K982062

JAN 13 1999

510(k) Summary for Cryo✓Check™ PNP Platelet Lysate

1. Submitter's Address and Contact Information

a) Company Address

Precision BioLogic Incorporated
900 Windmill Rd.
Unit # 100
Dartmouth, Nova Scotia
Canada
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b) Contact

Mr. Sandy Morrison
Manager, Technical Operations
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c) Date Prepared:

June 5, 1998

2. Device Name

a) Proprietary (trade) name: Cryo✓Check™ PNP Platelet Lysate

b) Common name: Platelet Extract (human)

c) Classification name: Partial Thromboplastin Time, Reagents, Controls

d) Classification information: Regulatory Class II
Hematology Panel
Product Code - 81 GIT

3. Device Description

a)

Cryo✓Check™ PNP Platelet Lysate is prepared from human platelets obtained from normal healthy donors. The platelets are collected, washed,

and resuspended in buffer and then frozen and thawed to yield a suspension of ruptured platelet membranes. This suspension is aliquoted into cryovials and stored frozen.

4. Intended Use

Cryo✓Check™ PNP Platelet Lysate is intended for use in the Platelet Neutralization Procedure (PNP). The PNP is useful in detecting the presence of lupus anticoagulants in human plasma.

5. Substantially Equivalent Device

a) 510(k) number: K873382

b) Trade Name: Platelet Extract Reagent

c) Manufacturer: BIO/DATA Corporation

d) Substantial Equivalence Comparison

Cryo✓Check™ PNP Platelet Lysate is similar to the equivalent device in that they are both intended for use in the PNP for detecting the presence of lupus anticoagulants; have the same target population; and are both made from human platelets.

Cryo✓Check™ PNP Platelet Lysate differs from the equivalent device in that it is a frozen liquid preparation and not a lyophilized product.
To our knowledge, this difference does not affect the intended use or performance of the device.

6. Non Clinical Performance Data

a) Tests Performed

i) PNP's of normal and known lupus anticoagulant positive patient samples comparing the performance of **Cryo✓Check™** PNP Platelet Lysate to the predicate device (see Table V-1)

ii) 8 hour open vial stability study to demonstrate consistent vial to vial PNP results with normal plasma and lupus anticoagulant positive plasma (see Table V-2)

iii) 14 hour open vial stability on an MDA-180 automated coagulation analyzer (see Table V-3)

iv) Comparison of PNP's of LA negative patient samples using **Cryo✓Check™** PNP Platelet Lysate on two different automated coagulation analyzer systems: 1. MDA-180 using a photo-optical clot detection system; 2. Stago ST4 using a mechanical clot detection system (see Table V-3)

b) Conclusions

i) **Cryo✓Check™** PNP Platelet Lysate demonstrated comparable specificity to the predicate device when tested against normal plasma and lupus anticoagulant positive patient plasmas when used in a platelet neutralization procedure.

ii) PNP procedures using **Cryo✓Check™** PNP Platelet Lysate exhibited consistent vial to vial reactivity over an 8-hour period.

iii) **Cryo✓Check™** PNP Platelet Lysate is stable for greater than 8 hours on an MDA 180 automated coagulation analyzer.

iv) **Cryo✓Check™** PNP Platelet Lysate yielded consistent results when used on 2 different automated coagulation systems.

Table V-1

Comparison of Cryo Check PNP Platelet Lysate to BIO/DATA Platelet Extract Reagent

Procedure: Platelet Neutralization Procedure
Instrument: Diagnostica Stago ST4
Reagent: Organon Teknika Automated APTT Lot# 161152

Sample	Baseline APTT (sec.)	Saline Dilution 50:50 APTT (sec.)	BIO/DATA PNP correction (sec.)	Cryo Check PNP correction (sec.)
Normal 1	31.4	35.8	-2.0	0.6
Normal 2	28.7	30.4	0.4	-0.9
Normal 3	32.6	32.3	-0.5	0.1
Normal 4	30.5	35.4	-0.4	0.9
Normal 5	31.9	34.7	-0.4	1.0
Lupus 1	75.6	63.1	22.7	22.1
Lupus 2	55.8	43.6	7.1	6.1
Lupus 3	51.7	40.9	7.6	4.5
Lupus 4	103.8	89.6	40.6	44.5
Lupus 5	62.5	49.4	6.5	7.3
Lupus 6	53.7	47	5.7	6.6
Lupus 7	47.1	41.2	4.5	3.4
Lupus 8	80.5	70	23.8	28.9
Lupus 9	64.7	57.7	15.3	19.5
Lupus 10	73.3	59.2	11.8	14.3

summary -

PNP's of normal plasmas			PNP's of Lupus plasmas		
	Cryo Check PNP Platelet Lysate	BIO/DATA Platelet Extract		Cryo Check PNP Platelet Lysate	BIO/DATA Platelet Extract
mean	0.34	-0.6	mean	15.72	14.56
correlation coefficient*		-0.510	correlation coefficient		0.987

*The low correlation coefficient with the normal samples is attributed to the short correction time values and does not indicate that either product is defective.

