

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product name:	High Positive™ Prekallikrein Activator (PKA) Control
1.1 Code:	PW52005
1.2 Recommended use:	In-vitro Control Reagent for Prekallikrein Activator (PKA) Assays
1.3 Manufacturer:	Pathway Diagnostics Ltd Eclipse House, Curtis Road Dorking, RH4 1EJ, UK Tel: + 44 1306 888777 Fax: + 44 1306 883883
1.4 Emergency Phone:	+ 44 1306 888777

2. COMPOSITION / INGREDIENTS INFORMATION**2.1 Kit contents:**

- High level Prekallikrein Activator (PKA) Human plasma fraction

3. HAZARDS IDENTIFICATION

3.1 Prekallikrein Activator (PKA) Control: Products derived from human plasma. Handle with care, observing the precautions recommended for bio-hazardous material. The human plasma used has tested negative for antibodies to HIV Type 1 and 2, Hepatitis C and Hepatitis B surface antigen. However since no test method can offer complete assurance that infectious agents are absent these human plasma should always be handled with care, observing the precautions recommended for a bio-hazardous material.

3.2 Emergency overview: General rules for handling biological material have to be followed

3.3 Health hazard: Minimal health hazard upon ingestion or risk of combustion.

4. FIRST AID MEASURES

4.1 Skin Contact:	If a component of this product contacts the skin wash the affected area with skin disinfectant.
4.2 Eye Contact:	If a component of this kit enters the eyes and causes discomfort, wash eyes gently under potable running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.
4.3 Inhalation:	Inhalation of any component in this kit is unlikely. If a component of this kit is inhaled seek medical advice immediately.
4.4 Ingestion:	If a component of this kit is ingested, wash mouth out with water and seek medical attention.
4.5 Other:	In case of injury and contamination with human plasma material it is strongly recommended to obtain medical attention.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media:	No limitation. For small fires, use dry chemical, carbon dioxide, or alcohol-resistant foam.
5.2 Flammable properties:	None

6. ACCIDENTAL RELEASE MEASURES

- 6.1 Personal precautions:** This kit contains materials of biological origin. Wear gloves to avoid personal contact. Use Universal Precautions during clean-up procedures
- 6.2 Clean up procedures:** Absorb liquid and place in container suitable for disposal. Dispose of in accordance with applicable local procedures.

7. HANDLING AND STORAGE

- 7.1 Handling:** For Professional use only.
Wash thoroughly after handling components of this kit. Do not eat or drink while using this product. This product should be handled only by qualified clinical or laboratory staff trained on the use of this kit and who are familiar with the potential hazards. This kit should be handled as though capable of transmitting infectious diseases. Universal Precautions should be followed when using this product.
- 7.2 Storage:** Store at +2°C to +8°C

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

- 8.1 Ventilation:** No particular ventilation requirements are necessary.
- 8.2 Respiratory protection:** None needed under normal conditions of use.
- 8.3 Hand protection:** Impervious gloves should be worn to prevent hand contact.
- 8.4 Eye protection:** Safety glasses are recommended to prevent eye contact.

9. Physical and Chemical Properties

- 9.1 Appearance:** Solid
- 9.2 Colour:** Colourless
- 9.3 Odour:** Odourless
- 9.4 Solubility:** Miscible with water
- 9.5 Viscosity:** No data available
- 9.6 pH-value:** pH 7.4 – pH 8.3

10. STABILITY AND REACTIVITY

- 10.2. Materials to avoid:** None known
- 10.2. Hazardous reactions:** None known if handled correctly
- 10.3. Hazardous decomposition:** Thermal decomposition may release irritating fumes or toxic gases

11. TOXICOLOGICAL INFORMATION

- 11.1. Acute toxicity:** Not known
- 11.2. Skin effects:** Not known
- 11.3. Eye effects:** Not known

11.4. Other: No cases of intoxication known so far. Human Plasma used for the production of the test product components is derived exclusively from donors who have been tested negative for antibodies against HIV 1/2, HCV and HBs antigen using approved test procedures. Nevertheless human plasma should be considered as potentially infectious and handled with care.

12. ECOLOGICAL INFORMATION

12.1. Ecotoxicity: No adverse effects on the environment are expected from the components of this product. There is no aquatic toxicity data for any component of this product at this time.

13. DISPOSAL CONSIDERATIONS

13.1. Product disposal: Incineration according to local and national legislation.
13.2. Packaging disposal: Dispose of in a manner in accordance with local and national regulations.

14. TRANSPORT INFORMATION

14.1. UN. No.: Not applicable
14.2. Road and rail transport (ADR/RID): Not applicable
14.3. Air transport (ICAO/IATA-DGR): Not applicable
14.4. Sea transport (IMO/IMDG): Not applicable
14.5. Inland navigation (AND(ADNR): Not applicable
14.6. Other information: None

15. REGULATORY INFORMATION

15.1: Not classified as dangerous acc. to European Community Directive 93/21/EEC
15.2: National legislation: For further product information, we recommend consideration of the corresponding appropriate National Legislation.

16. OTHER INFORMATION

16.1: This Safety Data Sheet complies with the European Community Directive 93/112/EC amended 91/155/EC.
16.2: All information and instructions provided in this Safety Data Sheet are based on the current state of scientific and technical knowledge at the date indicated on this Safety Data Sheet. Pathway Diagnostics Ltd. shall not be held responsible for any defect in the product covered by this Safety Data Sheet, should the existence of such a defect not be detectable considering the current state of scientific and technical knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

Prepared by: Pathway Diagnostics Ltd
 Eclipse House, Curtis Road
 Dorking, Surrey RH4 1EJ, UK

Date of Preparation: 29 January 2011

Pathway Diagnostics Ltd provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the materials contained in this kit by a properly trained person using this kit. Pathway Diagnostics Ltd shall not be held liable for any damage resulting from handling or use.