CE
Usage
Diagnostic
In Vitro

Abliance

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: 20/02/2019

DESCRIPTION

To use as normal and abnormal controls during coagulation tests

REAGENTS

R1: CONTROL 1
Freeze dried, human plasma (citrated), Level I

R2: CONTROL 2
Freeze dried, human plasma (citrated) Level II

R3: DIL
Diluent

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

SAFETY CAUTIONS [1] [2]

ABLIANCE reagent kits are designated for professional in vitro diagnostic use.
Human plasmas used as raw material were tested and founded negative regarding HIV1 and HIV2, antibodies anti-HCV, antigen HBs
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

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 10 hours at 2-8°C
- Don't use 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)

CALIBRATION

REF CA01: Use Cal plasma as described in the technical data sheet of reagent REF FI02, REF FI05.

QUALITY CONTROL

Used as indicated, control plasmas values must be within expected range.
In case of values found out of range, refer to **§ QUALITY CONTROL** of the technical data sheet of the reagent used.

ADDITIONAL EQUIPMENT

General laboratory equipment
Automatic or semi-automated Coagulation analyzer

Reference plasma:

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

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-K	R1 : 5 x 2 mL	R2 : 1 x 12 mL
AP05	APTT-K	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

SPECIFIED VALUES [3]

Specified Values may vary slightly from batch to batch (see table above).
Fibrinogen Value is determined against a secondary standard: SSC/ISTH Secondary Coagulation Standard NIBSC ref. SSCLOT4. PT% and INR values are traceable to WHO INTERNATIONAL STANDARD THROMBOPLASTIN, RABBIT, PLAIN (RBT) from NIBSC.

	LOT	
Level I	**Value**	**Range**
PT (%)		
PT (INR)		
APTT-K (sec)		
Fibrinogen (mg/dL)		

	LOT	
Level II	**Values**	**Range**
PT (%)		
PT (INR)		
APTT-K (sec)		
Fibrinogen (mg/dL)		

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
REF Catalogue number | See insert | LOT Batch number | → Dilute with
Biological hazard | DIL Diluent

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