

## Material Safety Data Sheet

### 1. Product Identification

#### 1.1. Identification of the products:

TAFI Activity Kit

Product no.: ADG871

For determination of **Thrombin Activatable Fibrinolysis Inhibitor** enzyme activity.

#### 1.2. Manufacturer:

American Diagnostica GmbH

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1.3 **Date of last revision:** 31.10.2012

1.4 **Changed information**

### 2. Hazard Identification

TAFI activity kit is not classified as dangerous acc. to EU guidelines.

Reagent 1, contains components derived from human and bovine tissue. The calibrator and control reagents contain human derived blood plasma. The human plasma used is tested on antibodies against HIV Type 1 and 2, Hepatitis C-virus, Treponema pallidum and Hepatitis B surface antigen. Hepatitis C was tested by PCR screen. The plasma was found to be negative. As complete absence of infectious agents can never be assured, all materials derived from human or bovine tissue or body fluids should always be handled with care, observing the precautions recommended for bio-hazardous material.

### 3. Composition and Information on Ingredients

Chemical characterisation: The kit consists of 6 reagents -> see Product insert. Reagent 1 and 2 are lyophilized solutions of several general purpose and analyte specific reagents to be reconstituted with deionised water or Reagent 3 respectively. Reagent 3 is a diluent consisting of 10% ethanol in water. The Calibrator and Controls are lyophilized human plasma containing different amounts of low molecular weight heparin (LMWH).

Hazardous ingredients	CAS No	Conc.	EU classification
<b>Reagent 1</b>			
CaCl <sub>2</sub> * 2 H <sub>2</sub> O	10035-04-8	< 0.5%	Xi, R36, S26
Tris-(hydroxymethyl)-aminomethane	77-86-1	< 0.5%	Xi, R36/37/38, S26, S36
5,5'-Dithio-bis-(2-nitrobenzoic acid)	69-78-3	< 0.1%	Xi, R36/37/38, S26, S36
<b>Reagent 2</b>			
Tris-(hydroxymethyl)-aminomethane	77-86-1	< 0.5%	Xi, R36/37/38, S26, S36
<b>Calibrator CAL, Controls C1/C2</b>			
Human Plasma (FNP)	-	-	-

#### **4. First-aid Measures**

**Skin Contact:**

Rinse with water.

**Eye Contact:**

Rinse immediately with plenty of water possibly containing a mild detergent. Contact physician in case of irritation.

**Inhalation:**

Contact physician in case of irritation.

**Ingestion:**

Wash out mouth with water provided person is conscious. Seek medical advice immediately.

**Other first aid information:**

None known

#### **5. Fire-fighting Measures**

**Extinguishing agents:**

The following are suitable: water, foam, dry powder or carbon dioxide.

**Unsuitable extinguishing media:**

None known

**Unusual fire fighting hazards:**

Besides the normally occurring toxic combustion gases no special degradation products are known.

**Special fire fighting procedure:**

None known

**Other recommendations:**

No special precautions and measures necessary.

#### **6. Accidental Release Measures**

**Personal precautions:**

Avoid eye contact.

**Precautions to protect the environment:**

Keep away from drains and ground water

**Cleanup procedures:**

Dam large quantities and pump them into a container. For the remaining amount use inert absorbent material. Small quantities can be flushed with a suitable detergent into the sewage system.

#### **7. Handling and Storage**

**Handling precautions:**

Avoid eye contact. Watch out for slippery conditions after spillage.

**Storage precautions:**

None

**Other information:**

None

## **8. Exposure Controls and Personal Protection**

### **Exposure controls:**

See section 7

### **Engineering control measures:**

No special control measures necessary.

### **Personal protective equipment**

Respiratory protection: None

Hand protection: Gloves

Eye protection: Safety glasses

Skin protection: Additional protective equipment is normally not required.

Other : ---

## **9. Physical and Chemical Properties**

	<b>Appearance/Color</b>	<b>Physical state</b>	<b>Odour</b>	<b>pH</b>
<b>R1</b>	off-white	lyophilisate	odourless	-
<b>R2</b>	off-white	lyophilisate	odourless	-
<b>R3</b>	Colorless, clear	solution	odourless	8,5 – 9,5
<b>CAL</b>	beige	lyophilisate	odourless	6.5 – 7.5
<b>C1</b>	beige	lyophilisate	odourless	6.5 – 7.5
<b>C2</b>	beige	lyophilisate	odourless	6.5 – 7.5

## **10. Stability and Reactivity**

### **Conditions to avoid:**

None known

### **Materials to avoid:**

None known

### **Hazardous decomposition products:**

None known

## **11. Toxicological Information**

### **Acute Toxicity:**

None known

### **Other information:**

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## **12. Ecological Information**

### **Ecotoxicity:**

None known

### **Other information:**

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### **13. Disposal Considerations**

**Product disposal:**

Incineration according to local and national legislation.

**Packaging disposal:**

Dispose of in a manner in accordance with local and national regulations.

### **14. Transportation Information**

No specific precautionary measures are required for the transportation of these products.

### **15. Regulatory Information**

None given

### **16. Other information**

Only for in vitro diagnostic purposes.

All information and instructions provided in this Material Safety Data Sheet are based on the current state of scientific and technical knowledge at the date indicated on this Material Safety Data Sheet. American Diagnostica GmbH shall not be held responsible for any defect in the product covered by this Material Safety Data Sheet, should the existence of such a defect not be detectable considering the current state of scientific and technical knowledge.