

SECTION 1. IDENTIFICATION**1.1 Product Identifier**

Product Name:	Other Means of Identification. Catalog #:
CRYOcheck™ Normal Reference Plasma	CCNRP-05, CCNRP-10
CRYOcheck Reference Control Normal	RCN-05, RCN-10
CRYOcheck Abnormal 1 Reference Control	ARP1-05, ARP1-10
CRYOcheck Abnormal 2 Reference Control	ARP2-10
CRYOcheck Lupus Positive Control	CCLP-05, CCLP-10
CRYOcheck Weak Lupus Positive Control	CCWLP-05, CCWLP-10
CRYOcheck Low Fibrinogen Control	CCLF-10
CRYOcheck Abnormal 1 Control	CCA1-10
CRYOcheck Abnormal 2 Control	CCA2-10
CRYOcheck Heparin Control	CCH-10
CRYOcheck APCR Positive Control	APCR-05
CRYOcheck Pooled Normal Plasma	CCN10-10, CCN-10, CCN-15, CCN-40
CRYOcheck Factor II Deficient Plasma	FDP02-10, FDP02-15
CRYOcheck Factor V Deficient Plasma	FDP05-10, FDP05-15
CRYOcheck Factor VII Deficient Plasma	FDP07-10, FDP07-15
CRYOcheck Factor VIII Deficient Plasma	FDP08-10, FDP08-15, FDP08-40
CRYOcheck Factor VIII Deficient Plasma with VWF	FDP08VWF-10, FDP08VWF-15
CRYOcheck Factor IX Deficient Plasma	FDP09-10, FDP09-15
CRYOcheck Factor X Deficient Plasma	FDP10-10, FDP10-15
CRYOcheck Factor XI Deficient Plasma	FDP11-10, FDP11-15
CRYOcheck Factor XII Deficient Plasma	FDP12-10, FDP12-15
CRYOcheck Prekallikrein Deficient Plasma	FDPK-10
CRYOcheck Platelet Lysate	PNP-10
CRYOcheck Clot S, Protein S Deficient Plasma Component	CCS-15, PS Deficient Component CCS-30, PS Deficient Component
CRYOcheck Clot C, Protein C Deficient Plasma Component	CCC-15, PC Deficient Component CCC-30, PC Deficient Component
CRYOcheck Factor VIII Inhibitor Kit, Positive Control Component	CCIK08, Pos Control Component
CRYOcheck Factor VIII Inhibitor Kit, Negative Control Component	CCIK08, Neg Control Component
CRYOcheck Lupus Negative Control	CCLN-05, CCLN-10

Product type:

Liquid

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Recommended Use:

Medical device or components of medical devices for in vitro diagnostic use.

Restrictions on Use:

For professional use only.

1.3 Details of the Supplier of the Safety Data Sheet

Manufacturer Contact Information:

Precision BioLogic Inc., 140 Eileen Stubbs Ave.,
Dartmouth, NS B3B 0A9, Canada

Email:

techsupport@precisionbiologic.com

Precision BioLogic Inc. Telephone Number:

[1-800-267-2796](tel:1-800-267-2796) / [+1-902-468-6422](tel:+1-902-468-6422)

1.4 Emergency Contact Information

USA Poison Control:	1-800-222-1222
Canada Poison Control Centers:	1-844-764-7669
EU National Helpdesks:	https://echa.europa.eu/support/helpdesks
UK National Poisons Information Service (NPIS):	https://www.toxbase.org/

SECTION 2. HAZARD IDENTIFICATION

2.1 Classification of the mixture

These products are not hazardous according to Regulations (EC) No 1272/2008 and OSHA 29CFR 1910.1200

Product definition:	Mixture
Classification of the mixture:	Not classified

These products are classified according to Regulations (EC) No 1272/2008 [CLP/GHS], (US) OSHA Hazard classification of ingredients listed in section 3 in accordance with 29 CFR 1910.1200, and Hazardous Product Regulation HPR (WHMIS 2015).

