

STABLE PLASMA PROTEIN SOLUTION

Scottish National Blood Transfusion Service

Protein Fractionation Centre



SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE  
**STABLE PLASMA PROTEIN SOLUTION**  
 400 ml of 4.8g/l protein of human venous plasma origin  
 Contains 8mmol/l caprylic acid, 140-180 mmol/l sodium  
 3-10 mmol/l citrate and 40-60 mmol potassium per litre of solution.  
 The contents should be used or discarded within 4 hours of opening.  
**STORE AT A TEMPERATURE BELOW 8°C, PREPAREDLY  
 IN A COOL DARK PLACE.  
 DO NOT FREEZE.**  
**DO NOT USE UNLESS SOLUTION IS CLEAR  
 AND FREE FROM DEPOSIT.**  
 PLEASE ENTER BATCH NUMBER IN PATIENT'S NOTES.  
 Protein Fractionation Centre,  
 Ellen's Glen Road, Edinburgh EH17 7QT.  
**STABLE PLASMA PROTEIN SOLUTION**  
 400 ml 4.8g SOM

Batch No 1194  
 Expiry Date MAY 1988  
 400 ml

Ellen's Glen Edinburgh EH17 7QT

Product Clearance Sheet

Product Name: SAP  
 Batch: 1196  
 Date Formulated: 9/78

Production Parameters		<input checked="" type="checkbox"/>	
Preliminary Inspection		<input checked="" type="checkbox"/>	
Volume Reconciliations		<input checked="" type="checkbox"/>	GRO-C <u>4/2/83</u>
Sterility Tests	(Append)	<input checked="" type="checkbox"/>	
Pyrogen Tests	(Append)	<input checked="" type="checkbox"/>	
Toxicity Tests	(Append)	<input checked="" type="checkbox"/>	GRO-C <u>9/6/83</u>
Analysis	(Append)		GRO-C <u>30/6/83</u>
Passed for inspection and packing			<u>30/6/83</u>

Inspection area cleared and ready for use			<u>29.7.83</u>
<u>580</u> Inspection			<u>29.7.83</u>
Labelling and Machine free from labels and cleared for use			<u>29.7.83</u>
<u>472</u> <sup>470 AB</sup> Labelled and Packed. Satisfactory		GRO-C	<u>29.7.83</u>
For Identity Tests. (Append) Satisfactory			<u>29.7.83</u>
<u>2</u> For Product Library			
<u>470</u> <sup>468 AB</sup> Passed for Issue			<u>10/8/83</u>
<u>468</u> Inventoried			<u>11.8.83</u>

PPPS ANALYSIS SUMMARY

BATCH: 1194

		<u>PPC LIMIT</u>	<u>BATCH RESULT</u>
Total Protein	g/l	45 - 50	<u>46.1</u>
Albumin by Cellulose			
Acetate Electrophoresis	%	< 88	<u>87</u>
Aggregated Protein	% >800,000 daltons	> 15	<u>1.2</u>
Sodium	mmol/l	130-150	<u>143</u>
Potassium	mmol/l	>0.05 mmol/g protein	<u>0.4</u>
Chloride	mmol/l	No Limit	<u>91.5</u>
pH		6.7-7.3	<u>6.88</u> (20°C)
Haem	absorbance 403nm	0.850	<u>0.14</u>
Ethanol	ml/l		<u>0.37</u>
	mg/g protein	> 10	<u>6.3</u>
Prekallikrein Activator	% BOB Ref I	> 20	<u>0.9</u>
Alkaline Phosphatase	IU/l	> 8	<u>0</u>
Immunoelectrophoresis		Certified As Normal	<u>As normal</u>
Polyacrylamide Gel Electrophoresis			

ADDITIONAL INFORMATION

PASSES\*/DOES NOT PASS CURRENT ANALYTICAL LIMITS  
ACCEPTABLE\*/NOT ACCEPTABLE FOR INSPECTION AND LABELLING

\* Delete As Appropriate

GRO-C  
LABORATORY MANAGER

2/6/83  
DATE



ALBUMIN ANALYSIS REQUEST 1

BATCH NO. P1194

Requested By: J.S

Date: 20.5.83

Return To: T.M.O.

