

ELite H5 CON



Cat. No.	Name	Level	Package Volume
HEM00024	ELite H5 CON L	Low	3 ml
HEM00025	ELite H5 CON N	Normal	3 ml
HEM00026	ELite H5 CON H	High	3 ml

INTENDED USE (For *in vitro* diagnostics only)

Elite H5 CON is a control designed to monitor accuracy and precision of automated hematology analyzers. Please refer to the assay table for specific instrument models.

SUMMARY AND PRINCIPLE

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials that provide a means of monitoring the performance of hematology blood cell counters. It is sampled in the same manner as a patient specimen.

MATERIAL

Elite H5 CON is an *in vitro* diagnostic material composed of human and mammalian erythrocytes, simulated leukocytes and simulated platelets suspended in a plasma-like fluid with preservatives.

PRECAUTION

Elite H5 CON 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 H5 CON upright at 2–8°C when not in use. Protect tubes from overheating and freezing. Unopened vials are stable through the expiration date. Opened vials are stable for 14 days, provided they are handled properly.

INDICATIONS OF DETERIORATION

After mixing, product should be similar in appearance to fresh whole blood. In unmixed tubes, 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.

3. Analyze the sample as instructed in the Quality Control section of the Operator Manual for your instrument.

4. 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 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. Reagent differences, maintenance, operating technique, and calibration may contribute to inter-laboratory variation.

PERFORMANCE CHARACTERISTICS

Assigned values are presented as a Mean and Range. The Mean is derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. The Range is an estimate of variation between laboratories and also takes into account inherent imprecision of the method and expected biological variability of the control material.

Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range.

For greater control sensitivity each laboratory should establish its own mean and acceptable range and periodically reevaluate the mean. The laboratory range may include values outside of the assay range. The user may establish assay values not listed on the Assay Sheet, if the control is suitable for the method.

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 prior to use invalidates both the sample withdrawn and any remaining material in the tube.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For technical assistance or additional information, please call your local distributor.



GIÁM ĐỐC
Nguyễn Thế Việt

USED SYMBOLS

REF	Catalogue Number	LOT	Lot Number		Expiry Date		See Instruction for use	CONT	Content
IVD	In vitro Diagnostics		Manufacturer		Storage Temperature		Biological Risk		