BIOLABO
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MANUFACTURER:
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D-DIMER Control 2

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

REF 13212 6 x 1 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD IN VITRO DIAGNOSTIC

PRINCIPLE AND INTENTED USE

For use to monitor the Reproducibility and Accuracy during the determination of D-Dimer in human plasma by turbidimetry or nephelometry with BIOLABO reagents REF 13210.
D-DIMER Controls are suitable for manual procedure or automated instruments.

REAGENTS

Vial R1 **D-DIMER Control 2**

Freeze-dried human plasma enriched with D- Dimer.

SAFETY CAUTIONS (1) (2)

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Each individual donation intended for use in manufacture of protein standard serum was tested negative for hepatitis B antigen (HBsAg), anti-hepatitis C (anti-HCV) and anti-HIV 1 and 2 by FDA approved test.
- However 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. Respect legislation in force in the country.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In the event of exposure the directive of the responsible health authorities should be followed.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.

Waste disposal: Respect legislation in force in the country.

REAGENTS PREPARATION

- Open the vial carefully and add exactly the volume of demineralised water **stated on the label** (1 mL).
- Recap and let stand for approx. 10 to 20 minutes at room temperature.
- Gently invert the vial several times to ensure homogeneity before use (avoid the formation of foam).
- WARNING: DO NOT SHAKE. STORE AWAY FROM LIGHT

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. D-DIMER Reagents REF 13210 (standard enclosed in the kit)
3. D-DIMER Control 1 REF 13211

STABILITY AND STORAGE

Store at 2 - 8°C, away from light in well capped original vial.
Do not freeze

- Unopened, D-DIMER Control 2 (vial R1) is stable until expiry date stated on the label.
- Once reconstituted, D-DIMER Control 2 is stable 12 hours at 4-25°C when free from contamination.

INTERFERENCES

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

CALIBRATION

Refer to technical sheet of the reagent in use.

QUALITY CONTROL

It is recommended to :
✓Participate to external quality control program.
✓Control as indicated in technical sheet of the reagent.
✓Validate target values and ranges when using other reagents that BIOLABO reagents.

PROCEDURE

This Control should be used with BIOLABO reagents REF 13210 or kits referring to the same method in accordance with technical data sheet of the reagent in use. D-DIMER Control 2 has to be handled as patient serum.

ASSIGNED VALUES (3)

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

D-DIMER Control 2 value is traceable to Reference D-Dimer Masterlot

It is expressed in DDU (D-Dimer Unit) and can be actually expressed in FEU (Fibrinogen equivalent unit) by multiplying the results by 1.74 factor.

It is recommended that each laboratory validates each new batch-specific value before use. For an optimal use, laboratories should establish their own targets and ranges. These target values have to be periodically assayed in order to ensure consistent assays results. If the control plasma result deviates from the recommended range, a new standard curve should be constructed

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*

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | sufficient for | → dilute with