TEST	S.O.P. NO.	UNIT	A SAMPLE	B SAMPLE
			SAMPLE NO. 76502	SAMPLE NO. 76503
Total Protein	81 156 0057 01	g/l	46.2	46.1
CAB	81 156 0016 01		✓	✓
% Albumin		%	88	87
Sodium	81 156 0008 01	m mol/l	140	143
Potassium	81 156 0008 01	m mol/l	0.41	0.40
Chloride	81 156 0006 01	m mol/l	90.0	91.75
pH	81 156 0007 01	20 °C	6.86	6.88
Bilirubin	81 156 0020 01	ml/l	0.37	0.37
Ethanol		mg/g Protein	6.3	6.3
P.K.A.	81 156 0063 01	% U.S. Ref. 1	0.1	0.9
Citrate	81 156 0058 01	m mol/l		

✓

Report Complete:

Date: 1.6.83

Signature: GRO-C

PROTEIN FRACTIONATION CENTRE

112

ALBUMIN ANALYSIS 2

SAMPLE RECEIVED - DATE 11.5.83

8624 BATCH No P1194  
9142

1. GEL FILTRATION S.O.P. No. 81 156 0030 01

Gel Type = S200T Run Number/Date  
Flow Rate = 20.1 ml/hr  
% Area Under Peak A (Monomer)  
A  
B  
C  
D

A SAMPLE	B SAMPLE
1307. 24.6 83	1310. 29.6 83
<u>89.8</u>	<u>85.2</u>
<u>5.6</u>	<u>5.1</u>
<u>1.6</u>	<u>1.8</u>
<u>2.5</u>	<u>11.2</u>

2. OSMOLALITY S.O.P. No. 81 156 0031 01

255 mOsm/kg      255 mOsm/kg

3. ALKALINE PHOSPHATASE S.O.P. No. 81 156 0063 01

44.0 IU/l      0 IU/l

4. IMMUNOELECTROPHORESIS S.O.P. No. 81 156 0025 01

Aras present for: Albumin  
Haptoglobins  
Transferrin  
Immunoglobulin

<u>++</u>	<u>++</u>
<u>+</u>	<u>+</u>
<u>+</u>	<u>+</u>
<u>+</u>	<u>+</u>

Comments:

Date of Run

17.6.83      17.6.83  
8-6-83 AM      8-6-83 AM

5. POLYACRYLAMIDE GEL ELECTROPHORESIS S.O.P. No. 81 156 0026 01

Gel Photo No./Date

342-B, 9.6.83      372-B, 9.6.83

Band present for: Albumin  
Transferrin  
Albumin Dimer  
Haptoglobin  
Series  
Polymer

<u>++</u>	<u>++</u>
<u>+</u>	<u>+</u>

Comments:

