BIOPHEN
Act. PC-r CONTROL PLASMA
223405

Human plasma, pathological control, for Act. PC-r assays

For in vitro diagnostic use only.

HYPHEN BioMed
www.hyphen-biomed.com
155, rue d'Eragny
95000 NEUVILLE SUR OISE
FRANCE
Tel. : +33 (0)1 34 40 65 10
Fax : +33 (0)1 34 48 72 36
info@hyphen-biomed.com

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ENGLISH

INTENDED USE:

Biophen Act. PC-r Control Plasma kit contains human plasma, presenting an Activated Protein C Resistance (APC-R), usually correlated with the genetic mutation of Factor V R506Q. This plasma is used as quality control plasma for the testing of Activated Protein C Resistance (APC-R).

Activated Protein C is a regulator of the coagulation cascade, by specifically inactivating factors Va and VIIIa, in the presence of phospholipids and calcium (1).

In most of the cases (more than 90%), Activated Protein C Resistance phenotype is caused by a Factor V gene mutation, called « Factor V Leiden ». The mutation, located on Factor V exon 10 (1691 G → A), of arginine to glutamine on position 506, renders Factor Va resistant to the cleavage by Activated Protein C. This genetic anomaly can be evidenced with a clotting method performed in the presence or the absence of Activated Protein C.

Activated Protein C Resistance is tested by using a clotting method performed with or without Activated Protein C (Hemoclot FVL), or with Activated Protein C (Hemoclot Quanti VL).

COMPOSITION:

Act. PC-r Control Plasma kit contains 12 vials of 0.5 ml of human plasma, presenting an APC-R, citrated and lyophilised.

Note:
- Each donor unit used for the preparation of BIOPHEN Act. PC-r Control, Plasma is a human plasma, which has been tested with registered methods for the presence of Hepatitis B Surface Antigen, Hepatitis C Antibodies (HVC), and antibodies to VIH1 and 2 and found negative. However, no test can completely exclude the presence of infectious agents. Any product of human origin, and more especially plasma, must be considered as being potentially infectious and must be handled with all the required cautions for this kind of material.
- BIOPHEN Act. PC-r Control Plasma contains an antibiotic (ciprofloxacin) as preservative.

STORAGE CONDITIONS:

Unopened reagents, must be stored at 2–8 °C. Kept in their original packaging they are then stable until the expiration date printed on the label.

Note : The stability studies at 30°C show that all the reagents can be shipped at room temperature without damage.

REAGENTS PREPARATION AND STABILITY:

Preparation:

– Reconstitute each vial with exactly 0.5 mL of distilled water.
– Shake thoroughly until complete dissolution of the content (vortex).
– Incubate at room temperature (18-25°C) for 30 min, while shaking the vial from time to time.
– Homogenise the content before each use.

Stability after reconstitution:

- 24 hours at 2-8°C.
- 8 hours at room temperature.

Do not freeze.

Cautions **:**

- In order to improve stability, reagents must be closed with their original screw caps following each use.
- Reagents must be handled with care, in order to avoid any contamination during use.
- It is recommended to homogenise each vial before use, in order to have a good reproducibility, all the time.

EXAMPLE OF RESULTS:

This value, indicated as an example only, was determined with a clotting method performed with or without Activated Protein C :

BIOPHEN Act. PC-r Control Plasma	**CT* ± APC**	**%FVL (Hemoclot Quanti VL)**
	1.33	51%

Specifications: CT* (+APC) / CT* (-APC) ≤ 1.80
%FVL between 25 and 75%

***Note** : CT*: clotting time*

PERFORMANCES:

- This plasma is validated internally and complies to the specifications previously described.

CHARACTERISTICS:

Plasma presenting an Activated Protein C Resistance, as determined with a clotting assay.
The exact value and the acceptance range obtained for each lot (ratio of CT with or without APC) are indicated on the flyer included in the kit.

LIMITS:

- Like all lyophilised plasmas, the plasmas from the BIOPHEN Act. PC-r Control Plasma kit are more or less cloudy after reconstitution. This is due essentially to the lipids that, after lyophilisation, become less soluble and can form a light deposit.
- Reagents must be handled with care, in order to avoid any contamination or activation during use. Any plasma containing a coagulum or a contamination must be rejected.

REFERENCES :

1. Samama M. et all. Prevalence and patient profile in Activated protein C resistance ; Coagulation and Transfusion medicine vol ; 104 450-454 (1995).
2. Rogier M. Bertina et all. Mutation in blood coagulation factor V associated with Resistance to Activated protein C. Nature, vol 369 64-66 (1994).
3. Catherine Leroy-Matheron et all. The 1691 G→ A mutation in the factor V gene : relationship to Activated protein C (APC) Resistance an thrombosies in 65 patients. Thrombosis and hemostasis vol 75 (1) 4-10 (1996).
4. Marc Vasse et all. Resistance to Activated Protein C : evaluation of three functional assays. Thrombosis research Vol 76 N° 1 47-59 (1994).