

SP-Multical

REF: 328 001 (1 vial) 1 x 3 ml
 REF: 328 002 (5 vials) 5 x 3 ml

Intended use

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

Description

SP-MULTICAL 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 SP- MULTICAL. 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 patient 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

| SYMBOLS IN PRODUCT LABELLING | | | |
|------------------------------|------------------------------|--|---------------------------------------|
| | Authorised Representative | | Use by/Expiration Date |
| | For in-vitro diagnostic use | | CAUTION. Consult instructions for use |
| | Batch Code/Lot number | | Manufactured by |
| | Catalogue Number | | (Xi) - Irritant |
| | Consult instructions for use | | Temperature Limitation |

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 SP-Multical.
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.

Literature

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 Saunders Company; 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)