6. HAEM S.O.P. No. 81 156 0024 01

10 g/l solution of albumin. OD at 403nm

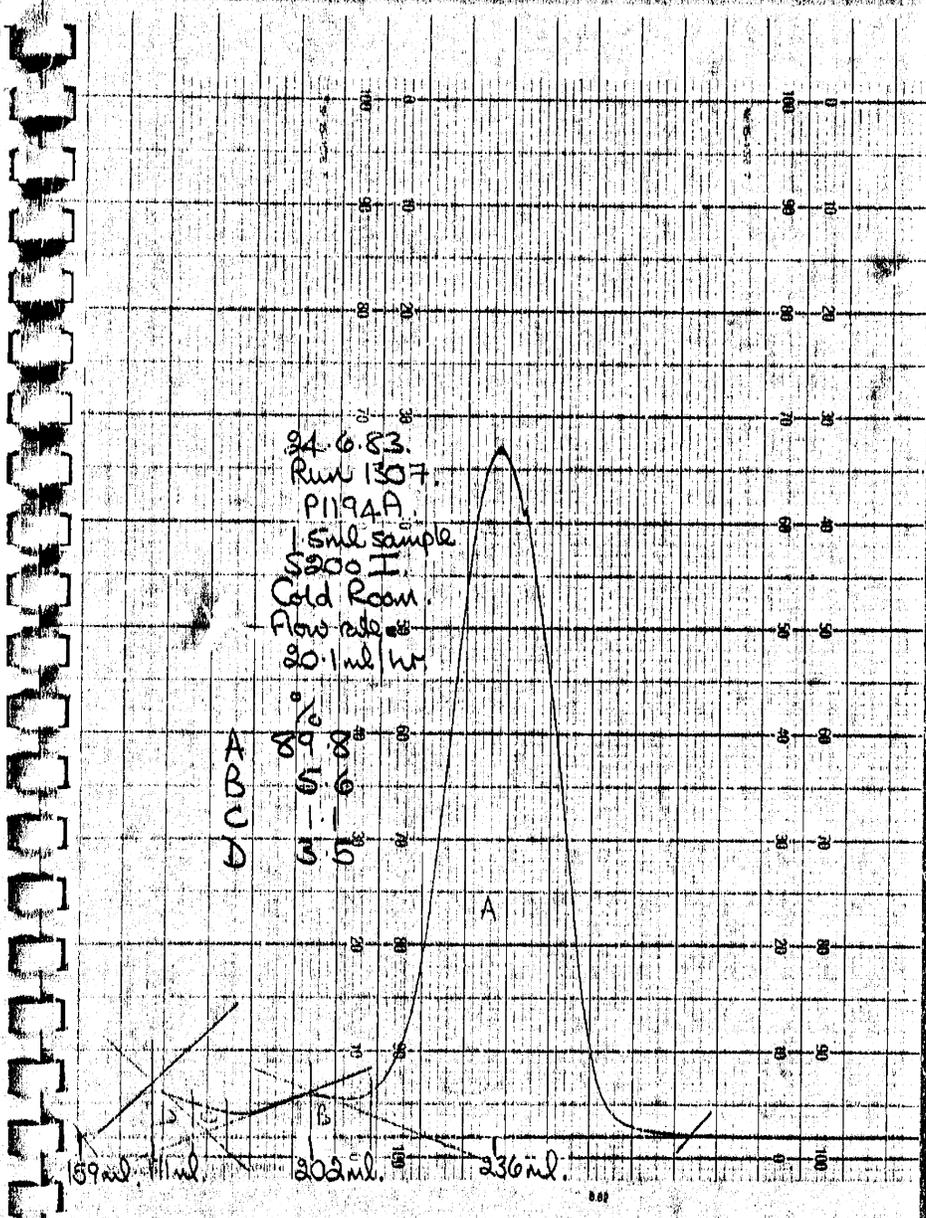
0.117      0.114

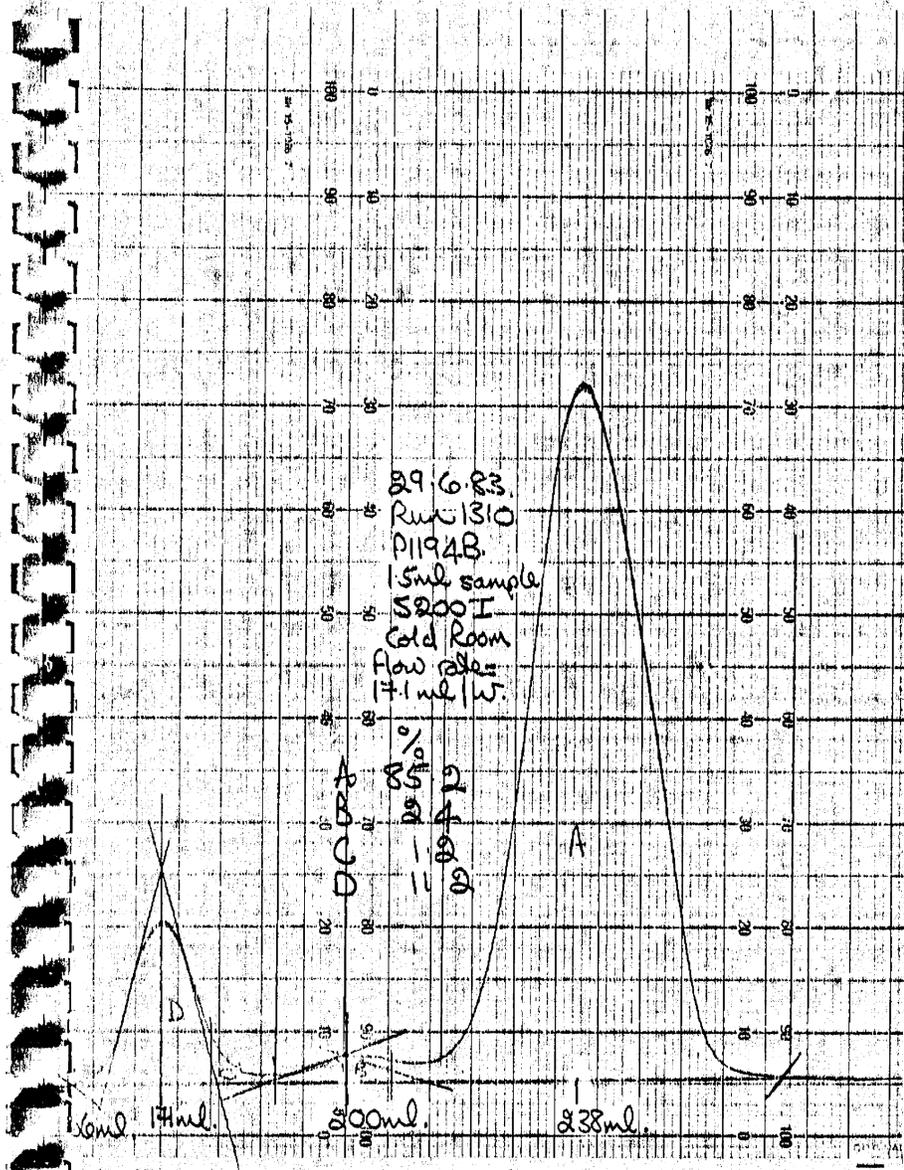
REPORT COMPLETE:

