Human Prekallikrein Activator (PKA) Reference standard

Cat. No. PKA-9H **Lot. No.** (See product label)

SPECIFICATION

Product Overview	Prekallikrein Activator (PKA), also known as activated FXII or activated Hageman Factor, is a contaminant in human albumin solutions and immunoglobulin solutions prepared from fractionated plasma. It is known that adverse events, including vasodilation and hypotension, may occur where albumin solutions are contaminated with significant levels of PKA and are infused into patients. This is of special concern since albumin may be administered as a plasma expander to counter hypovolemia and hence the treatment may exacerbate the existing problem.
Species	Human
Enzyme Unit	Each ampoule contains 29 IU of PKA when reconstituted in 1 ml of distilled water. Complete dissolution of the freeze dried plug may take up to 30 min and care should be taken to ensure that all solid material has been completely dissolved. Best results are obtained with gentle swirling.
Usage	No attempt should be made to weigh out any portion of the freeze-dried aterial prior to reconstitution. The Standard is intended to be used as a primary reference calibrator for secondary working standards in a similar assay. This standard is available in larger quantities and may be suitable as a working standard.
Notes	This preparation is not for administration to humans. The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. As with all materials of biological origin, this preparation should be

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	regarded as potentially hazardous to health. It should be used and discarded according to your own laboratorys safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.
Stability	Reference materials are held at Creative Biomart within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label. Samples were held at -20, 4, 20, 37 and 45 °C for 10.5 months and potencies determined in three laboratories to calculate loss of activity due to elevated temperature relative to the sample kept at -20 °C. Accurate predictions of percentage loss per year are difficult from single time points, however, analysis of the raw data according the Arrhenius model predict a loss PKA activity of only 0.13 % per year. Stability at ambient temperatures in also excellent allowing shipping of the IS without refrigeration. It is recommended that samples be stored at -20 °C for extended periods.
Storage	Ampoules stored at -20 °C should be brought to room temperature before opening and reconstitution of the freeze dried contents. Please note: because of the inherent stability of lyophilized material, Creative Biomart may ship these materials at ambient temperature. Vigorous mixing or vortexing should be avoided as this causes foaming leading to incomplete solubilisation of the ampoule contents. Once reconstituted, the PKA solution should be stored on ice and used within 1 day.

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