

Multi-calibrator for use in tests for quantitative in vitro determination of various analytes on photometric systems

ORDER INFORMATION

06 00122 70 04 0018 6 x 3 mL
06 00122 70 04 0060 20 x 3mL

DESCRIPTION

UniCal CC is a lyophilized calibrator based on human blood material (serum) and contains chemical additives and biological material of specified origin.

ORIGIN OF THE ADDITIVES

Analyte	Origin
Acid phosphatase total	Human prostate/potato
Albumin	Bovine plasma
Aldolase	Rabbit muscle
Alkaline phosphatase	Placenta (human, recombinant)
Alanine-Aminotransferase	Porcine (heart)
α-Amylase	Porcine (pancreas)
Pancreatic amylase	Porcine (pancreas)
Aspartate Aminotransferase	Human, recombinant
Cholesterol	Bovine plasma
Cholinesterase	Human serum
Creatin kinase	Rabbit muscle
γ-Glutamyltransferase	Human, recombinant
GLDH	Bacterium, recombinant
Lactatedehydrogenase	Porcine heart
Lipase	Pancreas (human recombinant)
Triglycerides	Chicken egg yolk

The concentration of the biological material does not exceed the maximum, lot specific target value concentration of the analyte.

CALIBRATOR STABILITY AND STORAGE

Unopened and stored at 2-8 °C, the UniCal CC is stable until the end of the indicated month of expiry.

Once reconstituted, the UniCal CC can be used within the period reported in the table below if stored tightly closed at the indicated temperature and bacterial contamination is avoided.

Stability of the components after reconstitution:

	- 20 °C *	+ 4 °C	+ 25 °C
Bilirubin (kept in the dark)	14 days	8 hours	3 hours
Other analytes	30 days	2 days	8 hours

* freeze only once!

Criterion for the stability stated is a recovery within ± 5 % of the initial value.

WASTE MANAGEMENT

Please refer to local legal requirements.

WARNINGS AND PRECAUTIONS

- Each individual blood donation used for production of UniCal CC was found to be non-reactive when tested with FDA-approved methods or CE-accepted methods for HBsAG, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood transmit infectious agents, it is recommended to handle UniCal CC calibrator with the same precautions used for patient specimens.
- UniCal CC contains biological material of specified origin. The calibrators should be handled as potentially infectious and with the same precautions used for patient specimens.
- Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
- For professional use only!

CALIBRATOR PREPARATION

The lyophilizate is sealed under vacuum; therefore the vial should be opened very carefully to avoid loss of dried material. For reconstitution add exactly 3 mL of distilled water. Close the vial carefully and allow the calibrator to stand for 30 minutes swirling occasionally. Avoid foaming! Do not shake!

Defrost reconstituted, frozen aliquots of UniCal U protected from light at room temperature (18 – 25°C). To homogenize after complete defrosting, slightly swivel aliquots and immediately afterwards use them for calibration in the same way as the freshly reconstituted UniCal U.

PROCEDURE

Please refer to the reagent package inserts for instructions for use.

CALIBRATOR VALUES

The concentrations of the calibrator analytes are lot-specific and given in the value sheet of the corresponding lot. The values were determined using the method and using the reagents specified by the given catalogue number. Determinations were performed under standardized protocols using Diasystem reagents and UniCal CC master calibrator or reference materials. The value sheet contains information on traceability.

LITERATURE

- Dati F. Reference materials and guidelines for standardization of methods in laboratory medicine. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1404-26.
- Moss DW, Henderson AR. Enzymes. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia: W.B Saunders Company; 1994. p. 735-896.
- Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395)

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