Creatine kinase (CK-MB Isoenzyme) Reference Standard

Cat. No. CKMB-10H **Lot. No.** (See product label)

SPECIFICATION

Product Overview	Each sample is in lyophilised form and equivalent to about 1 mL of a solution of purified creatine kinase from human heart. The preparation has been stabilised by incorporation in a matrix consisting of human serum albumin at a concentration of 50 g/L, PIPES buffer 25 mmol/L, ADP 2 mmol/L, 2-mercaptoethanol 5 mmol/L and NaCl 154 mmol/L. No contamination has been detected for alanine aminotransferase, lactate dehydrogenase, aspartate aminotransferase, hexokinase and glucose 6-phosphatase. The material is kept under dry nitrogen in sealed glass ampoules. The residual water mass fraction was found to be below 1%.
Species	Human
Usage	The material is intended to provide, when reconstituted, a solution with a known catalytic concentration of human CK-MB that can be used for intra-laboratory quality control of the 37 °C IFCC reference measurement procedure and to verify comparability of results from laboratories using this measurement procedure. The certified reference material can also be used for evaluation of in vitro test systems for CK-MB measurements by method comparison with the 37 °C IFCC reference measurement procedure. The material can also be used for single-point or (by dilution in the matrix) multi-point calibration of lower order procedures for measuring CK-MB activities provided they have the same or similar analytical specifity as the reference measurement procedure used for the certification. However, its use for this function requires the availability and use of an independent quality-control materialReconstitution of the material1. Allow the vial to equilibrate at room temperature.2. Tap the vertically-positioned vial gently to ensure that the lyophilised

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	material is at the bottom of the vial.3. Weigh the vial with its contents to the nearest 0.1 mg.4. Carefully remove the stopper.5. Reconstitution by slow addition to the sides of the vial (1.00±0.01) mL distilled water (20-22 °C) with calibrated volumetric equipment. Note the water temperature.6. Let stand for a few minutes at room temperature and mix by gently swirling. Keep the reconstituted material at 4 °C.7. Store the vial the following 30 minutes in a refrigerator at +4-8 oC before use.8. Calculate the volume of water at 20 °C from the mass of the volume taking into account the temperature-dependent density.9. The catalytic concentration of creatine kinase must be measured within 4 hours following reconstitution.
Quality Control Test	Catalytic concentration in reconstituted material as determined by the IFCC method at 37 °C described in Clinical Chemistry and Laboratory Medicine 40:635-642.
Notes	The material has been tested for the presence Hepatitis B surface antigen and for HIV1 and 2 antibodies and found negative. However, the product must be handed as any material of human origin. It is intended for in vitro analysis only. Avoid swallowing as well as prolonged and repeated contact with skin. Do not discharge the waste into the drain.
Storage	Unopened ampoules should be stored at -20 °C. However, the European Commission cannot be held responsible for changes that happen during storage of the material at the customer's premises, especially of opened samples.
Concentration	Catalytic concentration in reconstituted material: 101 U/L; 1.68 Ukat/L

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