



Instructions for use

Zafena Abnormal Plasma 0.4 mL

LOT L233M

2014-01

2-8°C

Prodnr: ZAF 102-1



Area of use. Zafena abnormal plasma, ZAF 102-1, is intended for quality assurance of PT/INR-values analyzed with Simple Simon[®]PT.

Product description, Zafena abnormal plasma, ZAF 102-1, is a lyophilized abnormal citrated plasma, manufactured of plasma from healthy voluntary plasma-donors. Zafena abnormal plasma, is reconstituted with 0.4 mL ZAP-buffer, ZAF 102-2, before use. The product contains the lyophilized plasma and ZAP-buffer.

Varnings and precautions.

The buffer, ZAF 102-2, and consequently the reconstituted control contain sodium-azide 4mM to prevent bacterial growth.

- Do not drink buffer, product ZAF 102-2 or reconstituted control, product ZAF 102-2.
- Do not pour buffer or control into drains with pipes of lead or copper. Sodium-azide reacts with named metals into explosive compounds. Flush with rich amounts of water if buffer or control is poured down drains.

Zafena abnormal plasma, is of human origin. The product is tested for hepatitis and hiv and found negative. Controlplasma should be handled as a plasma-sample and protective gloves is recommended.

Storage. Unopened and opened packages is to be stored refrigerated, 2-8°C.

Analyte levels. When analyzed with Simple Simon PT, the target value is INR **2.40**. This value is for ZAP lot L233M. The range is INR 2.15-2.65 (2.40 ±0.25). Traceability see below.

Instructions for use.

1. Reconstitute the content of one vial lyophilized control with 400µL cool (10-20°C) buffer. After taking ZAP-buffer from refrigerator, hold the vial in the hand for approximately 2 minutes to reach recommended temperature.
Pipette 2x200 µL using the green pipette which is included in the reader Simple Simon[®]PT.
2. Mix contents by rotate the vial approximately 1 minute. Allow the control to stabilizise for 10 minutes, then the control is ready for use.
3. Transfer the reconstituted control into enclosed plastic tube with red stopper.
4. Store the sealed plastic tube with control in a refrigerator.

Stability. PT-INR values varies <10% stored refrigerated, 2-8°C, for 14 days. This applies when control is kept in sealed plastic tube.

Standardization and traceability. Zafena abnormal plasma is verified against the international reference method at ISTH's (International Society of Thrombosis and Hemostasis) reference-laboratory in Leiden, Netherlands, using reference thromboplastin RBT/05. The verification was performed using Simple Simon[®]PT lot: I145M, this ZAP-lot is currently working as Zafenas reference-lot. INR levels are indirectly checked through plasma-samples and corresponding blood.