Table V-2

8 Hour Open Vial Stability Study

System Information:

1. Analyzer: MLA 900 C
2. APTT Reagent: Dade Actin FSL — Lot#: FSL164A — Expiry: Feb., 1999
3. Normal Plasma: **Cryo✓Check™** Normal (CCN) — Lot #: 1600 — Expiry: April, 2000
4. Lupus Plasma: **Cryo✓Check™** Lupus (CCLP) — Lot#: 6100 — Expiry: Sept., 2000
5. Platelets: **Cryo✓Check™** PNP Platelet Lysate (PNP) — Lot#: PL01 — Expiry: April, 2000

Test Method:

1. Baseline APTT's determined for normal plasma and lupus anticoagulant positive plasma
2. APTT's determined for 1:1 mixture of above plasmas diluted with saline
3. APTT's determined for 1:1 mixture of above plasmas with PNP Platelet Lysate
4. Corrections calculated by subtracting the time in seconds of the plasma : platelet lysate mixture from the time in seconds of the plasma : saline mixture

Test Results:

	Time = 0 hrs				Time = 8 hrs			
	Normal Plasma		Lupus Plasma		Normal Plasma		Lupus Plasma	
	APTT (seconds)	Correction (seconds)	APTT (seconds)	Correction (seconds)	APTT (seconds)	Correction (seconds)	APTT (seconds)	Correction (seconds)
Baseline	28.3	N/A	59.8	N/A	27.6	N/A	58.3	N/A
Saline	42.3	N/A	54.2	N/A	40.3	N/A	53.4	N/A
PNP Vial 1	37.2	5.1	39.3	14.9	36.4	3.9	42.9	10.5
PNP Vial 2	37.5	4.8	43.0	11.2	37.0	3.3	42.7	10.7
PNP Vial 3	38.0	4.3	41.4	12.8	36.5	3.8	42.1	11.3
PNP Vial 4	37.6	4.7	41.9	12.3	36.4	3.9	42.1	11.3
PNP Vial 5	37.7	4.6	42.2	12.0	36.0	4.3	42.4	11.0
	Mean	4.7	Mean	12.6	Mean	3.84	Mean	11.0
	SD	0.292	SD	1.39	SD	0.358	SD	.358

Table V - 3

ON BOARD STABILITY STUDY

CryoCheck PNP Platelet Lysate

Instrument: MDA 180 Reagent: Platelin-L
Lot # : 161132

Precision Biologicals Normal Control: CCN-10 lot# 1580; expires Mar.'00

test time	saline/1580 seconds	PNP/1580 seconds	Neutralization seconds
0 min	22.7	27.3	-4.6
30 min	22.6	27.2	-4.6
45 min	22.7	27	-4.3
1 hr	22.8	27.2	-4.4
2 hr	23.2	26.9	-3.7
3 hr	23.0	27.2	-4.2
4 hr	23.3	26.9	-3.6
5 hr	23.0	27.2	-4.2
6 hr	23.2	27	-3.8
7 hr	23.1	27.3	-4.2
8 hr	23.1	27.5	-4.4
9 hr	23.6	27.5	-3.9
10 hr	23.6	27.9	-4.3
11 hr	23.8	27.8	-4
12 hr	23.6	27.7	-4.1
13 hr	23.9	28	-4.1
14 hr	23.9	27.8	-3.9
mean	23.2	27.4	-4.14
Std. Dev.	0.427	0.356	0.291

Precision Biologicals Lupus Positive Control:CCLP-10 lot# 6100; expires Sept.'00

test time	saline/6100 seconds	PNP/6100 seconds	Neutralization seconds
0 min	54.8	37.5	17.3
30 min	54.1	37.2	16.9
45 min	54.6	37.2	17.4
1 hr	54.7	37.7	17
2 hr	54.5	37.4	17.1
3 hr	55.5	37.4	18.1
4 hr	55	37.1	17.9
5 hr	53.3	37.6	15.7
6 hr	55.4	37.7	17.7
7 hr	56.5	38.3	18.2
8 hr	55.6	38.1	17.5
9 hr	55.1	37.9	17.2
10 hr	55.2	38.7	16.5
11 hr	54.9	38.5	16.4
12 hr	55	38.8	16.2
13 hr	54.8	38.4	16.4
14 hr	57.4	38.5	18.9
mean	55.1	37.9	17.2
Std. Dev.	0.902	0.563	0.819

