CE IVD

Precision in Hemostasis

Behnk Elektronik

BE DDTrol 2 DDimer Plasma high

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

REF 773201: CON (6 x 1 mL)

INTENDED USE

This control plasma is designated for professional use in laboratory (automated method).
| BE DDTrol 2 is used for quality control during quantitative immunoturbidimetric determination of D-Dimer with Behnk reagents as follows:
REF 771500: BE DDimer Turbidimetric Immunoassay

PRINCIPLE

Refer to the IFU of the associated reagent.

REAGENTS

CON **DDTrol 2** D-Dimer Plasma high

Freeze-dried human plasma enriched with D-Dimer
Additives of components from bovine plasma
BSA < 4%
Sodium azide < 0,001%

Human origin

| SAFETY CAUTIONS [1] [2]

- Refer to current Material Safety Data Sheet available on request or on www.behnk.de
- Each human donor unit used to manufacture this product was tested and found non-reactive for HbsAg, antibody to Hepatitis C and antibody to HIV-1/HIV-2.
- Products from animal origin were approved ante- and postmortem by veterinarians inspection.
- However, no test method can offer complete assurance that infectious agents are absent. All specimens or reagents from biological origin should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions.
- Waste disposal: Respect legislation in force in the country.

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

Open the vial carefully and add exactly the volume of demineralised water (15-25 °C) stated on the label without delay.
Cap the vial and let stand for 15 minutes at room temperature.
Gently agitate until the content is completely dissolved.

STABILITY AND STORAGE

Before reconstitution:
Stored away from light, well caped in the original vial at 2-8 °C, lyophilised plasmas are stable until the expiry date stated on the label.
Once opened and reconstituted, free from contamination, plasma is stable:

- 7 days at 2-8 °C
- 24 hours at 15-25 °C

Do not freeze.

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.

MATERIAL REQUIRED BUT NOT PROVIDED

Basic medical analysis laboratory equipment
Coagulation analyzer with turbidimetric detection between 400-800 nm
Demineralised water
Behnk reagents as indicated in § Intended Use

CALIBRATION

Refer to the IFU of the associated reagent.

| CALCULATION

Refer to the IFU of the associated reagent.

To convert DDU results in Fibrinogen eq. units (FEU), multiply the result (DDU) by 2.5.

QUALITY CONTROL

To maintain consistent assay results, it is recommended to control as indicated in the IFU of associated reagent for D-Dimer determination.
It is recommended that each laboratory validate each new batch-specific value before use.

PROCEDURE

This plasma should be used as described in the IFU of the associated reagent.

| ASSIGNED VALUES [3]

The Batch-specific assigned value is indicated in the certificate of analysis (DDU) and on the label of the vial (DDU/FEU).

- BE DDTrol 2 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.

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

IFU_773201-EN_V03_20240730

Manufacturer	Expiry date	In Vitro Diagnostic	Temperature limitation	Catalogue number	See insert	Batch number	Store away from light	Sufficient for	Dilute with	Demineralized water	Biological hazard

Manufactured by
BIOLABO S.A.S
Les Hautes Rives
02160 Maizy, France

Made in France

Distributed by
Kommanditgesellschaft Behnk Elektronik GmbH & Co.
Hans-Böckler-Ring 27
22851 Norderstedt, Germany

T. +49 (0)40-529 861 0
F. +49 (0)40-529 861 99
info@behnk.de

Latest revision: www.behnk.de