

Code 800187

## For research use only

### Intended Use

Calibrator and control plasmas are used for calibration and control of the plasma based chromogenic assay for determination of Thrombin Activatable Fibrinolysis Inhibitor (TAFI) enzyme activity with Pefakit® TAFI (Code 800186).

### Introduction

The calibrator plasma of Pefakit® TAFI Calibrator is pooled plasma obtained from normal healthy donors. Calibrator and control plasmas were calibrated against the Secondary Coagulation Standard (SSC/ISTH, Lot. 2).

### Contents

|            |   |
|------------|---|
| <b>CAL</b> | <b>TAFI Calibrator</b><br>(human plasma)<br>1 vial (lyophilisate, to be reconstituted in 1.0 ml of deionized water) |
| <b>C1</b>  | <b>TAFI Control 1</b><br>(human plasma)<br>1 vial (lyophilisate, to be reconstituted in 1.0 ml of deionized water)  |
| <b>C2</b>  | <b>TAFI Control 2</b><br>(human plasma)<br>1 vial (lyophilisate, to be reconstituted in 1.0 ml of deionized water)  |

### Materials required but not provided

- Deionized water
- Calibrated pipette (1000 µl)
- Microtiter plates
- Microtiter plate reader or automated or semi-automated coagulation instruments which employ an optical detection channel.

**Note:** When using automated or semi-automated coagulation analyzers refer always to manufacturer's operator manual.

### Preparation and Use

Prepare calibrator and controls in the following way: Reconstitute in 1.0 ml of deionized water, incubate in closed vials for 15 min at room temperature and swirl gently before use.

**Calibration:** Prepare dilutions of calibrator plasma:

| Dilutions  | Calibrator plasma (µl) | Deionized water (µl) |
|------------|------------------------|----------------------|
| Dilution 1 | 0                      | 100                  |
| Dilution 2 | 30                     | 70                   |
| Dilution 3 | 70                     | 30                   |
| Dilution 4 | 100                    | 0                    |

TAFI activity of undiluted calibrator plasma is lot specific and given in the attached certificate. Calculate TAFI activity for each dilution.

Either by using a microtiter plate or an automated coagulation analyzer run the test with each calibrator dilution obtained and create a calibration curve by plotting % TAFI activity values against delta mE per min values obtained in the test.

### Vertrieb:

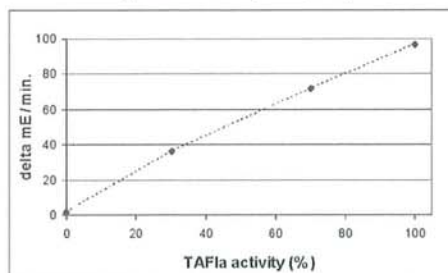
**LOXO GMBH, Postfach 11 30**

DE-69215 Dossenheim

Phone: 06221 868023 Fax: 06221 8680255

E-Mail: info@loxo.de Internet: www.loxo.de

Example for a typical calibration curve obtained with an automated coagulation analyzer (BCS):



### Controls:

After reconstitution controls are ready to use. Calculate % TAFI activity using the calibration curve and an appropriate curve fit software or calculate directly using the printed curve.

### Storage and Stability

The test kit may be used up to the expiry date given on the label when stored unopened at 2–8 °C.

Stability of the reagents after reconstitution:

| CAL | –20 °C   | 6 months       |
|-----|----------|----------------|
|     | 15–25 °C | 8 h (on-board) |
| C1  | –20 °C   | 6 months       |
|     | 15–25 °C | 8 h (on-board) |
| C2  | –20 °C   | 6 months       |
|     | 15–25 °C | 8 h (on-board) |

Frozen control plasmas should be thawed at 37 °C and gently mixed before use. Freeze only once.

### Expected Values

TAFI activity (%) of undiluted calibrator, controls 1 and 2 is lot specific and given in the attached certificate. Compare calculated % TAFI activities of controls 1 and 2 with certified values. If values outside these ranges are obtained the test results are not valid. When calibrator and controls are used in combination with other suitable tests expected values may be different and have to be determined locally under appropriate conditions.

### Precautions

Each donor unit used in the preparation of human source reagent has been tested for antibodies against HIV Type 1 and 2, Hepatitis C-Virus, Treponema pallidum as well as Hepatitis B surface-antigen and Hepatitis C-genome by PCR. The plasmas were found to be negative on the tested parameters. However, since no test can completely rule out the presence of blood borne diseases these control plasmas have to be handled as potentially infectious material.

### Manufacturer



DSM Nutritional Products Ltd Branch Pentapharm

Engelgasse 109, CH-4002 Basel

Phone: +41 61 706 48 48, Fax: +41 61 706 48 00

pentapharm@pentapharm.com, www.pentapharm.com