CE
In Vitro
Diagnostic

Behnk Elektronik

BE DDTrol 1 DDimer Plasma low

Quality control plasma for quantitative immunoturbidimetric determination of D-Dimer (DD) in human plasma

REF 773200: CON (6 x 1 mL)

| INTENDED USE

This control plasma is designated for professional use in laboratory (automated method).
BE DDTrol 1 is used for quality control of indicated methods (see § Procedure).

PRINCIPLE

Refer to the IFU of associated reagent.

REAGENTS

CON **DDTrol 1** D-Dimer Plasma low

Human Origin

Freeze-dried human plasma enriched with D-Dimer
| Additives of components from bovine plasma

BSA	< 4%
Sodium azide	< 0,001%

SAFETY CAUTIONS [1] [2]

- Refer to current Material Safety datasheet (MSDS) is available upon request.
- Use adequate protections (overall, gloves, glasses).
- Each individual donation of plasma was tested with approved tests and found negative for HBsAg, anti-HCV and anti-HIV I and II.
- However, as absence of infectious agents can never be proven, this plasma and all specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions.
- In the event of exposure, the directive of the responsible health authorities should be followed.
- Dispose of waste in accordance with the local regulations.

| Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based

PREPARATION OF REAGENTS

CON: Open the vial carefully reconstitute without delay with exactly 1.0 mL of demineralised water (15-25°C).
Recap and let stand for approximately 15 minutes at room temperature.
Mix gently until complete dissolution.

| STABILITY AND STORAGE

Store at 2 - 8° C, away from light in well capped original vial.
When stored and used as described, reagents are stable:
Before opening:

- Until expiry date stated on the label of the kit.

After opening:

- **CON** must be reconstituted immediately

After reconstitution, and when free from contamination:

- 24 h at 20-25 °C
- 7 days at 2-8 °C
- Do not freeze

Do not use reconstituted control plasma after expiry date stated on the kit label.

REFERENCE RANGE

Refer to technical sheet of the reagent in use.

LIMITS

Factors which may influence results are bacterial contamination, accuracy of reconstitution volume, respect of automated instrument procedure, temperature control.
Other limitations and interfering substances are indicated in the IFU of associated reagent.

PERFORMANCE

Refer to technical sheet of the reagent in use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Precision pipettes
2. Demineralised water

ASSIGNED VALUES [3]

The concentration of this control is batch-specific (See **ASSIGNED VALUES** on the label of the vial).

BE DDTrol 1 value is assigned with BE DDimer reagent against in-house reference material with traceability to a working calibrator assigned according to ISO 17511:2020, section 5.6.

It is expressed in DDU (D-Dimer Unit) and can be calculated in FEU (Fibrinogen equivalent unit) by multiplying the results by 2.5.
If the control plasma result deviates from the established range, a new calibration curve should be constructed.

CALIBRATION

Refer to technical sheet of the reagent in use.

QUALITY CONTROL

Refer to technical sheet of the reagent in use.
It is recommended that each laboratory validate each new batch-specific value before use.

SPECIMEN COLLECTION AND HANDLING

Refer to technical sheet of the reagent in use.

PROCEDURE

This Control should be used with BE DDIMER Reagents REF 771500 following its instruction for use.
DDTrol 1 has to be handled as patient plasma.

CALCULATION

Refer to technical sheet of the reagent in use.

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) *EN ISO 17511:2020 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control material*

| = Significant modifications

Manufacturer	Use by	In Vitro Diagnostic	Temperature limitation	Catalogue number	See insert	Batch number	Store away from light	Sufficient for	Dilute with	Demineralized water	Biological hazard
		IVD		REF		LOT		Σ	→	H2O	

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