ANIARA
Manufactured By: HYPHEN BioMed

BIOPHEN Protein C (PC) technical file (#A221202/A221205)

Intended use and applications

IVD: ☒ CE ☒ 510(k) ☐ RUO

Diagnosis of congenital or acquired PC deficiencies (eg in dicumarol therapy, hepatic diseases, recurrent venous thromboses, or in DIC contexts).

Principle

Quantitative determination of PC activity in human citrated plasma, using a chromogenic method, manual or automated.

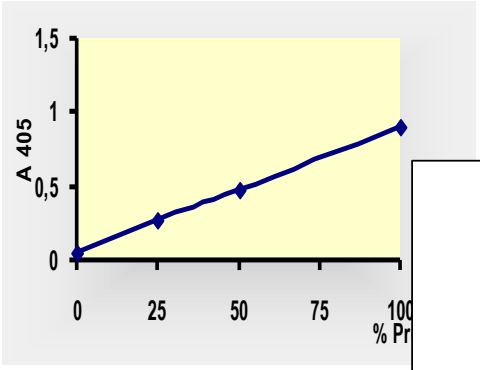
R1: Protac® (PC activator) lyophilised.

R2: aPC specific chromogenic substrate (SaPC-21), lyophilised.

Characteristics and advantages

- **Simple and rapid:** ready to use after reconstitution; total assay time < 15 min.
- Easy to use on major **coagulation analyzers, microplate or with basic equipment (** ~60-75 or 160-200 tests per kit (STAR-microplate).
- **Associated calibrators and controls** validated against the International Standard for PC (NIBSC).
- Dynamic range ~ **0 - 100% PC in human citrated plasma** (dilution **1:2** with physiological saline)
- Detection threshold < **5%**
- Highly **specific, sensitive, reproducible** (PC deficient plasma <5%; Intra assay CV 0.4-1.2 % ; Inter assay CV 1.3-2.0 %)
- **Highly stable (** 3 months at 2-8 C , 3 days at RT(18-25 C)).
- **Safe, optimized, standardized**: highly purified raw materials; inter lots correlation r2=0.95
- **No significant interference of** heparin<1IU/ml, bilirubin<0.1mg/ml, haemoglobin<1mg/ml, triglycerides<1.25mg/ml added to plasma.

Calibration curve (Manual method)

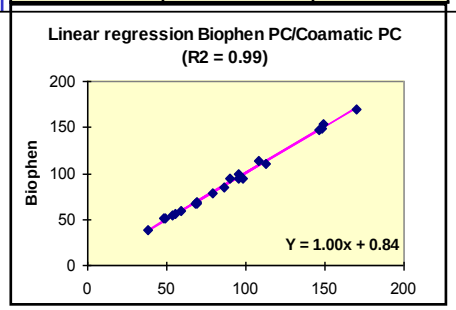


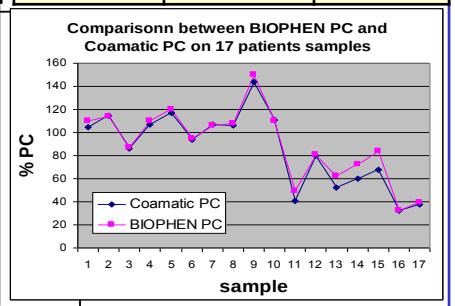
Performance comparison with commercial devices

Eg compared with Coamatic PC (Chromogenix) for PC measurement on patients plasmas:

On BCS	Coamatic	Biophen
N	21	21
Mean %PC	**89.8**	**87.5**
Median	86	85
SD	36.8	36.9
Min-Max	38-170	39-169

On STA	Coamatic	Biophen
N	17	17
Mean %PC	**86.1**	**89.9**
Median	94.0	95.0
SD	31.6	30.5
Min-Max	32-144	32-150





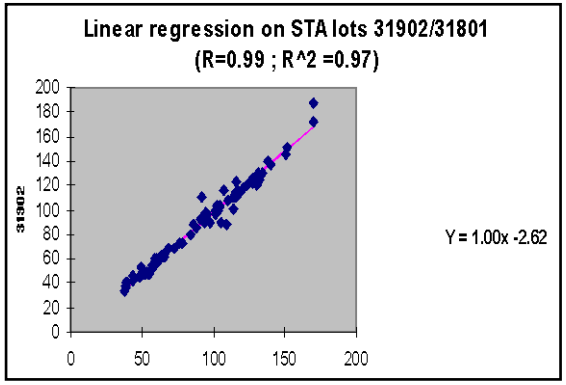
Excellent consistency, on various instruments.

Inter lots and inter-instruments

• Study on N=54: Inter lots by manual method: Y=1.02X-2 r2 = 0.95

lot:	STA		Manual method	
	31902	31801	31902	31801
Mean %PC	110.4	112.6	110.1	109.5
Median	108.0	109.5	106.0	106.0
SD	21.8	20.4	18.3	17.4
Min-Max	73-188	76-170	82-164	82-162

• Study on N=83:



Excellent correlation on the dynamic range from lot to lot, on multiple instruments.

Related products

1. Biophen Plasma Calibrator, Normal and Abnormal Control Plasmas (#A222101/A223201/A223301)
2. Hemoclot Protein C (#ACK031K)
3. Zymutest PC (#ARK027A)
4. Protein C deficient Plasma (#ADP100A/K)

ANIARA
7768 Service Center Drive • West Chester OH 45069
Phone: 513.770.1991 **Toll Free:** 866.783.3797 **Fax:** 513.573.9241 **Email:** info@aniara.com
www.aniara.com

Form AH125
02-2010
D.750.30/BI/1202/1205/1 (Aug2009)