2.2 Label Elements:

Signal Word:	No signal words
Hazard statement:	None
Adverse Human Health Effects and Symptoms:	No data available
Pictograms:	None
Precautionary Statements:	No data available

2.3 Other hazards not otherwise classified:

These products contain human plasma or platelets. All blood products should be treated as potentially infectious. Source material used in these products was found to be negative when tested in accordance with current required tests for transfusion-transmitted diseases. No known test methods can offer complete assurance that products derived from human blood will not transmit infectious agents. Accordingly, any human blood-based component should be handled and discarded as recommended for any potentially infectious human specimen.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance/Mixtures: Mixture

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4. FIRST AID MEASURES**4.1 Description of First Aid Measures**

Inhalation:	If inhaled, move person to fresh air. Get medical attention if adverse symptoms appear.
Skin Contact:	Remove contaminated clothes and shoes. Wash affected area immediately with soap or mild detergent and plenty of water. Get medical attention if symptoms occur.
Eye Contact:	Rinse immediately with plenty of water. Keep eyelid open with fingers while rinsing. Check for and remove any contact lenses. Get medical attention if irritation occurs.
Ingestion:	Rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical attention if symptoms occur.

4.2 Most Important Symptoms and Effects, Acute and Delayed

No known significant effects or critical hazards.

4.3 Immediate Medical Attention and Special Treatment

Note to physician: In case of exposure, the symptoms might be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

No action shall be taken involving any personal risk or without suitable training.

SECTION 5. FIRE-FIGHTING MEASURES**5.1 Extinguishing Media**

Suitable Extinguishing Media:	Products are non-flammable, low risk of fire by the inflammability characteristics of the products in normal conditions of storage, manipulation and use. In the case of the existence of sustained combustion as a result of improper manipulation, storage or use any type of extinguishing agent can be used.
Unsuitable Extinguishing Media:	Not applicable

5.2 Specific Hazards Arising from the substance or mixture

Specific hazards arising from the chemical/substance or mixture:	Due to their non-flammable nature, these products do not present a fire risk under normal conditions of storage, manipulation and use.
Hazardous thermal decomposition products:	Thermal decomposition may generate toxic and hazardous fumes of carbon dioxide, carbon monoxide, and other organic compounds.

5.3 Special Protective Equipment and Precautions/Advice for Fire-Fighters

Protective actions:	Isolate the scene by removing all persons from the vicinity of the incident if there is fire. No action shall be taken involving any personal risk or without suitable training.
Equipment for self-protection:	Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available.

SECTION 6. ACCIDENTAL RELEASE MEASURES**6.1 Personal Precautions, Protective Equipment, and Emergency Procedures**

For non-emergency personnel: Isolate leaks provided that there is no additional risk for the people performing this task. Do not walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders: Wear appropriate protective equipment (see Section 8). See also the information in "For non-emergency personnel".

6.2 Environmental Precautions

These products are not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods for Containment and Cleaning Up

Pre-treat the spill with a disinfectant with full biocidal activity. Soak up with inert absorbent material, and clean with plenty of water. Collect spilled material in appropriate waste disposal container. Dispose of via a licenced waste disposal contractor.

6.4 Reference to Other Sections

See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7. HANDLING AND STORAGE**7.1 Precautions for Safe Handling**

All blood products should be treated as potentially infectious. Human blood-based products should be handled and discarded as recommended for any potentially infectious human specimen.

Protective measures: Put on appropriate personal protective equipment (see Section 8).

Advice on general occupational hygiene: Do not eat, drink or smoke in areas where these mixtures are handled, stored and processed. Wash hands with soap and water after handling the mixture and before eating, drinking or smoking. Remove contaminated clothing and protective equipment before entering eating areas.
See Section 8 for additional information on hygiene measures.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Store at temperature indicated on the product label. Keep container tightly closed and sealed until ready for use. Avoid environmental release. Keep away from food and drinks. Store in accordance with local regulations.

