



ELite H CAL

Catalogue No.	Name	Package size
HEM00027	ELite H CAL	3 ml

INTENDED USE

ELite H CAL is designed for use in the calibration of hematology analyzers. Please refer to the assay table for specific instrument models.

SUMMARY AND PRINCIPLE

Hematology analyzers require periodic calibration in order to generate accurate patient results. This calibrator is a stable, whole blood preparation that can be used to verify and adjust calibration of select hematology instruments.

Calibrator values for ELite H CAL are derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. Instruments are calibrated with whole blood using values determined by reference methods.

MATERIAL

ELite H CAL is an *in vitro* diagnostic material composed of human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma like fluid with preservatives.

PRECAUTION

ELite H CAL is intended for *in vitro* diagnostic use only by trained personnel.

WARNING:

POTENTIAL BIOHAZARDOUS MATERIAL. For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA) and HIV-1/2. Each unit is also negative by a serological test for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in biosafety procedures.

STABILITY AND STORAGE

Store ELite H CAL upright at 2 - 8° C when not in use. **Protect tubes/vials from overheating and freezing.** Unopened tubes/vials are stable through the expiration date. Opened tubes/vials are stable for 7 days, provided they are handled properly.

INDICATIONS OF DETERIORATION

After mixing, product should be similar in appearance to fresh whole blood. In unopened tubes/vials, the supernatant may appear cloudy and reddish; this is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration.

Do not use the product if deterioration is suspected.

INSTRUCTIONS FOR USE

- Remove tubes from the refrigerator and allow them to warm to room temperature (15 - 25°C) for 15 minutes before mixing.
- To mix, hold a tube horizontally between the palms of the hands. Do not premix on a mechanical mixer.
 - Roll the tube back and forth for 20 - 30 seconds; occasionally invert the tube. Mix vigorously, but do not shake.
 - Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing.
 - Gently invert the tube 8 - 10 times immediately before sampling.
- Perform the calibration as instructed in the Calibration section of the Operator Manual for your instrument.
- After sampling:
 - If tube has been open for sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
 - Return tubes to refrigerator within 30 minutes of use.

EXPECTED RESULTS

Verify that the lot number on the tube/vial matches the lot number on the table of assay values. Assay values are determined on well-maintained, properly calibrated instruments using the instrument manufacturer's recommended reagents.

PERFORMANCE METHODS

- WBC:** A series of 1:500 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.
- RBC:** A series of 1:50,000 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.
- HGB:** Hemoglobin value is determined by spectrophotometric procedure according to CLSI Standard H15-A3 and is traceable to ICSH/WHO International Haemoglobinocyanide Standard.
- HCT:** Packed cell volume (PCV) is measured by the microhematocrit procedure according to CLSI Standard H7 A3. No correction is made for trapped plasma.
- PLT:** A series of 1:126 dilutions are made using calibrated glassware in 1% ammonium oxalate. Platelets are counted using a hemocytometer and phase contrast microscopy.

LIMITATIONS

The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube/vial prior to use invalidates both the sample withdrawn and any remaining material in the tube/vial.



GIÁM ĐỐC
Nguyễn Thế Việt

USED SYMBOLS

Catalogue Number

Manufacturer

See Instruction for Use

Lot Number

CE Mark - Device comply with the Directive 98/79/EC

Storage Temperature

Expiry date

In vitro Diagnostics

Content

Biological risks