

Certificate of Analysis



Ref. No.: COA0022

Lot: xxxxxx

Expiration Date: xxxx-xx

Description: Lyophilised Prekallikrein-Pool / Prekallikrein Substrate for the determination of Prekallikrein Activator (PKA) in human Albumin and Immunglobulin preparations according to Ph.Eur.
For Research Only. Not for use in diagnostic procedures. For *in vitro* use only

Volume: Reconstitute each vial with 2.0 mL aqua dest.
Allow to stand for 15 minutes at 15-25°C. Swirl gently before use.

Storage: Store unopened vial at 2-8°C. The stability after reconstitution is up to 24 hours at room temperature, 48 hours at 2-8°C or 2 months at -20°C when stored in the original vial. The frozen reagent should be thawed at 37°C and gently mixed before use. Do not refreeze.

Specification:	<u>Specification</u> ($\Delta OD_{405/10 \text{ min}}$)	<u>Result</u> ($\Delta OD_{405/10 \text{ min}}$)	<u>Disposition</u> (pass/fail)
Non-specific activity:	<0.01	0.004	pass
PK-activity at 32 IU/mL:	0.20-0.50	0.448	pass

CAUTION: Each donor unit used in the preparation of human source reagent has been tested by FDA approved methods for the presence of Hepatitis B surface antigen, antibodies to HIV 1, 2, Hepatitis C and found to be negative. However, since no test can completely rule out the presence of these blood borne diseases, the handling and disposal of human source reagents should be made with care.

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