Spectrum For Diagnostic Industries

Calibrator For Clinical Chemistry

IVD

REF.	Pack size
448 01 003	(1 x 3 ml) 5 vials
448 05 003	(5 x 3 ml) 5 vials

Intended use

Multiparameter calibration serum for the standradization of quantitative tests on clinical chemical Analytes

Description

Calibrator is an analyzed calibration material based on lyophilized human serum.

Storage and stability

Unopened bottles have to be stored in refrigerator at 2 – 8 °C and are stable up to the expiry date printed on the labels.

After reconstitution the tightly closed calibrator can be used within the times and temperatures given below:

General:
18 – 25°C => 8 hours
2 – 8°C => 2 days
< – 25°C => 30 days
Bilirubin (in the dark)
18 – 25°C => 4 hours
2 – 8°C => 8 hours
< – 25°C => 14 days
Acid Phosphatase
(Total and Prostatic)
18 – 25°C => 4 hours
2 – 8°C => 8 hours
< – 25°C => 14 days

- freeze only once

Warnings and Precautions

Each individual blood donation used for production of calobrator . was found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV.
As there is no possibility to exclude definitively that products derived from human blood transmit infectious agents, it is recommended to handle the calibrator with the same precautions as valid for specimens.

Preparation

The lyophilisate is vacuum sealed; therefore the vial should be reconstituted carefully with 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!

Procedure

Refer to the package inserts of the reagent kits

Expected Values

1. The expected value of specific assays are provided on the assay value sheet accompanying each kit, and are lot specific.
2. The expected values are obtained using replicate assay of each manufactured lot of calibrator
3. The individual laboratory values should fall within the expected values.
4. It must however be noted that each laboratory should establish its own normal values and reference range according to GLP.

Reference

1. 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.

2. Moss DW, Henderson AR. Enzymes . In: Burtis CA,Ashwood ER, editors. Tietz Textbook of Clinical Chemistry.
2nd ed. Philadelphia: W.B SaundersCompany; 1994. p. 735-896.

3. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395)

SYMBOLS IN PRODUCT LABELLING

IVD For in-vitro diagnostic use
LOT Batch Code/Lot number
REF Catalogue Number
Consult instructions for use
Temperature Limitation
Use by/Expiration Date
CAUTION. Consult instructions for use
Manufactured by

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