

# MATERIAL SAFETY DATA SHEET

ABX Pentra RF CP - A91A00533

2003/12/04

## 1. Product and company identification

### 1.1 Identification of the product:

**Product name:** ABX Pentra RF CP

**Product code:** Ref. ABX ==> A11A01613

### 1.2 Company identification:

**ABX Diagnostics** – Rue du Caducée – Parc Euromédecine –  
34184 MONTPELLIER CEDEX 4 – FRANCE

**TEL (33) 4 67 14 15 16 FAX (33) 4 67 14 15 17**

### 1.3 Emergency phone number:

Contact the nearest first-aid station.

## 2. Composition/information on ingredients

### Description of the kit:

**REAGENT** : Bi-reagent cassette.

**REAGENT 1** = 1 × 22 ml ( Buffer)

**REAGENT 2** = 1 × 9 ml (Latex suspension)

### Chemical nature:

**REAGENT 1** :

Glycine	1.3%
Sodium chloride	0.58%
Sodium ethylenediamine tetra acetic acid disodium dihydrate	1.9%
Bovine serum albumin	3.0%
Sodium azide	0.09%

**REAGENT 2** :

Glycine	1.22%
Sodium chloride	0.54%
Latex particle adsorbed human IgG	0.166%
Sodium azide	Less than 0.1%

### Hazardous ingredients: (name, concentration)

Reagents do not contain dangerous substances in quantities higher than limits reported by 67/548/EEC and 88/379/EEC directives, and following modifications and amendments, about classification, labelling and packaging of dangerous preparations. There is at the present no information or indication of hazardous property.

### Dangerous preparation according to 67/548/EEC - 88/379/EEC:

No

## 3. Hazards identification

### Most important hazards:

No adverse health effects should occur from routine use of this material in the manner specified by manufacture's instructions. The above health effects may be associated with overexposure to this product. With FDA licensed tests, the human source material in this product has been tested and is not reactive for Hepatitis B surface antigen, anti-Hepatitis C, and anti HIV-1/HIV-2.

It is recommended to handle this product in accordance with Standard Laboratory Precautions. No hazardous product as specified in Directive 67/548/EEC.

### Specific risks:

Skin and/or eye contact, inhalation, and ingestion.

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## 4. First-aid measures

<b><u>Inhalation:</u></b>	N/A.
<b><u>Skin contact:</u></b>	Wash off with water.
<b><u>Eye contact:</u></b>	Flush eyes with water.
<b><u>Ingestion:</u></b>	Seek medical advice. Direction for physician: symptomatic treatment by a physician.

## 5. Fire-fighting measures

<b><u>Extinguishing media:</u></b>	No restriction.
<b><u>Specific risks:</u></b>	N/A.
<b><u>Special protective equipment:</u></b>	N/A.
<b><u>Additional recommendations:</u></b>	Thermal decomposition: dangerous decomposition is not anticipated.

## 6. Accidental release measures

<b><u>Personal precautions:</u></b>	No known analysis method can totally guarantee the absence of transmissible pathogenic agent. It is therefore recommended that these products be treated as potentially infectious, and handle observing the usual safety precautions.
<b><u>Environmental precautions:</u></b>	Place all spill residue into a suitable containers, seal, label, and hold for disposal.
<b><u>Methods for cleaning / absorption:</u></b>	Absorb and place in the appropriate container for infectious wastes. Wash contaminated area with disinfectant.

## 7. Handling and storage

### **7.1 Handling:**

<b><u>Technical measures:</u></b>	No special requirements.
<b><u>Precautions:</u></b>	Avoid splashing or spraying this product's components.
<b><u>Handling recommendations:</u></b>	All employees who handle this material should be trained to handle it safely in accordance with Standard Laboratory Precautions.

