




RAMP[®] Clinical Test Device/Kit

Material Safety Data Sheet

SECTION 1	CHEMICAL PRODUCT AND COMPANY IDENTIFICATION				
Product Description	An <i>In vitro</i> 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	Response Biomedical Corp. 1781 - 75th Avenue W., Vancouver, B.C. Canada V6P 6P2				
Toll Free Telephone	+1.888.525.7267 (North America)				
Telephone	+1.604.219.6119 (Rest of World)				
Fax	+1.604.456.6066				
Email	techsupport@responsebio.com				
Web	www.responsebio.com				
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	<p>Test device/kit contains no hazardous substances in reportable quantities.</p> <p>East test kit vial buffer contains ProClin[®] (CAS 26172-55-4 2682-20-4) at a concentration of $\leq 0.1\%$ 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.</p> <p>Each test tip contains sodium azide (CAS 26628-22-8) at a concentration of $\leq 0.02\%$ w/v and is below the acceptable limit of LD₅₀ 27 mg/kg.</p> <p>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.</p>
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	<p>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.</p> <p>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.</p>
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:		
	<u>European Waste Catalogue</u> : 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
	<p>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.</p> <p>This Safety Data Sheet complies to the European Community Directive 93/112/EC amended 91/115/EEC.</p>
	<p><i>The information herein is believed to be correct as of the date hereof, but is provided without warranty of any kind. As the conditions and manner of use are outside the control of Response Biomedical Corp., no warranties, express or implied are made, and no liability in connection with any use of this information is assumed. Users should make their own investigations to determine suitability of the information for the specific purposes. The recipient of our products is responsible for observing any applicable state, federal, national, or local laws and guidelines.</i></p>