

UMA CO., LTD.

2-19-6 Yokosuka

Matsudo, Chiba, Japan



D-Dimer Calibrator Set

Calibrator for D-dimer Assay

Code No. 21D601

Code No. 21D601-1

❄ 2 - 8°C

IVD *In vitro* Diagnostics

PACKAGE

❗ **DO NOT** freeze

⌚ 18 months/block from light

Lyophilized / 0.5mL x 6 Levels (21D601)

Lyophilized / 1.0mL x 6 Levels (21D601-1)

1. PURPOSE OF USE

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

For *In Vitro* Diagnostics use only.

Shelf Life: 18 months from manufactured date.

Expiry date is printed on the label of set box.

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 calibration.

- Sodium Chloride 1%
- Bovine serum 99%

Reconstituted Calibrator solution D-dimer 0.5mL (or 1.0mL) x 6 Levels in set (Level 1, 2, 3, 4, 5 and 6).

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 calibrators, 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).

- Calibrator once dissolved should be store under frozen condition.

3. DIRECTION FOR USE

Preparation method of D-Dimer Calibrator Set.

1. Bring back the vial of D-Dimer Calibrator Set and purified water to room temperature before use.
2. Add 0.5 mL (or 1.0 mL) of purified water to each vial of D-Dimer Calibrator 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.

7. REFERENCES

1. Deborah Siegal, Wendy Lim, in Hematology (Seventh Edition), 2018

2. In house data, UMA Diagnostics

Storage

Storage at frozen and block from light for long expiry.

Bring back the solutions to room temperature before use.

8. MANUFACTURER

UMA Co., Ltd.

2-19-6 Yokosuka, Matsudo City, Chiba

Prefecture 270-0031

TEL: 047-710-4871 (dial-in)

FAX: 047-710-4872

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).