

**CAL PLASMA**

Coagulation Reference Plasma for calibration  
of the determination of Fibrinogen


**REF** CA01: R1: 5 x 1 mL + R2: 1 x 6 mL


Made in France Revision: 20/02/2019

**DESCRIPTION**

Human plasma to use as calibrator during Fibrinogen quantitative determination.

**REAGENTS**

**R1:** Cal plasma  
Freeze dried, human plasma (citrated) 

**R2:**   
Diluent

According to 1272/2008 regulation, these reagents are not classified as dangerous.

**SAFETY CAUTIONS** <sup>(1) (2)</sup>

ABLIANCE reagent kits are designated for professional in vitro diagnostic use.  
Potential Biohazard material: Human plasmas used as raw material were tested and founded negative regarding HIV1 and HIV2, antibodies anti-HCV, antigen HBs.  
However, as no test method may assure the absence of infectious agent, this plasma is to manipulate in compliance with safety precautions as potentially infectious.  
For further information, Material Safety datasheet is available upon request.  
Waste disposal: Respect legislations in place in the country

**PREPARATION OF REAGENTS**

1. Open a vial very carefully
2. Add exactly 1 mL of diluent
3. Recap and let stand for 15 minutes at room temperature.
4. Swirl gently (avoid the formation of foam) to ensure complete dissolution before use.

**WARNING: DO NOT SHAKE. STORE AWAY FROM LIGHT**

**STABILITY AND STORAGE**

**Before reconstitution, store freeze dried plasmas at 2-8°C, well cap in the original vial**

- Unopened, freeze dried plasmas are stable until expiration indicated in the box label.
- Once reconstituted, plasma is stable for 3 hours at 2-8°C
  - Don't use reconstituted plasma after expiry date indicated on the label of the box

**LIMITS**

Don't use cloudy plasma.  
Bacterial contamination, volume of reconstitution, setting of the instrument and accuracy of temperature may interfere with the results

**PROCEDURE**

Follow the Procedure described in the technical data sheet of the reagent used (listed in § ADDITIONAL EQUIPMENT)

**ADDITIONAL EQUIPMENT**

- General laboratory equipment
- Precision pipettes
- Automatic or semi-automatic Coagulation analyzer
- Demineralized water

Control plasma:

NP01	Control plasma	R1 : 5 x 1mL + R2 : 5 x 1 mL + R3 : 1 x 12 mL
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Reagents as follows:

FI02	Fibrinogen	R1 : 5 x 2mL R2 : 1 x 60mL
FI05	Fibrinogen	R1 : 10 x 5mL R2 : 2 x 125mL

**QUALITY CONTROL**

Use **REF** NP01: Control plasma  
When used as recommended in the insert, control values should be found within specified ranges.

Refer to § **Quality Control** of the package insert enclosed with the reagent in case of obtained value is not within specified values.

**SPECIFIED VALUES** <sup>(3)</sup>











<b>LOT</b>	
<b>Fibrinogen (mg/dL)</b>	

Specified Values may vary slightly from batch to batch (see table hereunder).

Fibrinogen Value is determined against a secondary standard: SSC/ISTH Secondary Coagulation Standard NIBSC ref. SSCLOT4

**REFERENCES**

- (1) Occupational Safety and Health Standards ; Bloodborne pathogens (29CFR1910.1030) Federal Register July 1, (1998) ; 6, p.267-280
- (2) Directive du conseil de l'Europe (90/679/CEE) J. O. de la communauté européenne n°L374 du 31.12.1990, p.1-12
- (3) Section 5.6 of ISO 17511- Measurements of quantities in biological samples- metrological traceability of values assigned to calibrators and controls

 Manufacturer	 Use by	 IVD in vitro diagnostic	 Temperature limitation
 Catalogue number	 See insert	 Batch number	 Dilute with
 Biological hazard	 Diluent		