### **7.2 Storage:**

<b><u>Technical measures:</u></b>	N/A.
<b><u>Storage conditions:</u></b>	Store in tightly closed containers, under a cool condition (2 – 10 °C) and protected from light.
<b><u>Incompatible materials:</u></b>	No restriction.
<b><u>Packaging materials:</u></b>	No restriction.

## 8. Exposure controls/personal protection

<b><u>Specific control parameters:</u></b>	N/A.
<b><u>Technical measures:</u></b>	Follow standard laboratory practices concerning manipulation of human origin products.
<b><u>Respiratory protection:</u></b>	None.
<b><u>Hand protection:</u></b>	Disposable gloves. Wash hands before breaks and at the end of work.
<b><u>Eye protection:</u></b>	Safety glasses.
<b><u>Skin protection:</u></b>	Protective clothing.
<b><u>Hygiene measures:</u></b>	N/A.

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## 9. Physical and chemical properties

<b>Physical state:</b>	Liquid.	<b>Auto-flammability:</b>	N/D.
<b>Colour:</b>	<u>REAGENT 1</u> : yellowish <u>REAGENT 2</u> : white	<b>Explosive properties:</b>	N/D.
<b>Odour:</b>	Odourless	<b>Oxidizing properties:</b>	N/D.
<b>pH:</b>	<u>REAGENT 1</u> : 8.3 <u>REAGENT 2</u> : 7.3	<b>Vapour pressure:</b>	N/D.
<b>Boiling point:</b>	N/D.	<b>Relative density:</b>	N/D.
<b>Melting point:</b>	N/D.	<b>Solubility:</b>	Soluble (in water).
<b>Flashing point:</b>	N/D.	<b>Partition coefficient:</b>	N/D.
<b>Flammability (solid, gas):</b>	N/D.	<b>Other data:</b>	N/D.

## 10. Stability and reactivity

<b>Conditions to avoid:</b>	N/A.
<b>Materials to avoid:</b>	N/A.
<b>Hazardous decomposition products:</b>	No.
<b>Other data:</b>	No hazardous reactions known when used appropriately.

## 11. Toxicological information

<b>Acute toxicity:</b>	Human serum should be regarded as a potentially infectious material.
<b>Chronic toxicity:</b>	Not known.
<b>Inhalation:</b>	Not known.
<b>Skin contact:</b>	Not known.
<b>Eye contact:</b>	Not known.
<b>Ingestion:</b>	Not known.
<b>Other data:</b>	Intoxication has so far not become known.

## 12. Ecological information

<b>Mobility:</b>	Not data yet available.
<b>Degradability:</b>	Not data yet available.
<b>Bioaccumulative potential:</b>	Not data yet available.
<b>Ecotoxicity:</b>	Not data yet available.
<b>Other hazardous effects:</b>	Not data yet available.

## 13. Disposal considerations

<b>Surplus or waste (residues):</b>	Used reagents must be disposed off in accordance with local, national and federal regulations. This reagent contains less than 0.1% of sodium azide as a preservative. As sodium azide may react with lead and copper to form explosive metal azides, this reagent should be disposed of by flushing with copious amounts of water.
<b>Contaminated packaging:</b>	N/A

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## 14. Transport information (International regulations)

**By land:** N/A.  
**By river:** N/A.  
**By air:** N/A.  
**By sea:** N/A.  
**General information:** This product is not subject to current regulations for transportation of hazardous goods.

## 15. Regulatory information

### Labelling according to EEC directives:

**Symbols:** The product does not require special labelling, in accordance with the appropriate EEC directives relatives to dangerous.  
**R phrases:** N/A.  
**S phrases:** N/A.  
**Substances:** N/A.  
**Other regulatory requirements:** Please refer to any other national measures that may be relevant.

## 16. Other information

This product is intended for IN VITRO diagnostics use only.  
NOT FOR USE IN HUMANS.

The information herein is believed to be correct as of the date hereof and excludes any guarantee related with the final use given to the product, being the recipient the last responsible for observing the local laws applicable in each case.