TECO DIAGNOSTICS
1268 N. Lakeview Ave.
Anaheim, CA 92807
1-800-222-9880

CK-MB CONTROL SET
LEVEL I - II

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions.

INTENDED USE
CK-MB

CONTENTS / MATERIALS PROVIDED
CK-MB Control Level I
CK-MB Control Level II
It contains the human serum. Sodium Azide (0.09 %) is added as preservative

MATERIALS REQUIRED BUT NOT PROVIDED:
1. Class A volumetric pipette for liquid transfer
2. Distilled or deionized water meeting the specifications equivalent to USP (United States Pharmacopeial Convention) purified water.

CONTROL STABILITY

Temperature-Conditions	Stability
Unopened at 2 - 8°C	Expiry date on the vial.
Opened and stored 25°C	5 days
Frozen and stored at -20°C	30 days

LIMITATIONS
1. Please open the vial caps carefully. When you open, be careful not to scatter any powdery substance around or to escape from the vial.
2. Dissolve with distilled water with volume stated on the vial. Injector should not be used for the transfer process since there may be errors between 5-20% in liquid transfer with the injector. Use calibrated micropipettes.
3. Temperature of dry serum in the vial and distilled water must be 20-25°C. After adding distilled water, close the vial cap tightly and store at 20-25°C around 5-10 minutes.
4. Wait for 30 minutes for dissolving process and mix thoroughly by gently inverting the vial at regular intervals, do not shake. Avoid formation of bubbles or foam. Protect from light. It is recommended to use a rotational mixer for routine mixing procedures.
5. After reconstitution, the control serums are usually divided into small quantities (150-250 microliters) into Eppendorf tubes or sample cups of the device and stored for freezing process. For serums prepared in this way, it is absolutely necessary to leave the serum at 20-25°C for 30 minutes before dividing it into small quantities. Do not refreeze after the serum is frozen and thawed once.
6. Control serum precipitation is faster than normal serum. In order for the first and last parts to be homogeneous and to avoid precipitation, perform the process as fast as possible during separation.
7. The quality of the distilled water to be used in the dilution of the control serum is very important. There may be significant deviations in the values due to bacterial contamination.
8. It is necessary to be careful against infectious agents in control serum. Refer to precautions section.

PREPARATION OF CONTROL
Lyophilized serum control should be reconstituted by adding distilled or deionized water with the amount stated on the label. Close the vial and wait for 30 minutes. Dissolve the contents of the vial by swirling gently to avoid the formation of foam. Do not shake.

INDICATIONS OF INSTABILITY OR DETERIORATION
The presence of extreme turbidity or microbial growth may indicate deterioration.

PRECAUTIONS
Human source material. Treat as potentially infectious material. Each plasma donor used in the preparation of this product has been tested by an FDA-approved method and found negative For the presence of HIV 1/2 HBsAg, HCV, HIV-Ag antibodies. However, none of the known testing methods can offer complete assurance that the hepatitis B virus, Human Immunodeficiency Virus (HIV) or infectious agents are not present. All human-based products should be handled in accordance with Good Laboratory Practice (GLP) principles using appropriate precautions.

WARNINGS
IVD: For in Vitro Diagnostic use only.
Do not use expired controls.
Controls with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.
Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

REFERENCES
1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register. July 1, 2001; 17:260–273.
2. Directive 2000/54/EC. Official Journal of the European Communities No. L262 from October 17, 2000.

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Manufactured by:
TECO DIAGNOSTICS
1268 N. LAKEVIEW AVE.
ANAHEIM, CA 92807
U.S.A.