



*Your Key To Reliable Quality Controls*  
P.O. Box 6714, Los Osos, CA 93412, USA

## **CARDIAC MARKERS CONTROL #150**

For In Vitro Diagnostic Use

### **INTENDED USE**

MORE DIAGNOSTICS' CARDIAC MARKERS CONTROL is intended to be used as an assayed control material for the measurement of CKMB, troponin, myoglobin and C-Reactive Protein (CRP).

### **INTRODUCTION**

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. MORE DIAGNOSTICS' CARDIAC MARKERS CONTROL produces meaningful levels of CKMB, troponin, myoglobin and CRP.

MORE DIAGNOSTICS' controls are prepared from human serum to which CKMB, troponin complex, myoglobin and CRP have been added. These human based controls can be run side by side with the patient samples through all phases of the test assay.

### **PRODUCT DESCRIPTION**

The serum used in this control product is prepared from normal human subjects. The analytes are adjusted to the desired concentrations and the values are confirmed during the manufacturing process. Quality control procedures used before, during and after manufacture insure that each lot is of the same quality.

The control is liquid for convenience and is stored frozen (see STORAGE & STABILITY for conditions). The control is available in single level boxes of 6 vials containing 3 mL per vial or tri-level box containing 2 vials each of 3 levels.

### **PRECAUTIONS**

1. Check to see that the lot number indicated on the VALUE SHEET corresponds to the lot number on each vial, to ensure correct analyte values.
2. The human sera used in preparation of this control has been tested by FDA approved methods and/or PCR methods and found to be negative/non-reactive for Hepatitis B Surface Antigen (HBsAg), Hepatitis C (HCV), HIV-1, HIV-2, HTLV-1 and HTLV-2. No known test methods can offer total assurance that products derived from human source material will not transmit these diseases. Therefore, human serum products should be handled in accordance with recommendations from HHS Publication No. (CDC) 93-8395 "Biosafety in Microbiological and Biomedical Laboratories".
3. This product contains sodium azide, which may react with copper or lead plumbing to form explosive azides. After use, flush drain with copious amounts of water to prevent azide buildup.

### **STORAGE AND STABILITY**

**FROZEN MATERIAL** – MORE DIAGNOSTICS' CARDIAC MARKERS CONTROL is stable until the date indicated on the bottle when stored at less than  $-26^{\circ}\text{C}$ . Storage at temperatures above  $-26^{\circ}\text{C}$  may result in a reduced shelf life. Laboratories that store higher than the recommended temperature should limit their inventory. **Self-defrosting freezers are not suitable for storage of this product.**

**THAWED MATERIAL** – SEE VALUE SHEET FOR THAWED STABILITY. **DO NOT REFREEZE AFTER THAWING.**

**CONTAMINATION** – If there is visible evidence of microbial growth or gross contamination in a bottle, do not use the material. **DISCARD IMMEDIATELY!**

### **PROCEDURE**

1. Remove vial from freezer and allow to warm to room temperature,  $18-28^{\circ}\text{C}$ .
2. Thoroughly mix by gentle swirling of the bottle prior to each sampling. Remove the amount required for the test procedure.
3. Tightly recap the bottle immediately after sampling.

4. Treat the control samples in the same manner as the patient sample, as specified in the assay procedure.
5. Store thawed control at 2–8°C. **DO NOT REFREEZE!**

#### **LIMITATIONS**

This product is to be used as control material and is not intended to be used for calibration.

Each lot of control has its own determined values.

Compatibility of this control has been demonstrated only with methods shown on the VALUE SHEET. Caution should be employed when using these controls with methods for which values have not been printed.

The means and ranges indicated on the VALUE SHEET were obtained from replicate analyses. These values should be used as guidelines, as individual laboratories may not obtain the mean values for the constituents as listed for each lot. Techniques, equipment differences and reagent changes can result in different values, however, the mean values obtained should fall within the expected range. Each laboratory should determine its own means and ranges.

#### **EXPECTED VALUES**

SEE ACCOMPANYING VALUE SHEET

**FOR ORDERING:**  
**CALL: (800) 758-0978 OR (805) 528-6005**  
**OR FAX: (805) 528-3532**