

CONTROL BLOOD



HAEM 8 CONTROL L	1 x 2,5 ml	Cat. No 8-601
HAEM 8 CONTROL N	1 x 2,5 ml	Cat. No 8-602
HAEM 8 CONTROL H	1 x 2,5 ml	Cat. No 8-603
HAEM 12 CONTROL L	1 x 2,5 ml	Cat. No 8-604
HAEM 12 CONTROL N	1 x 2,5 ml	Cat. No 8-605
HAEM 12 CONTROL H	1 x 2,5 ml	Cat. No 8-606
HAEM K-DIFF CONTROL L	1 x 2,5 ml	Cat. No 8-607
HAEM K-DIFF CONTROL N	1 x 2,5 ml	Cat. No 8-608
HAEM K-DIFF CONTROL H	1 x 2,5 ml	Cat. No 8-609

INTENDED USE

Control Blood is assigned for quality control of automated, semi-automated and manual procedures that measure whole blood parameters. Control material will provide values within the expected range indicated on the assay sheet when assayed routinely (like a patient sample) on a properly calibrated and functioning instrument. Daily determination of these controls confirms the precision and accuracy of hematological analysers.

PRODUCT DESCRIPTION

Control Blood is the mixture composed of human RBC's, leukocytes and animal derived platelets in a plasma like fluid with preservatives.

INSTRUCTION FOR USE

1. Remove the vial from the refrigerator and allow to warm at room temperature (18-30°C) for 20 minutes.
2. Place the control on a mechanical mixer for 20 minutes or mix the control manually according step 3. Do not use a Vortex-mixer.
3. Roll the vial forth and back for 30 seconds, holding the vial horizontally between the palms of the hands. Next, gently invert the vial 10 times. Do not shake. Continue mixing in this manner until the cells are completely suspended.
4. After mixing allow the vial to stand about 15 seconds for small air bubbles dispersion. Gently invert the vial 10 times immediately before sampling. Analyze the control blood as a patient sample.
5. After sampling wipe the vial ring and the inner side of cap with lint-free swab and replace the cap.
6. Place the vial back in the refrigerator within 30 minutes after measuring the controls. Store in upright position.

STORAGE AND STABILITY

Control Blood when unopened remains stable at 2-8°C until expiry date given on the product label.

Opened vials, when stored at 2-8°C and handled according to the instruction, remain stable for:

HAEM 8 CONTROL L, N, H	4 weeks
HAEM 12 CONTROL L, N, H	3 weeks
HAEM K-DIFF CONTROL L, N, H	3 weeks

EXPECTED VALUES

The expected values and standard deviation for each control parameter are calculated from results of multiple determinations on analysers calibrated with whole blood and by manual reference methods. The values obtained on Control Blood should be within the expected range. The expected ranges listed on the assay sheet are

useful for routine control of analysers. It is not recommended to use control material for analysers calibration

PRECAUTIONS

- Control material should be treated as potentially infectious.
- Control material are intended only for in vitro diagnostic use by trained personnel.
- Human blood components used to produce Control Blood were tested for HBsAg and anti-HIV antibody and found to be non-reactive. No known test methods can provide complete assurance that human blood derived products will not transmit infectious diseases. Keep special precautions when handling or disposing of vials, as with patients samples.
- Do not interchange caps, the color of the cap is helpful on identifying the level of the control blood.

WASTE MANAGEMENT

Please refer to local legal requirements.

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MANUFACTURER

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