA Buffer with stabilizers, ready to use

Characteristics and advantages

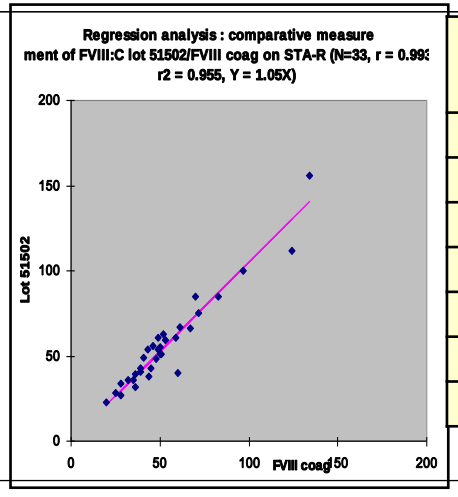
- **Complies with European Pharmacopoiea recommendations**
- **Fully homogeneous assay, safe, optimized, standardized**: highly purified human proteins (and FX in large excess); special R4+ buffer with stabilizers; highly characterized synthetic phospholipids; inter lots correlation r2=0.96
- **Simple and rapid:** ready to use after reconstitution; total assay time < 10 min.
- Easy to use on major **coagulation analyzers, microplate or with basic equipment (** ~65 -100 tests per kit (STAR- microplate)).
- **Associated calibrators and controls** validated against the International Standard for FVIII:C (NIBSC).
- Dynamic range ~ **0 - 25% (low range for vWD and haemophilia A) or ~0-200% FVIII:C (high range for concentrates and high plasma FVIII:C)** (dilution 1:10 or 1:40 in R4+)
- Detection threshold ~**0.5%** for the low range
- Highly **specific, sensitive, reproducible** (FVIII:C deficient plasma <1%; Intra assay CV <3% ; Inter assay CV <5%
- **Highly stable (** 72 hours at 2-8 C , 24 hours at RT(18-25 C), or frozen).
- No significant interference of heparin<1IU/ml added to plasma.

Calibration curves (STAR)



Performance comparison with commercial devices on plasmas, recovery

Compared with a conventional FVIII:C clotting assay on STAR, on plasmas



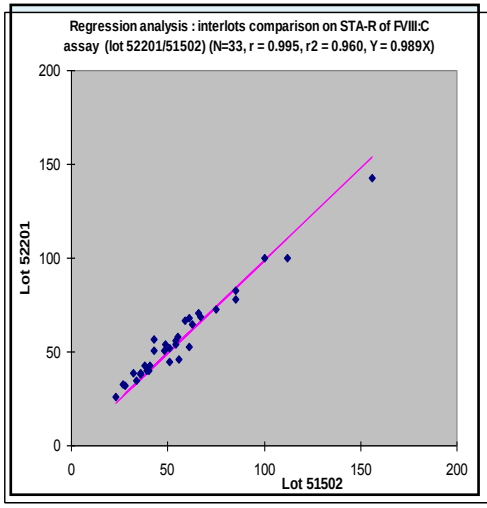
Recovery: normal in FVIII:C deficient	Clotting	Biophen
0%	2.0	0.2
1%	3.0	1.1
2%	4.0	2.1
5%	6.8	4.7
10%	11.7	10.4
50%	50.7	49.6
100% FVIII:c	104.2	104.4

Biophen STAR Low rg.	
Haemophiliacs N=10	
Mean %VIII:C	7.8
Min-Max %	1-13
FVIII:C %: Recovery : (normal in FVIIIc deficient)	
25%VIII:C	25
10	10
5	5
2	2
1	1
0	0

Excellent consistency and recovery, on the high and low range.

Inter lots

• Inter lots: N=33 r2 = 0.96



Excellent interlots correlation.

Related products

1 Biophen Plasma Calibrator, Normal and Abnormal Control Plasmas (#A222101/A223201/A223301)
2. FVIII:C deficient Plasma (#ADP040A/K)
3. Zymutest vWF (#ARK030A)
4. vWF deficient plasma (#ADP150A/K)
5. Biophen FIX (#A221802/A221805)

Related references:

1. S. E. Rodgers, E. M. Duncan, M. Sobieraj, J. V. Lloyd, Evaluation of three automated chromogenic FVIII kits for the diagnosis of mild discrepant haemophilia A Int J Lab Hematol. 2008 Jan 7; : 18190586 (P,S,E,B)
2. Duncan EM, Rodgers SE, Sobieraj-Teague M, Casey CR, Lloyd JV. Laboratory diagnosis of teh discrepant phenotype of mild haemophilia using a modified chromogenic FVIII assay. J Thromb Haemost 2007; 5 Suppl2: P-S-157.

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