

CK-MB Controls (Level I and Level II)

1.0 Intended Use

Biotron Diagnostics CK-MB Isoenzyme Control has been assayed for CK-MB and is intended to be used as a human serum control product for CK-MB.

2.0 Summary and Principle

The determination of the content of the CK-MB isoenzyme is a valuable diagnostic tool in the evaluation of many pathological conditions, including acute myocardial infarction. These controls are designed for use in both manual and automated systems. The use of control material is necessary to estimate test precision in a test system and to detect systematic analytical deviation that may arise from reagent or analytical instrument variation. These control levels are available for the clinical laboratory to evaluate the patient CK-MB isoenzyme level in normal and abnormal conditions. Since King Diagnostic controls consist of an all human preparation, they can be run side by side with the patient sample through all phases of the test method. These human controls eliminate possible altered values found in non-human based materials.

3.0 Reagent

Biotron Diagnostic CK-MB Isoenzyme Controls are prepared from human serum and human derived isoenzyme and are available in two levels. This product is freeze-dried for extended shelf life.

3.1 Reagent Storage

CK-MB Isoenzyme Controls are stable until the date indicated on the vial when stored at 2-8°C.

Reconstituted vials are stable for seven days when stored at 2-8°C. If turbid or gross contamination appears after reconstitution, discard immediately.

3.2 Warning

Check the range of isoenzyme values specific for the lot number of control being used.

These products have been found to be non-reactive for Hepatitis B Surface Antigen (HBsAg) and negative for antibody to Human Immunodeficiency Virus (HIV), when tested by the FDA approved third generation methods. No known methods for HBsAg and HIV can offer total assurance that products derived from human blood will not transmit these diseases. Therefore, human serum products and patients samples should be considered potentially hazardous and handled as if capable of transmitting infectious agents.

Caution: control material contains azides which can react with copper or lead plumbing to form explosive azides. After use, flush with copious amounts of water to prevent azide build up.

4.0 Procedure

- 4.1 Remove vials from refrigerator and allow to warm to room temperature for 15 to 20 minutes.
- 4.2 Remove the seal and rubber stopper from vials. Volumetrically add exactly 3.0 ± 0.05 ml of distilled or deionized water using a calibrated pipet. The water used for reconstitution should be at room temperature, 18-26°C.
- 4.3 Recap the vial and gently swirl 10 times.
- 4.4 Let the vials remain at room temperature for 20 minutes, then invert gently 10 times.
- 4.5 Let the vials remain at room temperature for an additional 20 minutes. Then invert 10 times and gently swirl.
- 4.6 Use immediately or refrigerate at 2-8°C for future use.

5.0 Limitations

- 5.1 Biotron Diagnostic CK-MB controls have been evaluated using the Biotron Diagnostic CK-MB reagent.
- 5.2 Each lot of control has its own determined value.

5.3 Individual labs may not obtain the mean values as listed for each lot. Technique, equipment and experimental error may produce slightly different values, however, the values should fall within the expected range. Each laboratory should determine their own mean values for this product.

6.0 Expected Results

See attached sheet for expected ranges.

7.0 Technical Support

Call Biotron at 1-800-595-8766 for technical service.

Recorder : Cat No 103045 (4x3ml)

8.0 Reference

- 8.1 Gerhardt W., et. al. Clin Chem Acta78: 29, 1977
- 8.2 Giegel J.L., et. al. Clin Chem 28: 1364, 1982
- 8.3 Mercer D.W., Clin Chem 20: 36, 1974
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- 8.5 Roberts R., et. al. The Lancet 319, 1977
- 8.6 Vaidya H.C., et. al. Clin Chem 32: 657, 1986
- 8.7 Wicks R.W., et. al. Clin Chem 28: 54, 1982
- 8.8 Willerson J.T., et. al. Proc Natl Acad Sci USA 74: 1711, 1977