

**UMA CO., LTD.**

2-19-6 Yokosuka

Matsudo, Chiba, Japan



**MEASURE Human Lyo L-1**

Low Level Control for Measure various analytes Assay

Code No. 21C515

❄ 2 - 8°C

**IVD** *In vitro* Diagnostics

**PACKAGE**

❄ **DO NOT** freeze

🕒 18 months/block from light

Lyophilized / 5.0mL vial (21C515)

### 1. PURPOSE OF USE

Control for quantitative determination of various analytes in blood in clinical chemistry.

MEASURE Human Lyo L-1 is a low level multi control for measurement analytes in sample.

For *In Vitro* Diagnostics use only.

### 2. STRUCTURE AND COMPOSITION OF KIT

Lyophilized from including lyophilized materials prepared from Human serum and stabilizers to maintain concentration of analytes for the accurate control.

MEASURE Human Lyo L-1

- Human serum < 1%
- Sodium Azide < 0.01%

Reconstituted Control solution 5.0mL vial.

### 3. DIRECTION FOR USE

*Preparation method of MEASURE Human Lyo L-1.*

1. Open the screw cap and remove gently the rubber stopper of the vial so that the contents of the vial does not come out of the vial. And add 5.0 mL of the purified water precisely.
2. Put after the rubber stopper on the vial, and then stand for 45 minutes at room temperature, sometimes mix gently. Before use, please be sure that contents are completely dissolved.
3. Please use it after aliquot into a clean container to avoid contamination of the contents of the vial. The sampling, please use a clean pipette.

#### Storage

The reconstituted calibrator solution will be stable for various period depend of condition list below:

Criterion: Recovery within  $\pm 10\%$  of initial assigned value.

MEASURE Human Lyo L-1

Condition Analyte	Room temp.	2 - 8°C	-20°C
CK	24hrs	5 days	14 days
CKMB	24hrs	5 days	14 days
D-BIL	24hrs	5 days	14 days
T-BIL	24hrs	5 days	14 days
Others	24hrs	7 days	30 days

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 vial.

### 6. PRECAUTION FOR USE AND HANDLING

- This product is made of human 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. MANUFACTURER

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