7.3 Specific End Uses

These products are medical devices or components of medical devices intended for in vitro diagnostic use. Use the product in accordance with Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 Control Parameters:** None
- 8.2 Exposure Controls:** No exposure limit value known.

8.2.1 Appropriate Engineering Controls

Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

8.2.2 Individual Protection Measures

- Eye/Face Protection:** Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin Protection:** Handle with chemical-resistant, impervious gloves complying with an approved standard. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
- Respiratory Protection:** Respiratory protection is not required.
- Body Protection:** Personal protective equipment (PPE) should be selected based on the task being performed and the risks involved.
- Other skin protection:** Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved.

8.2.3 Environmental Exposure Controls

Avoid any release into the environment.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on Basic Physical and Chemical Properties**

- Physical state:** Liquid
- Odor:** Odorless
- Odor Threshold:** Not applicable
- Color:** Yellowish
- pH:** Neutral pH
- Melting point/freezing point:** Not available
- Initial boiling point and boiling range:** Not available
- Flash point:** Product does not sustain combustion.
- Evaporation rate:** Not available

9.1 Information on Basic Physical and Chemical Properties

Flammability:	Not applicable
Upper/lower flammability or explosive limits:	Not applicable
Vapor pressure:	Not available
Vapor density:	Not applicable
Relative density:	Not applicable
Solubility:	Not applicable
Partition coefficient: n-octanol/water:	Not applicable
Auto-ignition temperature:	Not applicable
Decomposition temperature:	Not applicable
Viscosity:	Not applicable
Explosive properties:	Not applicable
Oxidizing properties:	Not applicable

9.2 Other Information: Not applicable

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical Stability

Chemically stable under recommended conditions of storage, handling and use.

10.3 Possibility of Hazardous Reactions

Under the normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to Avoid, Including Static Discharge, Shock or Vibration

Not applicable

10.5 Incompatible Materials

Avoid strong acids, avoid alkalis or strong bases.

10.6 Hazardous Decomposition Products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects

Acute toxicity:	Not available
Skin corrosion/irritation:	Not available
Serious eye damage/irritation:	Not available
Respiratory or skin sensitization:	Not available
Germ cell mutagenicity:	Not available
Carcinogenicity:	Not available
Reproductive toxicity:	Not available
Summary of evaluation of the CMR properties:	Not available
STOT-single exposure:	Not available
STOT-repeated exposure:	Not available
Aspiration hazard:	Not available
Symptoms related to the physical, chemical and toxicological characteristics:	No specific data
Delayed and immediate effects, and chronic effects from short-term and long-term exposure:	Not available
Numerical measures of toxicity, including Acute Toxicity Estimates (ATEs):	Not available
Indication of whether the chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest editions) or found to be a potential carcinogen by OSHA:	Not found

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity:	Not available
12.2 Persistence and Degradability:	Not available
12.3 Bioaccumulative Potential:	Not available
12.4 Mobility in Soil:	Not available
12.5 Results of PBT and vPvB Assessment:	Not applicable
12.6 Other Adverse Effects:	No known significant effects or critical hazards.

SECTION 13. DISPOSAL CONSIDERATIONS**13.1 Disposal Methods and Special Precautions for Product Disposal**

The generation of waste should be avoided or minimized wherever possible. Disposal of these products, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licenced waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Special Precautions

The product is a human blood-based product and should be handled and discarded as recommended for any potentially infectious human specimen.

13.2 Disposal Methods for Packaging

The generation of waste should be avoided or minimized wherever possible. Incineration or landfill should only be considered when recycling is not feasible.

Special Precautions

This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14. TRANSPORT INFORMATION

(ADR/RID, ADN, IMDG and ICAO, TDG&DOT Classification, IATA)

14.1 UN Number:	Not regulated
14.2 UN Proper Shipping Name:	Not applicable
14.3 Transport Hazard Class:	Not applicable
14.4 Packing Group:	Not applicable
14.5 Environmental Hazards:	Not applicable
14.6 Additional Information:	Not applicable

14.7 Special Precautions for User

Transport within user premises: Always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.8 Transport in Bulk According to Annex II of MARPOL and the IBC Code:	Not applicable
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SECTION 15. REGULATORY INFORMATION**15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture**Canada Regulations and Lists:

NPRI:	No components listed
CEPA Toxic substances:	No components listed
DSL/NDL:	All components are listed or exempt.

