

日本国以外でご使用の場合 / For use in the countries except Japan

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

SPOTCHEM™ CALIBRATOR Hb KIT

Summary

The SPOTCHEM CALIBRATOR Hb KIT is provided for calibration of the SPOTCHEM Analyzer for hemoglobin testing. It consists of stable hemoglobin solution, distilled water and a Calibration Hb Card.

Composition

Calibrator Hb, 0.5 mL in vial2 vials
Distilled water, 20 mL in vial2 vials
Calibration Hb Card1 card
(Magnetic Card for entry of calibration values)

Preparation Procedure

Reagent strips and instruments to be used

Reagent Strips : SPOTCHEM or SPOTCHEM II reagent strips 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.

Two procedures are necessary to adjust the Calibrator Hb :

1. Making Low Calibrator Hb
2. Making High Calibrator Hb

1. Making Low Calibrator Hb

- 1) Collect precisely 40 μ L of well mixed Calibrator Hb with an auto-pipette.
- 2) Release the Calibrator Hb into the sample tube (the tube for serum, with the blue cap).
- 3) Collect precisely 400 μ L (2 times of 200 μ L) of distilled water with an auto-pipette.
- 4) Add the distilled water to the sample tube which contains 40 μ L of Calibrator Hb and put the blue cap on.
- 5) Slowly invert the sample tube to mix the contents.
Note) DO NOT shake the vial vigorously to avoid generating air bubbles.

2. Making High Calibrator Hb

- 1) Collect precisely 40 μ L of well mixed Calibrator Hb with an auto-pipette.
- 2) Release the Calibrator Hb into the sample tube (the tube for serum, with the blue cap).
- 3) Collect precisely 200 μ L of distilled water with an auto-pipette.
- 4) Add the distilled water to the sample tube which contains 40 μ L of Calibrator Hb and put the blue cap on.
- 5) Slowly invert the sample tube to mix the contents.
Note) DO NOT shake the vial vigorously to avoid generating air bubbles.

Calibration

Place the sample tubes containing Low and High Calibrator Hb into their correct positions on the Calibration Rack, and perform the calibration according to the instructions in the Operating Manual of the respective SPOTCHEM Analyzer.

Precautions

1. Before use, make sure that the lot number of the Calibration Hb Card corresponds to that of the Calibrator Hb.
2. Once you open the Calibrator Hb, use it within 24 hours.
3. When inverting the sample tube, be careful not to generate air bubbles.
4. The Calibrator Hb is prepared from bovine blood. However, since the cause of serum hepatitis and other ailments have not yet been fully elucidated, use utmost care for handling the Calibrator Hb to the same degree as used for handling patient's serum.
5. Exercise the normal precautions required for handling blood samples, containers, used reagent strips and pipette tips. Follow local regulations for disposal of biohazardous waste.
6. Although the Calibrator Hb Kit may be used until it reaches the expiration date, do not use it if the Calibrator shows any signs of discoloration or deterioration.

Storage

Store in a refrigerator at temperatures between 2 and 8°C.
DO NOT freeze the kit.

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.



Rev. : APR. 2007