Prekallikrein activator

QC of human IgG and albumin products in compliance with the European Pharmacopoeia

- Standardized ready-to-use chromogenic assay kits to measure PKA
- PKA standard & controls are calibrated against the 3rd International Standard for PKA
- Unique blocking reagent eliminates the problem of high blanks in IgG fractions
- Full compliance with the European and US Pharmacopoeia guidelines

The determination of prekallikrein activator (PKA) levels is a requirement for batch release of human albumin and immunoglobulin preparations according to the European and US Pharmacopoeia guidelines.

According to the Pharmacopoeia guidelines, PKA assays are performed using a Prekallikrein pool, produced in-house or purchased commercially, and an externally sourced chromogenic substrate and PKA standard. The in-house production of the Prekallikrein pool is time-consuming and technically difficult to perform consistently.

The new alternative from Eurobio Scientific for batch release testing:

- a ready-to-use Prekallikrein Pool together with your separate components
- our complete PKA assay kits

Key features

- Assay kits of matched reagents that are Pharmacopoeia compliant
- Standard & mid-level kit control calibrated against the 3rd International Standard for PKA
- Assay reliability and continuity with minimal batch-to-batch variation
- Unique high-blank blocking reagent to accurately measure PKA levels in immunoglobulin preparations, even at low levels
- New lyophilised Prekallikrein Pool that is quick and easy to reconstitute to a clear solution that is stable for up to 6 months
- High activity for improved assay sensitivity
- Long shelf life and large batch sizes enabling continuity across multiple testing centres
- Separate high and low PKA accuracy controls for use in any PKA test configuration

Two PKA kits are available:

PW301EP can be used for the determination of PKA in human blood products and biologicals. The alternative PW302EP kit can be used for the same purpose but is optimized for measurement of immunoglobulin products by overcoming the susceptibility to high test blank levels. To eliminate this problem, this kit includes an additional blanking step to run with the existing method recommended by the Pharmacopoeia.

The PKA standard and the kit control in both assay kits are calibrated against the 3rd International Standard for PKA. The Prekallikrein Pool in the kits is prepared according to the procedure recommended by the European Pharmacopoeia; it is very stable and has minimal batch-to-batch variation. All assay components are quality controlled and a Certificate of Analysis is provided. Optional high & low PKA controls can be used and are available separately.

PKA test principle

The test measures PKA present in the blood product which will activate a known concentration of prekallikrein to release the enzyme kallikrein. The kallikrein formed releases chromogene p-nitroaniline (pNA) from the chromogenic kallikrein substrate. The rate at which pNA is released is measured photo-metrically in a microtitre plate reader. The amount of pNA released is proportional to the amount of PKA present in the preparation. The assay can be performed as rate method or by end point.

Procedure

> Dilute 100 µl of sample 1:1 with diluent.
> Add 50 µl of Prekallikrein solution, mix and incubate for 45 minutes at 37°C.
> To 25 µl of above incubates, add 100 µl of diluted kallikrein substrate.
> Transfer to plate reader set at 405 nm and 37°C.
> For rate assay: measure absorbance change from 2-4 minutes.
> For end point: incubate for exactly 5 minutes, read OD.
> Calculate values by subtracting OD from the blanks and read from standard curve.
> Validate results by determining whether Just Positive and High Positive controls are in range.

Products

Catalogue No.	Product	Tests
PW301EP	Prekallikrein activator (PKA) assay Kit - EP method	90 tests
PW302EP	Prekallikrein activator (PKA) assay Ig Kit - EP method	90 tests
PW30505	Human Prekallikrein pool	5 x 2.0 ml
PW53005	Low positive PKA control	5 x 0.50 ml
PW52005	High positive PKA control	5 x 0.50 ml

eurobio SCIENTIFIC

TECOmedical GmbH
A Eurobio Scientific Company
Marie-Curie-Str. 1
53359 Rheinbach, Germany
Phone: +49 2226 872 455
Mail: info@tecomedical.com
www.tecomedical.com
www.eurobio-scientific.com