DATE: 30.6.83

SIGN:

GRO-C





Batch: P.1196

Date: 10/3/83

Autoclave load and date	Filter change	Bubble point, etc.
Auto 3 Load 8/5/83		BATCH #/31
Auto 2 Load 8/5/83		BATCH 3/1/83 No. 1003/22/10/8011
		52 psi

Autoclave operation and filling protocol data and modifications.

Use good cap autoclave: 2966, 2967, 2965 - 9/5/83  
 Use good bottle filled, No. 5916  
 Kinase - DB/274, DB/275 CAPS - DC/51

Washed volume \_\_\_\_\_ Filter wash volume \_\_\_\_\_  
 Filling completed by GRO-C

Autoclave Load

Crates	mm./p.m.	A.M./p.m.	Date	Remarks
1-60	3-15	1-15	10/5/83	Cabinet no. 1. Run Safefactory. C.L.G.

Stand at 100 Prior to Pouring

Crates	mm./p.m.	A.M./p.m.	Date	Remarks

Step	Time	Initial	Remarks
(1) Wash			
(2) Wash			
Final Inspection			

FILLING ROOM RECORD

Product Batch Number F113 194

Date Of Filling 10.5.85

Type Of Vial/Bottle BIN

Filling Machine Piston

Setting U.S.M.K.

Volume Of Fill 100ml

Batch Of Vial/Bottle 2969, 2970, 2971

2969, 2970, 2971

Batch Of Bung/Stopper 276, 275, 278, 277

Batch Of Cap 51 + 52

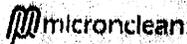
Batch Number Of Jar/Churn A. 79

Batch Of Piston/Syringe A.P. 76

INCIDENTS DURING FILLING

FILLING TEAM CH, JB, KD, EM

PB, CD, AL



REGIONAL TRANSFUSION SERVICE 001-228  
ROYAL INFIRMARY, EDINBURGH 7291 Ext. 86

HBs Ag/HBs Ab TESTING

NAME William Cameron

SERIAL No. (if applicable)

LABORATORY FOR TEST

DEPARTMENT

REPORT TO BE RETURNED TO

DATE 12/5/83

FOR LABORATORY REPORT ONLY

DATE TESTED 16/5/83

Ref: H0308

HBs Ag	Pos	Neg
HBs Ab	<input type="checkbox"/>	<input checked="" type="checkbox"/>
nL	<input type="checkbox"/>	<input type="checkbox"/>
HBs Ab-I.U./ml		

GRO-C Signed

**REQUEST FOR TOXICITY TEST**

(E.P. Vol. 11, 1971, p. 81)  
(Manufacturer's Licence No. 9.69)

**SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE**

Protein Fractionation Centre, 21 Ellen's Glen Road, Edinburgh EH17 7QT

Telephone: 031-664 2317

Telex: 72428

**REQUEST FOR PYROGEN TEST**

Test Centre: LAW

Product: 511 Batch No.: 81194 Date: 17/1/83

Quantity Dispatched: ..... Container(s) totalling: 4.22 millilitres

Container Distinguishing Marks: 81194.1.2.3

Dispatcher: P. G. G. G. Advance Notification

Letter	Phone	Telex
--------	-------	-------

7 ml / kg

Test date: 17/1/83

Rabbit No.	Weight	Vol. injected	Peak or Maximum Temperature Rise	Mean peak or mean Temperature Rise
K173	2.1 Kg	6.3 mls	Nil	
K378	2.1 Kg	6.3 mls	0.1°C	
K373	2.2 Kg	6.6 mls	0.1°C	

Result checked by: GRO-C

Remarks on conduct and result of test: Animal response, etc.



