TruCal PCT

Order Information

Cat. No.	Kit size
1 7310 99 10 082	6 x 1 mL

Intended Use

Calibrator set for use in DiaSys tests for quantitative in vitro determination of procalcitonin (PCT) on automated photometric systems.

Description

TruCal PCT is a set of six liquid stable, aqueous calibrators with different levels.

Contain recombinant PCT and biological additives from bovine origin.

The calibrator set is used to calibrate the DiaSys test Procalcitonin FS.

Storage

The calibrators, both opened and unopened, must be stored at 2 – 8°C. Avoid contamination and protect from light. Do not freeze.

Stability

Unopened: Up to the date of expiry indicated on the kit
Opened: 12 months

Proper storage and handling of this product must be observed.

Warnings and Precautions

1. Contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Contain material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
4. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
5. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of calibrators and controls.
6. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Preparation

The calibrators are ready to use.

Materials Required

General laboratory equipment

Procedure

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

Calibrator Values

Values have been made traceable to a commercially available test on Roche cobas e 411.

Values listed below are valid for the indicated lot only.

Literature

1. Stenman UH, Standardization of immunoassays, In: Price CP, Newman DJ, editors, Principles and practice of immunoassay, New York: Stockton Press; 1997, p. 243-68.
2. Röhle G, Siekmann L. Quality assurance of quantitative determination. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1393–1401.
3. Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Washington 2009 (HHS Publication No. [CDC] 21–1112).

Additions and/or changes in the document are highlighted in grey. For deletions, please refer to the customer information for the corresponding edition number of the package inserts.

IVD CE

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	Lot No.	Expiry Date	Calibrator Value
TruCal PCT Level 0	39101	2027-05-22	0.00 ng/mL
TruCal PCT Level 1	39102	2027-05-22	0.867 ng/mL
TruCal PCT Level 2	39103	2027-05-22	3.34 ng/mL
TruCal PCT Level 3	39104	2027-05-22	8.69 ng/mL
TruCal PCT Level 4	39105	2027-05-22	19.5 ng/mL
TruCal PCT Level 5	39106	2027-05-22	55.0 ng/mL