SAFETY DATA SHEET (SDS)

Revision Date: 2015-06-16

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME	**CATALOG #**
Serum/Urine FDP-E Calibrator	KAI-114C

Synonyms: Serum/Urine Fibrin/Fibrinogen Degradation Product Fragment E Calibrator

Intended Use: For the calibration of the Serum/Urine FDP-E (Fibrin/Fibrinogen Degradation Product Fragment E) 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

2. HAZARDS IDENTIFICATION

Lyophilized Calibrator	
GHS Classification:	Does not fulfill criteria for classification as dangerous or hazardous
Hazard Symbol:	None
Signal Word:	None
Hazard Statements:	None
Precautionary Statements:	None
Other:	This product contains human plasma ingredients. It has been prepared from human plasma 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.

Diluent	
GHS Classification:	Does not fulfill criteria for classification as dangerous or hazardous
Hazard Symbol:	None
Signal Word:	None
Hazard Statements:	None
Precautionary Statements:	None

3. COMPOSITION / INFORMATION ON INGREDIENTS

Lyophilized Calibrator	
Single substance or Mixture:	Mixture
There are no ingredients that fall under GHS classification.	

Diluent		
Single substance or Mixture:	Mixture	
Ingredient	**CAS #**	**Amount**
Sodium Azide	26628-22-8	0.05 w/v%

4. FIRST-AID MEASURES

Inhalation:	Get fresh air. If experiencing difficulty breathing, obtain medical attention.
Skin Contact:	Wash off skin thoroughly with water. Remove contaminated clothing and wash before re-use. In cases of redness or itching, get medical attention.
Eye Contact:	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.
Ingestion:	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

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Wear proper protective equipment to avoid adhering to skin.
Environmental Precautions:	Do not wash away into sewers, watercourse, or rivers. If material has entered surface drains, it may be necessary to inform local authorities.
Methods and Materials for Containment and Cleaning Up:	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

Handling:	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.
Storage:	Store between +2 and +8 degrees C, tightly closed.
Warning:	The diluent contains 0.05 w/v% sodium azide as a preservative. Sodium Azide forms an explosive compound by contact with lead and copper plumbing. Flush with copious amounts of water.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

9. PHYSICAL AND CHEMICAL PROPERTIES

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

Diluent	
Physical State:	Liquid
Color:	Colorless or slightly yellow
Odor / Odor Threshold:	Almost odorless
pH:	8.2 - 8.5 (at 25℃)
Melting Point / Freezing Point:	No information available
Initial Boiling Point and Boiling Range:	No information available
Flash Point:	Not applicable
Evaporation Rate:	No information available
Upper / Lower Flammability or Explosive Limits:	No information available
Vapor Pressure:	No information available
Vapor Density:	No information available
Relative Density:	No information available
Solubility(ies):	Miscible in water
Auto-ignition:	Product is not self-igniting
Decomposition Temperature:	No information available
Viscosity:	No information available

10. STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions.
Hazardous Reactions:	Sodium Azide forms an explosive compound by contact with metals.

11. TOXICOLOGICAL INFORMATION

There are no ingredients that fall under GHS classification.

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Product:	The product has to be disposed of in accordance with local regulations.
Contaminated Packaging:	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.

UN Number:	N/A
UN Proper Shipping Name:	N/A
Transport Hazard Class:	N/A
Packing Group:	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.