RAMP® Clinical Test Device/Kit

Material Safety Data Sheet

SECTION 1	CHEMICAL PRODUCT AND COMPANY IDENTIFICATION
Product Description	An *In vitro* diagnostic test device/kit composed of hard plastic parts and/or vials of diluents, some of which are coated with, or contain, minute quantities of immunoassay reagents used to measure reactions to human source (blood, mucous, etc.) material specimens supplied by a patient.

Catalogue Number

Product	Catalogue Numbers		
BNP	C1116		
CK-MB	C1102	90006	
D-dimer	C1106	90080	
Flu A + B	C1107		
Myoglobin	C1103	90001	
NT-proBNP	C1104	C1105	90029
RSV	C1108		
Troponin I	C1101	90012	
Procalcitonin	C1112	90086	

Supplier

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SECTION 2	COMPOSITION/INFORMATION ON INGREDIENTS
General	The test device/kit is composed of hard plastic parts and/or vials of diluents, some of which are coated with, or contain, minute quantities of immunoassay reagents stored in a sealed pouch containing desiccant.

Dangerous Components

Ingredient	Component	CAS No.	Content	Hazard Classification
ProClin® 300	Buffer	26172-55-4	≤ 0.1% v/v	R : 20-24/25-34 S : (1/2)24/25-46
ProClin® 950	Buffer	2682-20-4	≤ 0.1% v/v	R : 20-24/25-34 S : (1/2)24/25-46
Sodium Azide	Tip	26628-22-8	≤ 0.02% w/v	R : 28, R32 N : R50/53 S : (1/2)28-45-60-61
Animal Proteins Animal Serum	Buffer Cartridge Tip	None	≤0.1 – 5.0% w/v	None

ProClin® is a registered trademark of Rohm and Hass Company

The Flu A + B and RSV test device/kits contain control swabs which contain inactivated Influenza A and Influenza B or RSV antigen strains.

Remainder of composition consists of non-hazardous ingredients.

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SECTION 3	HAZARDS IDENTIFICATION
Health Hazard	Test device/kit contains no hazardous substances in reportable quantities. East test kit vial buffer contains ProClin® (CAS 26172-55-4 2682-20-4) at a concentration of ≤ 0.1% v/v. Effects of ProClin® in buffer at this concentration level has not been tested and may be an irritant to skin and eyes if spilled. Each test tip contains sodium azide (CAS 26628-22-8) at a concentration of ≤ 0.02% w/v and is below the acceptable limit of LD_{50}27 mg/kg. Animal proteins are present in the test kit buffer vials, cartridges and tips. They present no hazard if spilled or subjected to fire. There is no known risk of HIV and Hepatitis in animal sera. All sources of animal products are either from the United States, countries where BSE has not been reported, or are certified to be BSE-free from the manufacturer. It is recommended however, to take precautions as for any potentially infectious material.
Classification	The test device/kit is not classified as dangerous according to Directive 1999/45/EC. This classification is according to the latest editions of the EU-lists, and extended by company and literature data.
SECTION 4	**FIRST-AID MEASURES**
Emergency First Aid	Call an internal First Aider where available or else contact a Physician immediately.
Inhalation	Inhalation of buffer from test kit vials may cause irritation. Remove to fresh air. Seek medical advice as needed.
Ingestion	Ingestion of buffer from test kit vials may cause irritation. If swallowed, rinse mouth with water and drink large quantities of water to dilute. Seek medical advice as needed.
Skin Contact	Contact with buffer from test kit vials may cause skin irritation. In case of skin contact, immediately wash skin with soap and copious quantities of water.
Eye Contact	Contact with buffer from test kit vials may cause eye irritation. Flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. Seek medical advice as needed.
SECTION 5	**FIRE-FIGHTING MEASURES**
General	This product is made up of hard plastic parts and/or plastic vials that when burned will give off carbon monoxide and other toxic gases. Use a self-contained breathing apparatus (SCBA) when fighting fires with this product involved.
Extinguishing media	In case of fire: use water, dry chemical, chemical foam, or other appropriate standard means to extinguish the fire.
Unusual Fire and Explosion Hazards	Not flammable. This product does not present any fire or explosion hazard.
SECTION 6	**ACCIDENTAL RELEASE MEASURES**
General	Unused test device/kit vials and components are not hazardous.
After Spillage	Spills or leaks of buffer from test kit vials should be cleaned up immediately using Good Laboratory Practices and disposed in accordance with the facility's solid waste and/or biological safety program disposal procedures. Clean up any spillage with laboratory recommend disinfectant/detergent. Wear gloves and protective glasses.
Absorbent Material	No restriction
SECTION 7	**HANDLING AND STORAGE**
Handling	See product Instructions for Use for special temperature requirements and handling instructions for the test device/kit before application of human source material test specimen. After application of human source (blood, mucous, etc.) material test specimen, handle used test components in accordance to the facilities' biological safety program. When used with a whole blood specimen, the Bloodborne Pathogen Standard applies.
Storage	Store in original packaging at temperatures and conditions as indicated in the test device/kit Instructions for Use.

