

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.

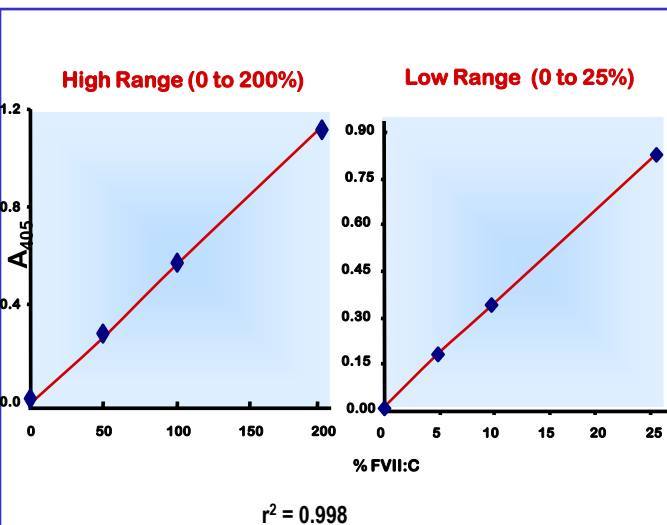
R3: FXa specific chromogenic substrate (Sxa-11), lyophilised with a thrombin inhibitor.

R4+ : Special Tris-BSA Buffer with stabilizers, ready to use

Characteristics and advantages

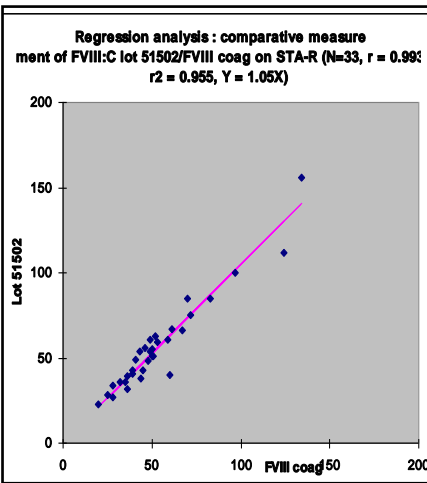
- Complies with European Pharmacopoeia recommendations
- **Fully homogeneous assay, safe, optimized, standardized:** highly purified human proteins (and FX in large excess); special R4+ buffer with stabilizers; highly characterized synthetic phospholipids; inter lots correlation $r^2=0.96$
- **Simple 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



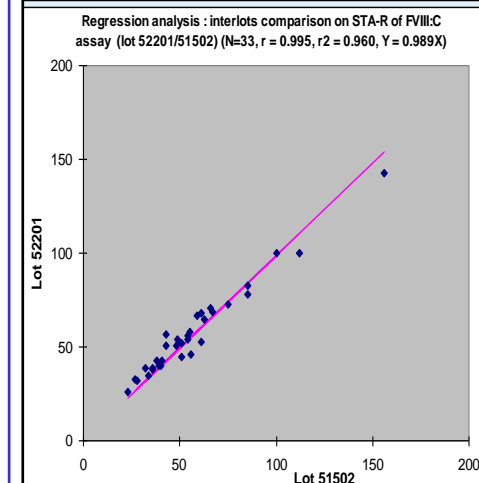
| Recovery: normal in FVIII:C deficient | Clotting | Biophen |
|---------------------------------------|----------|---------|
| 0% | 2.0 | 0.2 |
| 1% | 3.0 | 1.1 |
| 2% | 4.0 | 2.1 |
| 5% | 6.8 | 4.7 |
| 10% | 11.7 | 10.4 |
| 50% | 50.7 | 49.6 |
| 100% FVIII:c | 104.2 | 104.4 |

| Biophen STAR Low rg. | |
|--|------|
| Haemophiliacs N=10 | |
| Mean %FVIII:C | 7.8 |
| Min-Max % | 1-13 |
| FVIII:C %: Recovery : (normal in FVIIIc deficient) | |
| 25%FVIII: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 $r^2 = 0.96$



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.