

H.D.M. Labs Inc

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CERTIFICATE OF ANALYSIS

PRODUCT:	<i>Creatine Kinase MB isoenzyme Antigen Grade</i>
ABBREVIATION:	CK-MB
SYNONYMS:	CK-MB, CK-2
CAT. NO:	xxx-xx
SOURCE:	Human Heart
COLOR:	light straw
FORM:	50% glycerol, 5 mM Succinate, 1 mM EDTA & DTE, 10 mM Sodium chloride, pH 7.0.
LOT NO:	CKMB-9/07
UNIT DEFINITION:	One unit will transfer one μ mole of phosphate from Creatine Phosphate to ADP per minute at 37°C. Measured at 340 nm as one equimolar amount of NADH produced by a coupled reaction.
ACTIVITY:	511 U/mL @ 37°C
PROTEIN:	34 mg Protein/ml by Coomassie
SPECIFIC ACTIVITY:	14.94 IU/mg Protein
STORAGE:	2-8 Deg C
PURITY:	Greater than 99% pure according to SDS-PAGE
ELECTROPHORESIS:	CKMB 100% (no other CK showing on electrophoresis)
EXPIRATION DATE:	September, 2008

CERTIFICATION: The Donors are of US origin and have been tested and found to be **NEGATIVE** for **HbsAg, HCV, HIV-1 & 2, Syphilis and HIV-1 Antigen** by currently approved FDA methods. We certify this to be true to the best of our knowledge. However, because no test method can offer complete assurance that HIV, HBsAg, HCV, Syphilis or other infectious agents are absent, this material should be handled at the Bio-safety Level 2 as recommended for any potentially infectious human serum or blood specimen in the CDC/NIH manual "Biosafety in Microbiological and Biomedical Laboratories", 1993. **THIS MATERIAL IS SOLD FOR IN-VITRO DIAGNOSTIC USE ONLY IN MANUFACTURING OR RESEARCH. THIS MATERIAL IS NOT SUITABLE FOR INJECTION.** Negative test results were found when pooled product sample and or individual donor samples were tested for viral DNA by HIV-1 Antigen DNA Polymerase Chain Reaction (PCR) Viromed Safety Laboratories using protocol C39061.00 or by Roche Amplichor method.

