

## CONTROL PLASMA

Coagulation Control Level I and Level II  
For intralaboratory Quality Control

**REF** NP01: R1: 5 x 1 mL + R2: 5 x 1 mL + R3: 1 x 12 mL

Made in France

Revision: 23/12/2014

### DESCRIPTION

For use as normal and abnormal controls during coagulation tests

### REAGENTS

**R1:** Control Plasma Level I CONTROL 1

Freeze dried, human plasma (citraté)

**R2:** Control Plasma Level II CONTROL 2

Freeze dried, human plasma (citraté)

**R3:** Diluent DIL

### INSTRUCTION OF USE

1. Open a vial very carefully; avoid loss of freeze dried powder
2. Add exactly 1 mL of diluent (take care to reconstitution volume that influences the accuracy of the components values)
3. Recap and let stand for 15 to 20 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 room temperature.
- It is not recommended to store at 2-8°C or freeze.
- Don't use after expiry date indicated on the label of the box

### INTERFERENCES

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

### REAGENTS AND ADDITIONAL EQUIPMENT

General laboratory equipment  
Coagulation analyzer or stopwatch and bath (37°C± 0.5)

Reference plasma:

CA01	Cal plasma	R1 : 5 x 1 mL + R2 : 1 x 6 mL
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Reagents as follows:

PT02	Thromboplastin	R1 : 5 x 2 mL R2 : 1 x 12 mL
PT05	Thromboplastin	R1 : 10 x 5 mL R2 : 1 x 60 mL
AP02	APTT-TCA	R1 : 5 x 2 mL + R2 : 1 x 12 mL
AP05	APTT-TCA	R1 : 10 x 5 mL + R2 : 1 x 60 mL
FI02	Fibrinogen	R1 : 5 x 2 mL R2 : 1 x 60 mL
FI05	Fibrinogen	R1 : 10 x 5 mL R2 : 2 x 125 mL

### SAFETY CAUTIONS

ABLIANCE reagent kits are designated for professional in vitro diagnostic use.

Good Laboratory Practices must be applied during use of reagents, reference or control plasmas, and human samples (to manipulate as potentially infectious)

For further information, Material Safety datasheet is available upon request.

Waste disposal: Respect legislations in place in the country

### QUALITY CONTROL

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 obtained values are not within specified values.

### SPECIFIED VALUES

Level I	LOT	
	Specified Values	Range
Thromboplastin PT %		
Thromboplastin PT INR		
APTT-TCA seconds		
Fibrinogen mg/dL		

Level II	LOT	
	Specified Values	Range
Thromboplastin PT %		
Thromboplastin PT INR		
APTT-TCA seconds		
Fibrinogen mg/dL		

*Specified Values may vary slightly from batch to batch (see table above). Fibrinogen Value is determined against an internal master lot (traceable to a secondary SRM 98/612)*

 Manufacturer	 Use by	 In vitro diagnostic	 Temperature limitation
 Catalogue number	 See insert	 Batch number	→ Dilute with