BIOLABO
www.biolabo.fr

MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

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
Tel: (33) 03 23 25 15 50
support@biolabo.fr
Latest revision: www.biolabo.fr

CE

IVD

Made in France

I: corresponds to significant modifications

INTENDED USE

This control plasma is designated for professional use in laboratory (automated method).
D DIMER Control 2 is destinated for quality control during quantitative immunoturbidimetric determination of D-Dimer with reagents as follows:
REF 13210, REF K1210, REF K2210

PRINCIPLE

Refer to the IFU of associated reagent.

REAGENTS

R1 **D-DIMER CONTROL 2**

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

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.

I VALUES AND RANGES (3)

The batch specific value is indicated on the certificate of analysis and on the label of the vial.
D-DIMER value (DDU) is assigned with BIOLABO Reagent D-Dimer against in-house reference material with traceability to a working calibrator assigned according to ISO 17511: 2020, section 5.6.

DDU Value can be converted in FEU (Fibrinogen equivalent unit) by multiplying the results by 2,5.

REFERENCE INTERVALS

Refer to the IFU of associated reagent

LIMITS

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

PERFORMANCES

Refer to the IFU of associated reagent

MATERIAL REQUIRED BUT NOT PROVIDED

1. Reagents (§ **Intended use**) and Coagulation analyser.
2. Demineralized water
3. General laboratory equipment
4. D-DIMER Control 1 REF 13211

SAFETY CAUTIONS (1) (2)

- Material Safety Data Sheet is available upon request.
- 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 post mortem 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.
- 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.

REAGENTS PREPARATION

- Open the vial carefully and add exactly 1 mL of demineralized water (15-25°C).
- Recap and wait for approximately 15 minutes at room temperature.
- Gently agitate until the content is completely dissolved..

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:

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

Once opened:
- R1 must be reconstituted immediately,

Once reconstituted and when free from contamination:
- 7 days at 2-8°C and 24h at 20-25°C.
- Do not freeze

SPECIMEN COLLECTION AND HANDLING

Refer to the IFU of associated reagent

PROCEDURE

Run in accordance with the IFU of associated reagent

CALCULATION

Run in accordance with the IFU of associated reagent

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

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with