HRF "in-house" positive control

test time	saline/HRF seconds	PNP/HRF seconds	Neutralization seconds
0 min	69.6	41.3	28.3
30 min	70	41.8	28.2
45 min	70.4	41.5	28.9
1 hr	70.1	41.1	29
2 hr	72.1	42.2	29.9
3 hr	72.2	42.7	29.5
4 hr	72.2	42.9	29.3
5 hr	70.5	42.1	28.4
6 hr	71.5	42.4	29.1
7 hr	74.3	43.8	30.5
8 hr	74.6	44.7	29.9
9 hr	75.2	45.1	30.1
10 hr	76.1	45.5	30.6
11 hr	76.8	45.8	31
12 hr	75.9	45.7	30.2
13 hr	77.9	46.1	31.8
14 hr	77.9	46.7	31.2
mean	73.4	43.6	29.8
std. Dev.	2.889	1.910	1.055

Table V -4

Cryo Check PNP Platelet Lysate
Comparison of Reactivity on 2 Automated Coagulation Analyzers
With Normal Patient Samples

	Instrument: MDA 180 Type: Photo-Optical Clot Detection			Instrument: ST4 Type: Mechanical Clot Detection		
Sample #	50:50 Sal./Sample APTT (sec.)	50:50 PL/Sample APTT (sec.)	neutraliz. (sec.)	50:50 Sal./Sample APTT (sec.)	50:50 PL/Sample APTT (sec.)	neutraliz. (sec.)
1	23.1	25.6	-2.5	23.0	25.7	-2.7
2	18.8	19.7	-0.9	29.2	32.7	-3.5
3	25.2	26.3	-1.1	31.2	33.6	-2.4
4	24.4	27.6	-3.2	30.1	34.7	-4.6
5	25.1	27.2	-2.1	28.4	33.7	-5.3
6	22.0	23.8	-1.8	27.4	31.1	-3.7
7	32.4	34.9	-2.5	37.8	42.4	-4.6
8	23.7	26.1	-2.4	28.9	33.8	-4.9
9	21.2	23.7	-2.5	27.5	31.9	-4.4
10	24.1	24.7	-0.6	30.1	33.0	-2.9
11	21.2	23.1	-1.9	26.3	30.6	-4.3
12	26.3	25.9	0.4	27.7	32.7	-5
13	24.7	28.1	-3.4	34.0	34.7	-0.7
14	22.7	25.8	-3.1	31.8	35.9	-4.1
15	24.7	27.6	-2.9	32.5	37.1	-4.6
16	19.2	21.9	-2.7	24.8	27.8	-3
17	30.9	33.2	-2.3	37.7	42.2	-4.5
18	20.6	24.2	-3.6	27.2	31.1	-3.9
19	23.9	25.1	-1.2	28.8	31.7	-2.9
20	18.3	20.7	-2.4	24.1	27	-2.9
21	24.7	26.9	-2.2	29.1	33.1	-4
22	24.6	25.5	-0.9	31.0	32.4	-1.4
23	23.7	24.0	-0.3	28.9	31.4	-2.5
24	19.9	22.4	-2.5	25.1	29.7	-4.6
25	22.9	26.4	-3.5	29.7	33.9	-4.2
		mean	-2.084		mean	-3.664
		std.dev.	1.051		std.dev.	1.151

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 13 1999

Mr. Sandy Morrison
Manager, Technical Operations
Precision BioLogic Incorporated
900 Windmill Road
Unit # 100
Dartmouth, Nova Scotia
CANADA
B3B 1P7

Re: K982062
Trade Name: Cryo✓ Check™ PNP Platelet Lysate
Regulatory Class: II
Product Code: GGW
Dated: June 5, 1998
Received: June 15, 1998

Dear Mr. Morrison:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K982062

Device Name: **Cryo✓Check™** PNP Platelet Lysate

Indications for Use

Cryo✓Check™ PNP Platelet Lysate is intended for use in the Platelet Neutralization Procedure (PNP) which is useful in detecting the presence of lupus anticoagulants (LA) in human plasma.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982062

Prescription Use ✓