

## BE DDTrol 2 D-Dimer Plasma high

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

REF 773201: CON (6 x 1 mL)

### PRINCIPLE

BE DDTrol 2 is used for quality control of indicated methods (see § Procedure).

### REAGENTS

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



Freeze-dried plasma enriched with D-Dimer

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

Behnk reagents are designated for professional in vitro diagnostic use.

- 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.

### PREPARATION OF REAGENTS

**CON:** Open the vial carefully and add exactly 1.0 mL of demineralised water, reconstitute without delay.

Recap and let stand for 15 minutes at room temperature.

Mix gently by swirling and inverting before use, to homogenise the content.

**Warning: do not shake. Store away from light**

### STABILITY AND STORAGE

Before reconstitution:

The lyophilised plasmas are stable until the expiry date stated on the label, when stored away from light, well capped in the original vial at 2-8 °C.

Once opened and reconstituted, plasma is stable:

- 12 hours at 20-25°C, 1 week at 2-8°C and 6 months at -20°C

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

### LIMITS

Factors which may influence results are bacterial contamination, accuracy of reconstitution volume, respect of automated instrument procedure, temperature control.

### MATERIAL REQUIRED BUT NOT PROVIDED

- Precision pipettes
- Demineralised water

### PROCEDURE

This Control should be used with BE DDIMER Reagents REF 771500 following its instruction for use.

DDTrol 2 has to be handled as patient plasma.

### ASSIGNED VALUES

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

DDTrol 2 value is traceable to Reference D-Dimer Masterlot.

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.

### REFERENCES

- Occupational Safety and Health Standards : Bloodborne pathogens (29CFR1910.1030) Federal Register July 1, (1998) : 6, p.267-280
- Directive du conseil de l'Europe (90/679/CEE) J. O. de la communauté européenne n°L374 du 31.12.1990,p.1-12