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SECTION 8	EXPOSURE CONTROLS/PERSONAL PROTECTION
Personal Protective Equipment	Use standard Good Laboratory Practices when handling or using a test device or test kit vials. Minimize exposure to immunoassay reagents.
Eyes	Wear safety glasses or chemical goggles if splashing is possible.
Skin	Standard laboratory rubber or latex gloves.
Clothing	Where appropriate protective clothing to prevent or minimize skin contact.
Respirators	None
SECTION 9	**PHYSICAL AND CHEMICAL PROPERTIES**
Appearance	In vitro diagnostic product. The test device/kit is an article containing solid components impregnated on a test membrane sealed within a plastic holder. The test kit vials contain liquid reagents that are clear in colour. Refer to Instructions for Use for further description.
Odour	None
pH Value	6 to 8
Boiling Point	Not determined
Melting Point	Not determined
Specific Gravity	No information available
Substance does not have any Oxidizing Properties	Not determined
Ignition Temperature	Not determined
Explosion Limits	Not explosive
Vapor Limits	Not determined
Density	Not determined
Solubility in Water	No information available
Viscosity	Not determined
SECTION 10	**STABILITY AND REACTIVITY**
Stability	Stable under condition of use until the “Use by” date indicated on the product labeling.
Conditions to Avoid	High temperatures or pressures may render the test device/kit unusable due to deformation of the hard plastic parts, although no additional hazards are expected.
Substances to Avoid	None known
Hazardous Decomposition Products	None known
SECTION 11	**TOXICOLOGICAL INFORMATION**
Carcinogenicity	Product is not listed as a carcinogen.
LD50 Oral	Irritant
LD50 Eye	Irritant
LD50 Skin	Irritant
LC50 Inhalation	None known
Toxicologic Information	Not thoroughly investigated.
SECTION 12	**ECOLOGICAL INFORMATION**
Water Hazard Class	This product is readily miscible with water and has no known potential for bioaccumulation.

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SECTION 13 DISPOSAL CONSIDERATION

General Information

UNUSED

Disposal should be made in accordance with existing facility solid waste disposal policies.

USED

Treat material as you would human body fluids. Used materials should be decontaminated and disposed of using an autoclave or by incineration as "other waste" – containing biological material. Disposal should, therefore be made in accordance with existing facility practices employed for biohazardous material that is consistent with federal, state, and local regulations.

To ensure compliance with anti-pollution and other laws of the country concerned, it is recommended that the relevant (local) authorities and/or approved waste-disposal companies are contacted for information. See European waste catalogue note below:

European Waste Catalogue: 18 01 03 – Wastes whose collection and disposal is subject to special requirements in order to prevent infection.

RCRA Series	Waste Code
D – Maximum Concentration of Contaminants	Not applicable
D – Chronic Toxicity Reference Levels	Not applicable
F – Series Waste	Not applicable
K – Series Waste	Not applicable
P – Series Waste	P105 Sodium Azide (trace amount)
U – Series Waste	Not applicable
Substances Banned from Land Disposal	Not applicable

SECTION 14 TRANSPORT INFORMATION

General Information	Fragile containers, handle with care. Protect from extreme fluctuating temperatures.
RID/ADR	Not regulated as a hazardous material.
IATA/ICAO	Not regulated as a hazardous material.
IMO	Not regulated as a hazardous material.
US DOT	Not regulated as a hazardous material.

SECTION 15 REGULATORY INFORMATION

Hazard Symbol	Harmful, Irritant 
Clean Air Act	This material is not recognized as an air contaminant.
Clean Air Act	This material is not on any CWA list.
EEC Criteria	Not classified as hazardous. The preparation is exempt from the EU labeling guidelines in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the Instructions for Use.

Relevant R-Phrases	**Code**	**Phrase**
	R21/22	Harmful in contact with skin and if swallowed.
	R36/38	Irritating to eyes and skin.

Relevant S-Phrases	**Code**	**Phrase**
	S24/25	Avoid contact with skin and eyes.
	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	S29/35	Do not empty into drains, dispose of this material and its container in a safe way.
	S36/37	Wear suitable protective clothing and gloves.

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SECTION 16	OTHER INFORMATION

All individuals using Response Biomedical test devices or test kit vials should follow general good laboratory safety procedures as established and implemented by each institution in compliance with federal, state, and local requirements. When used with a whole blood specimen the Bloodborne Pathogen Standard applies.

This Safety Data Sheet complies to the European Community Directive 93/112/EC amended 91/115/EEC.

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