Eurotrol
Your Global Reference Point for Quality Control

(GB) Eurotrol ICSH HiCN Standard

Intended purpose
Eurotrol ICSH HiCN Standard is a 1:251 prediluted assayed real haemiglobincyanid (HiCN) reference standard solution for in-vitro diagnostic use in the performance assessment and calibration of the Hb-photometer.
The purpose of this reference is to check calibration and other performance related characteristics of the instrument. Instruments designed to carry out this measurement must meet stringent requirements for accuracy and precision to establish the appropriate patients' treatment.

IVD Medical Device
The Eurotrol ICSH HiCN Standard complies with the European Directive 98/79/EC on in vitro diagnostic medical devices and carries the CE mark.

Summary
Eurotrol ICSH HiCN Standard is a reference material available at one level, with a known concentration. Eurotrol ICSH HiCN Standard is 1:251 prediluted and the corresponding whole blood concentration of total haemoglobin (tHb) is in the physiological range. Eurotrol ICSH HiCN Standard is prepared from a bovine stroma-free haemoglobin solution, without any dyes or preservatives (1). It is intended that Eurotrol ICSH HiCN Standard should be used to check calibration and other performance related characteristics of Hb-photometers. Instruments designed to carry out this measurement must meet stringent requirements for accuracy and precision to establish the appropriate patients treatment.

Reagents
Eurotrol ICSH HiCN Standard provides one physiologically relevant level. Ampoules are packed in boxes containing 5 ampoules per box. Each ampoule holds 5.0 mL solution.

Storage and stability
Eurotrol ICSH HiCN Standard should be stored unopened in the refrigerator at 2–8 °C. Stored unopened at this temperature the product is guaranteed stable until the expiry date, as indicated on the ampoule label and outer box. After opening the ampoule, the product is stable for 30 minutes.

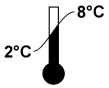
Procedures
1. Allow the ampoule to stand for at least 30 minutes at room temperature (15–30 °C).
2. Swirl the ampoule gently. Allow bubbles to rise before opening the ampoule.
3. Protect fingers with gauze, tissue or gloves and carefully snap off the neck of the ampoule.
4. Eurotrol ICSH HiCN Standard is now ready for use. Follow the instruction for measuring, according to the instructions in the appropriate manual of the analyser.
   Note: Eurotrol ICSH HiCN Standard is 1:251 prediluted and doesn't require further dilution before and/or during measurement procedure.
5. Please refer to local guidelines for recommended frequency of use.

Precautions
1. For in vitro diagnostic use only.
2. *Animal Blood Product. Bovine based materials do not carry biohazards for man, such as HepB, HepC and HIV.*
3. This product should not be disposed of in general waste. Consult local environmental authorities for proper disposal.

Reference values
Reference values are available on the enclosed assay sheet. Eurotrol ICSH HiCN Standard is measured using the HiCN reference method (2,3). Values on the assay sheet are determined by the International Council for Standardization in Haematology (ICSH) by use of a world wide network of reference laboratories.

This product is manufactured according to Eurotrol specifications.
For further information please contact Eurotrol B.V., e-mail: office@eurotrol.com, T +31 318 695777 or F +31 318 695770.
Manufactured by Eurotrol b.v., Keplerlaan 20, 6716 BS Ede, The Netherlands

Symbols used:

	Attention, see instructions for use	LOT	Batch number
	Use by		Temperature limitation
IVD	In Vitro Diagnostic Medical Device	REF	Reference number
	Manufacturer	CE	CE Mark

References

1. Holtz AH, Some experience with a cyanhemiglobin solution, Bibliographica haematologica 1965;21: 75-78.
2. Van Kampen EJ and Zijlstra WG, Standardisation of haemoglobinometry. II, The haemoglobin cyanide method, Clin. Chim. Acta 1961;6: 538-544.
3. International Council for Standardisation in Haematology, Recommendations for reference method for haemoglobinometry in human blood and specifications for international hemiglobincyanide reference preparation, J. Clin. Pathol. 1978;31: 139-143.

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