SECTION 1. IDENTIFICATION

1.1 Product Identifier

Product Name:	Other Means of Identification. Catalog #:
CRYO*check*™ Normal Reference Plasma	CCNRP-05, CCNRP-10
CRYO*check* Reference Control Normal	RCN-05, RCN-10
CRYO*check* Abnormal 1 Reference Control	ARP1-05, ARP1-10
CRYO*check* Abnormal 2 Reference Control	ARP2-10
CRYO*check* Lupus Positive Control	CCLP-05, CCLP-10
CRYO*check* Weak Lupus Positive Control	CCWLP-05, CCWLP-10
CRYO*check* Low Fibrinogen Control	CCLF-10
CRYO*check* Abnormal 1 Control	CCA1-10
CRYO*check* Abnormal 2 Control	CCA2-10
CRYO*check* Heparin Control	CCH-10
CRYO*check* APCR Positive Control	APCR-05
CRYO*check* Pooled Normal Plasma	CCN10-10, CCN-10, CCN-15, CCN-40
CRYO*check* Factor 2 Deficient Plasma	FDP02-10, FDP02-15
CRYO*check* Factor 5 Deficient Plasma	FDP05-10, FDP05-15
CRYO*check* Factor 7 Deficient Plasma	FDP07-10, FDP07-15
CRYO*check* Factor 8 Deficient Plasma	FDP08-10, FDP08-15, FDP08-40
CRYO*check* Factor 8 Deficient Plasma with VWF	FDP08VWF-10, FDP08VWF-15
CRYO*check* Factor 9 Deficient Plasma	FDP09-10, FDP09-15
CRYO*check* Factor 10 Deficient Plasma	FDP10-10, FDP10-15
CRYO*check* Factor 11 Deficient Plasma	FDP11-10, FDP11-15
CRYO*check* Factor 12 Deficient Plasma	FDP12-10, FDP12-15
CRYO*check* Prekallikrein Deficient Plasma	FDPK-10
CRYO*check* Platelet Lysate	PNP-10
CRYO*check* Clot S, Protein S Deficient Plasma Component	CCS-15, PS Deficient Component CCS-30, PS Deficient Component
CRYO*check* Clot C, Protein C Deficient Plasma Component	CCC-15, PC Deficient Component CCC-30, PC Deficient Component
CRYO*check* Factor VIII Inhibitor Kit, Positive Control Component	CCIK08, Pos Control Component
CRYO*check* Factor VIII Inhibitor Kit, Negative Control Component	CCIK08, Neg Control Component
CRYO*check* 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

1.4 Emergency Telephone Number

USA Poison Control: 1-800-222-1222

Canada Provincial Poison Control Centers: www.capcc.ca

EU National Helpdesks: https://echa.europa.eu/support/helpdesks

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**.** Source material used in these products was found to be negative when tested in accordance with current FDA required tests for communicable disease. However, 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 its 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

14.6 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

14.7 Transport in Bulk According to Annex II of MARPOL and the IBC Code:	Not applicable

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/NDSL:	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

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 assure 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
DEA Lists=United States Drug Enforcement Administration Lists
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, 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 with VWF
Revision 04	Revision Date: April 18, 2022	Changes: Corrected Typographical error (Update CCIK8 to CCIK08 and CCN-10-10 to CCN10-10