

UMA CO., LTD.

2-19-6 Yokosuka
Matsudo, Chiba, Japan



D-Dimer Control Set

Control for D-dimer Assay
Code No. 21D501

↓ 2 - 8°C

IVD *In vitro* Diagnostics

PACKAGE

⊕ DO NOT freeze

⌚ 18 months/block from light

Lyophilized / 0.5mL x 2 Levels

1. PURPOSE OF USE

Control for quantitative determination of Measure D-dimer in blood by Immunoassay.

For *In Vitro* Diagnostics use only.

2. STRUCTURE AND COMPOSITION OF KIT

Lyophilized form including the lyophilized materials of D-dimer prepared from bovine serum and stabilizers to maintain D-dimer for accurate control.

- Sodium Chloride 1%
- Bovine serum 99%

Reconstituted Control solution D-dimer 0.5mL x 2 Levels in set (Level Low and Level High).

3. DIRECTION FOR USE

Preparation method of D-Dimer Control Set.

1. Bring back the vial of D-Dimer Control Set and purified water to room temperature before use.
2. Add 0.5 mL of purified water to each vial of D-Dimer Control Set. Cap the vials and dissolve by inverting gently or put on the rolling mixer 10 minutes.
3. Leave it at room temperature for 30 minutes and use it after mixing well.

Storage

Storage at frozen and block from light for long expiry.

Bring back the solutions to room temperature before use.

4. ASSIGNED VALUE

Please refer to the CoA for each lot number.

5. STORAGE AND SHELF LIFE

Storage : Store in cool and dark place (2 - 8°C).

Shelf Life: 18 months from manufactured date.

Expiry date is printed on the label of set box.

6. PRECAUTION FOR USE AND HANDLING

- This product is made of bovine serum as a base. Take same precautions against infection as patient samples such as to wear gloves. Do not pipette by mouth.

- If this product is spilled from the container, disinfect with 80% of alcohol spray and wipe it out wearing gloves for protection of infection.

- All samples and controls, as well as their containers must be treated according to the handling manual for discarding infectious waste materials, or treat them according to the following methods.

· Sterilize with an autoclave at 121°C for 20 minutes, however do not process wastes containing sodium hypochlorite with an autoclave.

· Immerse at least one hour in sodium hypochlorite solution (active chloride concentration of over 1000 ppm).

- Controls once dissolved should be store under frozen condition.

7. REFERENCES

1. Deborah Siegal, Wendy Lim, in Hematology (Seventh Edition), 2018
2. In house data, UMA Diagnostics

8. MANUFACTURER

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