



2 - 8°C

IVD In vitro Diagnostics

PACKAGE

⚠ **DO NOT** freeze

18 months/block from light

Lyophilized / 2.0mL vial

1. PURPOSE OF USE

Calibrator for quantitative determination of Bilirubin (Measure T-Bil and D-Bil) in blood.

For *In Vitro* Diagnostics use only.

2. STRUCTURE AND COMPOSITION OF KIT

Lyophilized from including lyophilized bilirubin prepared from Human serum and stabilizers to maintain concentration of bilirubin for the accurate calibration.

Reconstituted Calibrator solution 2.0mL vial.

3. DIRECTION FOR USE

Preparation method of BIL Calibrator.

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 2.0 mL of the purified water precisely.
2. Put after the rubber stopper on the vial, and then stand for 20 minutes at room temperature and AVOID LIGHT, 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:

Condition	Room temp.	2 - 8°C	-20°C
Analyte			
D-BIL	24hrs	5 days	14 days
T-BIL	24hrs	5 days	14 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 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).

- Calibrators once dissolved should be store under frozen condition.

7. REFERENCES

1. P.J.H. Jones, T.C. Rideout, in Comprehensive Biotechnology (Third Edition), 2011
2. In house data, UMA Diagnostics

8. MANUFACTURER

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