

# SAFETY DATA SHEET (SDS)

Revision Date: 2015-06-16

## 1. PRODUCT AND COMPANY IDENTIFICATION

### PRODUCT NAME

High-Sensitive D-Dimer Control

### CATALOG #

K115C-10M

Intended Use: For use as an assayed quality control material for monitoring the High-Sensitive D-Dimer (hs D-Dimer) immunoturbidimetric *in vitro* assay.

### MANUFACTURER INFORMATION

Manufacturer: **KAMIYA BIOMEDICAL COMPANY**

Address: 12779 Gateway Drive  
Seattle, WA 98168  
U.S.A.

Phone: +1 206-575-8068

FAX: +1 206-575-8094

Website: [www.k-assay.com](http://www.k-assay.com)

## 2. HAZARDS IDENTIFICATION

<b>GHS Classification:</b>	Does not fulfill criteria for classification as dangerous or hazardous
<b>Hazard Symbol:</b>	None
<b>Signal Word:</b>	None
<b>Hazard Statements:</b>	None
<b>Precautionary Statements:</b>	None
<b>Other:</b>	This product contains human serum ingredients. It has been prepared from human sera that tested negative for HBsAg, HCV antibodies, and HIV antibodies by FDA-approved methods. In view of the fact that no test method can completely assure the absence of hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), or other infectious agents, the product should be treated like patient specimens that are potentially infectious and handled with appropriate caution.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

Single substance or Mixture: Mixture

There are no ingredients that fall under GHS classification.

## 4. FIRST-AID MEASURES

<b>Inhalation:</b>	Get fresh air. If experiencing difficulty breathing, obtain medical attention.
<b>Skin Contact:</b>	Wash off skin thoroughly with water. Remove contaminated clothing and wash before re-use. In cases of redness or itching, get medical attention.
<b>Eye Contact:</b>	Rinse eyes immediately with water for several minutes with eyelids open. Remove contact lenses, if present and easy to do. Repeat rinsing. Get medical attention.
<b>Ingestion:</b>	If conscious, wash out mouth thoroughly with water then drink 1-2 glasses of water. Get medical attention. Do not induce vomiting without medical advice.

## 5. FIRE-FIGHTING MEASURES

<b>Extinguishing Media:</b>	No restrictions
<b>Specific Hazards:</b>	No fire or explosion hazards. Packaging material will burn in a fire.
<b>Special Protective Equipment:</b>	Wear self-contained breathing apparatus and protective suit, if necessary.

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## 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions:</b>	Wear proper protective equipment to avoid adhering to skin.
<b>Environmental Precautions:</b>	Do not wash away into sewers, watercourse, or rivers. If material has entered surface drains, it may be necessary to inform local authorities.
<b>Methods and Materials for Containment and Cleaning Up:</b>	After absorbing liquid with absorbent material e.g. cotton, wool or paper towel, flush the spill site with plenty of water. Keep in suitable, closed containers for disposal.

## 7. HANDLING AND STORAGE

<b>Handling:</b>	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.
<b>Storage:</b>	Store between +2 and +8 degrees C, tightly closed.
<b>Warning:</b>	None

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Respiratory Protection:</b>	None
<b>Eye Protection:</b>	Protective glasses
<b>Hand Protection:</b>	Protective gloves. Wash hands after use.
<b>Skin Protection:</b>	Wear suitable, impermeable protective clothing.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid
<b>Color:</b>	Colorless or slightly yellow
<b>Odor / Odor Threshold:</b>	Odorless
<b>pH:</b>	No information available
<b>Melting Point / Freezing Point:</b>	No information available
<b>Initial Boiling Point and Boiling Range:</b>	No information available
<b>Flash Point:</b>	Not applicable
<b>Evaporation Rate:</b>	No information available
<b>Upper / Lower Flammability or Explosive Limits:</b>	No information available
<b>Vapor Pressure:</b>	No information available
<b>Vapor Density:</b>	No information available
<b>Relative Density:</b>	No information available
<b>Solubility(ies):</b>	Miscible in water
<b>Auto-ignition:</b>	Product is not self-igniting
<b>Decomposition Temperature:</b>	No information available
<b>Viscosity:</b>	No information available

## 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable under recommended storage conditions.
<b>Hazardous Reactions:</b>	No information available

## 11. TOXICOLOGICAL INFORMATION

There are no ingredients that fall under GHS classification.

## 12. ECOLOGICAL INFORMATION

<b>Toxicity:</b>	No information available
<b>Persistence and Degradability:</b>	No information available
<b>Bioaccumulative Potential:</b>	No information available
<b>Mobility in Soil:</b>	No information available
<b>Hazard to the Ozone Layer:</b>	No information available

## 13. DISPOSAL CONSIDERATIONS

<b>Product:</b>	The product has to be disposed of in accordance with local regulations. Do not wash away into surface water or sanitary sewer systems.
<b>Contaminated Packaging:</b>	After washing with water, the empty containers should be taken to an approved waste handling site for disposal.

## 14. TRANSPORT INFORMATION

This product is considered to be non-hazardous for transport.

<b>UN Number:</b>	N/A
<b>UN Proper Shipping Name:</b>	N/A
<b>Transport Hazard Class:</b>	N/A
<b>Packing Group:</b>	N/A

## 15. REGULATORY INFORMATION

Regulatory information with regard to this preparation in your country or region should be examined on your own responsibility.

## 16. OTHER INFORMATION / DISCLAIMER

This product is for *in vitro* use only. It is not to be used internally in humans or animals.

The information, data, and recommendations contained herein are based upon information believed by **KAMIYA BIOMEDICAL COMPANY (KBC)** to be accurate, but does not purport to be all-inclusive and shall be used only as a guide. **KBC** neither warrants the accuracy of this information nor assumes any legal responsibility in connection with its dissemination. **KBC** shall not be held liable for any damage resulting from handling or from contact with the above product.

It is the user's responsibility to determine the suitability of this information and the adoption of necessary safety precautions. All materials and mixtures may present unknown hazards and should be used with caution. When necessary or appropriate, independent opinions regarding the risk of handling or exposure should be obtained from trained professionals.

We reserve the right to revise this document periodically, as new information becomes available.