



2 - 8 °C

IVD In vitro Diagnostics

PACKAGE

DO NOT freeze

18 months/block from light

Lyophilized / 1.0mL x 2 Levels

1. PURPOSE OF USE

Control for quantitative determination of Measure HbA1c II in blood by Immunoassay.

For In Vitro Diagnostics use only.

2. STRUCTURE AND COMPOSITION OF KIT

Lyophilized form including the lyophilized materials of Human hemoglobin A1c (prepared from lysed red blood cell sample) and stabilizers to maintain hemoglobin A1c for the accurate calibration.

- HbA1c in buffer 7.5 < 5%
- Sodium Azide < 0.001%

Reconstituted Control solution HbA1c 1.0mL x 2 Levels in set (Level Low and Level High).

3. DIRECTION FOR USE

Preparation method of HbA1c Control Set.

- Bring back the vial of HbA1c Control Set and purified water to room temperature before use.
- Add 1.0 mL of purified water to each vial of HbA1c Control Set. Cap the vials and dissolve by inverting gently or put on the rolling mixer 10 minutes.
- Leave it at room temperature for 50 minutes and use it after mixing well.

Do not require the pre-dilution for the controls with hemolysate solution like as patient samples. The concentration of hemoglobin is already adjusted.

Storage

Reconstituted can be used for

- 24hrs at room temperature
- 10 days at 2 - 8°C
- 30 days at frozen (< -20°C)

Bring back 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 human blood cell 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

- M.J. York, in A Comprehensive Guide to Toxicology in Nonclinical Drug Development (Second Edition), 2017
- In house data, UMA Diagnostics

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