

Intended use and applications

IVD: CE 510(k) RUO

Clotting assay proposed for testing the presence of Factor V-L (Factor V Leiden) in human citrated plasma, by its resistance to the action of Activated Protein C (aPC), using a manual or automated method.

Principle

In presence of APC, the prolongation of clotting time (CT) is directly related to the concentration of Normal FV, and inversely related to the amount of FVL (mutation R506Q), insensitive to the action of APC.

Patients with FVL are exposed to an increased thrombotic risk.

R1: Clotting mixture, lyophilised.

R2A / R2B : Purified (h) FX with cephalin, without or with aPC, lyophilised.

R3: (h)FIXa, with calcium, lyophilised.

Performance comparison with commercial devices

Eg compared with Coatest aPCrV (Chromogenix):

STAR (N=27)	COATEST APCr V		
	Ratio	R ≥ 2 (normal)	R ≤ 2 (FVL)
	HEMOCLOT FVL	R ≥ 2 (normal)	24
	R ≤ 2 (FVL)	0	3

	On BCS (N=93)	
	Coatest APCrV	Hemoclot FVL
Nb of Normal plasmas (R>2.0)	77	77
Nb of APCr Plasmas (R<2.0)	25	25
Control Normapool (ratio)	2.51	2.14
Control Plasmapep (ratio)	2.71	2.39
BIOPHEN ActPCr Control (ratio)	1.88	1.61

Excellent consistency, on various instruments.

Characteristics and advantages

- **Reliable, simple and rapid:** total assay time < 5 min.
- **Excellent discrimination between Heterozygous, Homozygous and Normals.**
- Two Clotting Times (with (CT2) or without (CT1) aPC, on 1:5 plasma dilution) and calculation of ratio (CT2/CT1):
 Normal plasma (normal FV): CT2/CT1 ≥ 2.00
 Plasmas from patients carrying the R506Q mutation of Factor V (Factor V-L) : CT2/CT1 ≤ 1.80.
 1.80 < CT2/CT1 < 2.00 ?? ⇒ confirm using molecular biology.
- Easy to use **on major coagulation analyzers or with basic equipment** (~2 or 4 series of 40 patients on STAR).
- **Highly stable** (24 hours at 2-8°C , 8 hours at RT(18-25°C) or frozen)
- **Safe, optimized, standardized** with highly purified human factors
- **No interference of plasma factor deficiencies (other than that of FV), results interpretable for heparinized plasmas.**

Inter lots and inter-instruments

	Manual method				STA			
	LOT 1		LOT 2		LOT 1		LOT 2	
	R<2	R>2	R<2	R>2	R<2	R>2	R<2	R>2
For N=64 plasmas « without selection »	6	58	6	58	6	58	6	58
For N=18 « supposed APCr »	10	8	10	8	10	8	10	8
For N=24 « dicumarol treated »	1	23	1	23	1	23	1	23

Excellent consistency from lot to lot, on multiple instruments.

Related products

1. Normal and ActPCr Control Plasmas (#A223201/A223405)
2. Hemoclot FVL Quanti (#ACK065K)
3. Hemoclot FV reagent (#ACK071K)
4. Zymutest FV (#ARK009A)

Form AH127
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