

High Positive™ Prekallikrein Activator (PKA) Control

A high positive control for assays of Prekallikrein Activator in biological fluids

PRODUCT CODE: PW52005

5x0.5ml

For Research Use Only

Product Description

Intended use

The method for the determination of Prekallikrein Activator (PKA) in human plasma derived products is based on the activation of a prekallikrein preparation from human plasma. The PKA present in the sample activates plasma prekallikrein to plasma kallikrein, which then hydrolyses a chromogenic peptide substrate for plasma kallikrein. The amount of colour generated is monitored spectrophotometrically and is directly proportional to the amount of PKA present in the sample.

High Positive Prekallikrein Activator (PKA) control can be used as a control for assays of PKA in conjunction with the Just Positive™ borderline positive control.

Composition

High Positive Prekallikrein Activator (PKA) Control is prepared from a plasma fraction containing PKA and albumin.

Additional material required

- A Pathway Diagnostics Prekallikrein Activator (PKA) assay kit, (shown below), or an "in-house" PKA assay:

REF PW30100 Prekallikrein Activator (PKA) assay kit
90 tests

REF PW301EP Prekallikrein Activator (PKA) assay kit
90 tests

Warnings and Precautions

- For Research use only.
- The Prekallikrein Activator (PKA) control has been prepared from human plasma and as with all blood and plasma samples it should be treated as potentially infectious and handled with appropriate care.
- Each single plasma donation used in the production of this product has been tested and found to be non reactive for HbsAg, Anti-HIV 1 & 2, Anti HCV and Syphilis. **However as a human source product it be treated as a potentially infectious and handled appropriately.**
- The High Positive Prekallikrein Activator (PKA) control is supplied in glass vials and these should be visually inspected before use. In the event of cracked or broken vials care should be taken to avoid cuts and abrasions. Broken glass should be disposed of in a suitable receptacle and any work areas affected by spillages should be decontaminated using suitable materials.

Stability and Storage

The expiry date printed on the bottle labels refers to the storage of unopened bottles stored at 2 to 8°C.

The reconstituted High Positive Prekallikrein Activator (PKA) Control is stable for 4 hours at 4°C and should not be stored for re-use.

Preparation and performance of the test

- Open the vial carefully and reconstitute the contents in **0.5ml** of sterile distilled water.
- Allow the reconstituted High Positive™ Prekallikrein Activator (PKA) Control to stand for 10 minutes at room temperature then swirl gently to ensure adequate mixing.
- Test the reconstituted High Positive™ PKA Control in the same way as a test sample, but **without further dilution** according to the Pathway Diagnostics Prekallikrein Activator (PKA) assay kit instructions. If the control is being tested using an in-house PKA assay the High Positive™ PKA Control should be tested in the same way as a test sample with a high PKA concentration.

Test standardisation and limitations

The production and standardisation of High Positive Prekallikrein Activator (PKA) Control is controlled by the use of the 2nd International Standard for PKA^(1,2).

The level of PKA in High Positive™ Prekallikrein Activator (PKA) Control is batch specific and assigned using the Pathway Diagnostics Prekallikrein Activator (PKA) assay kit. The control is intended as an accuracy control of the Pathway Diagnostics Prekallikrein Activator (PKA) assay, but can also be used as a control in "in-house" PKA assays.

The batch specific control ranges assigned using the Pathway Diagnostics PKA test are shown in the table printed on the reverse side of this insert.

Literature

1. Longstaff C, Behr-Gross M-E, Daas A, Lackner F. An international collaborative study to replace the 1st international standard for prekallikrein activator. *Vox Sanguinis* 2005; 88:143-151.
2. Longstaff C, Behr-Gross M-E, Daas A, Lackner F. Collaborative Study to Establish a new Biological Reference Preparation for Prekallikrein Activator. *Pharmeuropa-Bio*, 2005-1, 1-11.



High Positive™ Prekallikrein Activator (PKA) Control

Batch CB01801

The following control ranges were established using the Pathway Diagnostics PreKallikrein Activator Assay kits PW30100 and PW301EP calibrated against the 2nd International standard for PKA:

Control	Batch	Mean IU	Range IU
High Positive Control for PKA	CB01801	15.6	14.1 – 17.5