US Regulations and Lists:

TSCA:	All components are listed or exempt.
SARA 302/304 and SARA 311/312 EPA List of Lists	Not applicable, no products were found.
Massachusetts	No components listed
New Jersey	No components listed
Pennsylvania	No components listed
California Prop. 65	No components listed

EU Regulations and Lists:

EU Regulation (EC) No.1907/2006 (REACH):

- Annex XIV List of substances subject to authorisation
No components listed
- Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixture and articles
Not applicable

C&L Inventory All components are listed

UK Regulations and Lists:

UK Regulation 2021 No. 904 (REACH):

Control of Substances Hazardous to Health Regulations (COSHH) 2002 No components listed

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out for this substance/mixture by the supplier.

SECTION 16. OTHER INFORMATION**Full text of H-Statements Referred to Under Section 2**

Not applicable

Key literature References and Sources for Data

This SDS was prepared on the basis of sheets of individual components and online databases (e.g. ECHA, RTECS) as well as our knowledge and experience, taking into account current legislation.

Procedure Used to Derive the Classification for Mixtures

(EU) Classification for mixtures according to Regulation (EC) 1272/2008 [CLP]
Hazard Communication Standard, 29 CFR 1910.1200 (HCS)
Hazardous Product Regulation HPR (WHMIS 2015)

Training Advice

Provide workers with adequate training to ensure that the product is handled safely in accordance with national and community legislation.

Abbreviations and Acronyms:

WHMIS=Workplace Hazardous Materials Information System
GHS=Globally Harmonized System of Classification and Labelling of Chemicals
OSHA=Occupational Safety and Health Administration
CLP=Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
FDA=Food and Drug Administration
STOT=Specific Target Organ Toxicity
PBT=Persistent, Bioaccumulative and Toxic
vPvB=very Persistent and very Bioaccumulative
ADR=European Agreement concerning the International Carriage of Dangerous Goods by Road
RID=European Agreement concerning the International Carriage of Dangerous Goods by Rail
ADN=International Carriage of Dangerous Goods by Inland Waterways
IMDG=International Maritime Dangerous Goods
ICAO=International Civil Aviation Organization
TDG=Transportation of Dangerous Goods Act
DOT=Department of Transportation
UN=United Nations
IATA=International Air Transport Association
NPRI=National Pollutant Release Inventory
CEPA=Canadian Environmental Protection Act
DSL=Canada Domestic Substances List
NDSL=Canada Non-Domestic Substances List
TSCA=Toxic Substances Control Act
SARA=Superfund Amendments and Reauthorization Act
EPA=United States Environmental Protection Agency
REACH=Registration, Evaluation, Authorisation and Restriction of Chemicals
ECHA=European Chemical Agency
RTECS=Registry of Toxic Effects of Chemical Substances

Notice to Reader:

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Preparation Information

Precision BioLogic Inc.

Revision History

Revision 00	Revision Date: March 19, 2019	Changes: Not applicable.
Revision 01	Revision Date: May 1, 2019	Changes: Added PNP and added Clot C and Clot S deficient plasma components.
Revision 02	Revision Date: April 27, 2020	Changes: Added Lupus Negative Control; clarifications.

Revision 03	Revision Date: August 20, 2021	Changes: Added Factor VIII Deficient Plasma with VWF.
Revision 04	Revision Date: April 18, 2022	Changes: Corrected typographical error (updated CCIK8 to CCIK08 and CCN-10-10 to CCN10-10).
Revision 05	Revision Date: Sept 27, 2023	Changes: Updated Emergency Contact Information.
Revision 06	Revision Date: June 14, 2024	Changes: Updated to harmonize translated versions; typographical corrections.