LIMULUS TEST RESULTS

Ref: S.O.P. No. 81 157 0003 01

PRODUCT BATCH NUMBER: P1194

SAMPLE	END-POINT TITRE	ENDOTOXIN EQUIVALENT
Unbact	2/10	20.25 µg/ml
Past	2/10	20.25 µg/ml

LYSATE BATCH No. 962227

LYSATE SENSITIVITY: 0.025

DATE OF ASSAY: 20.5.93

SIGNATURE: GRO-C

STERILITY TEST SHEET

(Manufacturer's Licence No. 9.61; 9.62)

Product and Batch No: P 1194

Sterility Test No: 93/259

Start: Post-Dnst 10-5-83

Vol. Sample Tested: cont/cont

Preservative:

Membrane/Filter:

Date Submitted: 11-5-83 By: GRO-C

Date Tested: 19/5/83

CONTAINER	MEMBRANE	THIOGLYCOLLATE MEDIUM 22°C												TRYPTONE SOYA BROTH 20°C													
		F	S	S	T	T	F	S	S	T	T	F	S	1	2	3	4	5	6	7	8	9	10	11	12	13	14
5l																											
10l																											
15l																											
20l																											
25l																											
30l	MA(TH)	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	
35l	MA(TSB)	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	
40l																											
45l																											
50l																											
55l																											
60l																											

Results: Pass

Tested By: GRO-C

Examined By: GRO-C

Return To: GRO-C



P1194

REQUEST FOR COLONY COUNT (Manufacturer's Licence No. 9.83) P1194/1195					Poured			Examined			20°	Comment
Sample Provided	By	Date	Time	Kept	Diln	By	Date	Time	By	Date		
SMALL					N	SS	1.5	1.5	TM	1.5	12	
PRE-EKS	AK	9/5/83		+40c.								
LARGE					N						11	
PRE-EKS												
POST-EKS					N						<1	
Pool		12/3/83	9.15		N						<1	
Piston Tubing			12.00		N						<1	
Cartridge Tubing					N						<1	



CENTRIFUGAL P1194/1195

REQUEST FOR COLONY COUNT (Manufacturer's License No. 9 63)						Poured			Examined			Comment
Sample Provided	By	Date	Time	Temp	Diln	By	Date	Time	By	Date	20°	
C1 (I)	Cu	9/15/83	0940	+5°C	N		9/15		TM	1115	<1	
C1 (II)	JM	--	1105	--	N						37	
C2	AJ	--	0930	--	N						6	
C3	J.M.	--	1305	--	N						6	
C4	Cu	--	1425	--	N						30	
C5 (I)	J.M.	--	1405	--	N						<1	
C5 (II)	Cu	--	1445	--	N						12	

P1194

T. S. A. SETTLE PLATES  
MAN. LICENCE REF: 9.65

PRODUCT BATCH NO: P.1194/1195

DATE FILLED: 10/5/53

SITE OF EXPOSURE	COLONY COUNT	ORGANISM IDENTIFICATION
Amphons 1 inca	0	
Amphons 2	0	
Piston Trolley	1	St. CO. P. R. M. 1015
Bottle Trolley	1	St. KYLOSUS

EXAMINED BY: GRO-C

DATE: 12/5/53



BIOLOGICAL INDICATORS

Autoclave No.                      Load No.                      Date

Cycle                                      Indicator Type *Cuscut P-1194/1198*

Load Contents *DIN BUNAS*

*DB/274*

Submitted by GRO-C

Date Received *10/5*                      Date Due Off *12/5*

Incubation *4 hrs @ 58°C*                      Control *Positive at 24 hours*

<u>Indicator Identification</u>	<u>Position in Autoclave</u>	<u>Result</u>
<i>M</i>		<i>Negative at 48 hours</i>

