

ALWAYS KEEP THIS PACKAGE INSERT ON HAND AND CAREFULLY READ IT BEFORE USE.

SPOTCHEM™ CALIBRATOR KIT

Summary

SPOTCHEM CARIBRATOR KIT is provided for calibration of the SPOTCHEM Analyzer. It consists of two kinds of lyophilized serum, distilled water and a Calibration Card.

Composition

Calibrator Low (lyophilized), for 3 mL in vial ...2 vials(Box A)
 Calibrator High (lyophilized), for 3 mL in vial ...2 vials(Box A)
 Distilled water, 20 mL in vial2 vials(Box B)
 Calibration Card1 card(Box B)
 (Magnetic Card for entry of calibration values)

Preparation Procedure

Reagent strips and instruments to be used

Reagent Strips : SPOTCHEM or SPOTCHEM II reagent strips
 except for hemoglobin testing

Analyzer : SPOTCHEM SP-4410, SP-4420 or SPOTCHEM
 EZ SP-4430

- * Use the reagent strips according to the instructions in the respective Package Insert.
- * Use the analyzer according to the instructions in the respective Operating Manual.

1. Remove Calibrator-contained vials (Box A) from a freezer and let them stand at room temperature for more than 20 minutes.
2. Remove the caps from the vials and, using a pipette, add precisely 3 mL of distilled water (approx. 25°C) into the Calibrator vials respectively and place the caps back on them.
3. Leave the Calibrator vials at room temperature for further 20 minutes, then slowly invert them to completely mix and dissolve the contents.

NOTE : DO NOT shake the vials vigorously to avoid generating air bubbles. After preparation, strictly follow the precautions stated below and pay due attention to the stability of each analyte.

Instructions for Use

1. Dispense 500 µL of dissolved Low and High solutions into the serum sample tubes respectively, place the sample tubes into their correct positions on the Calibration Rack, and perform calibration according to the instructions in the Operating Manual of the respective analyzer.
2. For calibration of HDL-Cholesterol test, prepare Low solution of precisely twofold dilution using distilled water, and perform calibration according to the instructions in the Operating Manual of the respective analyzer.
3. For those using the SP-4420 and SP-4430 :
 - Use only Low solution for Total Protein, Albumin and Fructosamine.
 - Use only High solution for Total Cholesterol, HDL-Cholesterol (Direct Method), Inorganic Phosphate and Magnesium.
 - Use only Low solution for HDL-Cholesterol and prepare it as instructed on the 2. above. Proceed calibration according to the instructions in the Operating Manual of the SP-4420•SP-4430 carefully.

Precautions

1. The table below shows the stability of each analyte after the Calibrator is reconstituted. Taking the stability into consideration, each analyte should be measured within the time specified in the following table, especially in the order of CPK, ALP and LDH and so on.

Storage temperature after reconstitution	CPK	ALP	LDH	Amy
2-8°C	3	3	3	6
20-25°C	1	2	6	6
Storage temperature after reconstitution	GOT	GPT	GGT	Others
2-8°C	6	6	6	12
20-25°C	6	6	6	8

[unit : hour]

2. Before use, make sure that the lot number of the Calibration Card corresponds to that of the Calibrators.
3. Adjust the Calibrators to the room temperature before you start preparation procedure. If the Calibrators are dissolved with distilled water of temperatures lower or higher than 25°C, correct readings may not be produced.
4. The Calibrators are lyophilized and kept in a vacuum-conditioned vial. Be careful not to scatter the contents when you open the caps of the vials.
5. When dispensing calibrator into the sample tube, be careful not to generate air bubbles.
6. The Calibrators are prepared from human sera, and have been proved negative for HBs antigen and HCV antibody by radioimmunoassay (RIA), and for HIV antibody by enzyme immunoassay (EIA). However, since the cause of serum hepatitis and other ailments have not yet been fully clarified, exercise utmost care for handling the Calibrators.
7. Exercise the normal precautions required for handling blood samples, containers, used reagent strips and pipette tips. Follow local regulations for disposal of biohazardous waste.
8. Although the Calibrator Kit may be used until it reaches the expiration date, do NOT use it if any of the Calibrator shows signs of discoloration or deterioration.

Storage

- BOX A : Store in a freezer at temperature lower than -18°C.
- BOX B : Store at temperatures between 1 and 30°C. DO NOT freeze them.

Expiration

1 year from the manufactured date (the expiration date is printed on the outer box).

MANUFACTURER

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This product conforms to European
 Directive 98/79/EC.

