

Human haemoglobin Reference Standard

Cat. No. GB-8H Lot. No. (See product label)

SPECIFICATION

Product Overview The material has been characterized by BCR. The material information has been revised under the responsibility of IRMM. The information given should be regarded as guidance values and not as binding ones.

Species Human

Applications The material is intended to be used for quality control and for calibration of HPLC based HbA1c detection methods.

Usage To make it ready for use, the material has to be reconstituted according to the following procedure:
 a. Allow the test sample to reach room temperature before opening.
 b. Tap ampoule gently on bench to collect all dispersed material at bottom end.
 c. Reconstitute by slow addition to the sides of the ampoule 1.0 ml deionised water.
 d. Allow to stand for 15 minutes at room temperature.
 e. Mix gently by rotation.
 f. Store ampoule open (lying on its sides) at + 4 °C for (48±3) hours before use.
 g. Dilute the reconstituted RM 405 with the appropriate haemolyzing reagent taking into account that the total haemoglobin (Fe₄) concentration is = 0.23 mmol/l (15 g/l).
 h. Before injection, treat the material as for a patient sample.

Quality Control Test MonoS-HPLC at 15 °C.

Notes The material has been tested for the presence Hepatitis B surface antigen and for HIV1/HIV2 antibodies and found negative. However the material is of human origin and should be handled with adequate care. It is intended for in vitro analysis only.

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Storage	Upon arrival the material shall be stored at -20 °C.
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Concentration	glycated haemoglobin (HbA1c): 62.9 g/kg
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