Examined by GRO-C

Date *12/2/83*

BIOLOGICAL INDICATORS

Autoclave No. 1      Load No. 5      Date 9-5-83

Cycle      Indicator Type ATTEST

Load Contents

210 Bil approx Borneo 2968 P1214

Submitted by GRO-C

Date Received 9/5      Date Due Off 9/5

Incubation 48hrs @ 57°C      Control Positive at 24 hours

<u>Indicator Identification</u>	<u>Position in Autoclave</u>	<u>Result</u>
U X Y Z	BC TR BBR TFL	} Negative at 48 hours

Examined by GRO-C      Date 10/5/83

BIOLOGICAL INDICATORS

Autoclave No. 1      Load No. 4      Date 9-5-83

Cycle      Indicator Type ATTEST

Load Contents

210 fal capped bottles 2967

PH 14

Submitted by GRO-C

Date Received 9/5      Date Due Off 11/5

Incubation 48 hrs @ 52°C      Control Positive at 24 hours

<u>Indicator Identification</u>	<u>Position in Autoclave</u>	<u>Result</u>
<p>BC</p> <p>TC</p> <p>BBR</p> <p>TFE</p>		<p>Negative at 48 hours</p>

XXXX

Examined by GRO-C

Date 11/2/83

63

BIOLOGICAL INDICATORS

Autoclave No. 1      Load No. 2      Date 9-5-83

Cycle      Indicator Type A-meb

Load Contents

210 Foil capped Bottles 2966 P1214

Submitted by [GRO-C]

Date Received 9/5      Date Due Off 11/5

Incubation 4 hrs @ 50°C      Control Positive at 24 hours

<u>Indicator Identification</u>	<u>Position in Autoclave</u>	<u>Result</u>
RP 0 BC TZ BBR TFL		} Negative at 48 hours

NT-22

Examined by [GRO-C]

Date 11/8/83

P1194  
 2 Temp check on no. 5/11  
 probe of Honeywell  
 GRO-C

60	59	58	57	56	55	54	53	52	51
41	42	43	44	45	46	47	48	49	50
30	31	32	33	34	35	36	37	38	39
20	21	22	23	24	25	26	27	28	29
10	11	12	13	14	15	16	17	18	19
1	2	3	4	5	6	7	8	9	10

BATCH NO P1194

Run Started 3:15pm  
 Run Finished 1:15a.m  
 Temperature checked during  
 run and found to be 60.00c

Position of temperature probes in batch

- 1 1
- 2 171
- 3 740
- 4 331
- 5 450
- 6 510

PASTEURISATION CABINET NO 2


DATE \_\_\_\_\_

BATCH NO \_\_\_\_\_

Run Started \_\_\_\_\_  
 Run Finished \_\_\_\_\_  
 Temperature checked during  
 run and found to be \_\_\_\_\_

Position of temperature probes in batch

- 1 \_\_\_\_\_
- 2 \_\_\_\_\_
- 3 \_\_\_\_\_
- 4 \_\_\_\_\_
- 5 \_\_\_\_\_
- 6 \_\_\_\_\_

SIGNED \_\_\_\_\_  
 GRO-C

2200

LARGE

41

Formulation of albumin concentrate Batch: P1194/1195  
 Operator: GRO-C Date: 9/5/83

1st Dilution  
 50 ~~25~~ l Concentrate @ 322 g/l =  $\frac{50 \times 322}{52} = 309$  l @ 52 g/l

Washes to be added:

	Batch	Type	Volume	Conc. g/l	Total g
1	P1142	EKSWASH	32		
2					
3					
4					
Total			32		

∴ Water to be added =  $309 - 32 = 277$  l  
 less 10% = 1 l

(5A) Volume 300 l; Na<sup>+</sup> 72 mmol/l (Total Na<sup>+</sup> 216 mol) T.P. 49.9 g/l

2nd Dilution  
 300 l solution @ 49.9 g/l =  $\frac{300 \times 49.9}{47.5} = 315$  l @ 47.5 g/l

∴ Water to be added =  $315 - 300 = 15$  l  
 315 l @ 140 mmol/l = 44.1 mol  
 Na<sup>+</sup> present at 5A = 21.6 mol  
 ∴ Na<sup>+</sup> to be added as NaCl =  $22.5$  mol = 1315 g NaCl @ (58.44 g/mol)

\* (5B) Volume 315 l; Na<sup>+</sup> 138 mmol/l PH 6.84 T.P. 46.8 g/l

Filtered through 34 x 10 cm BRS pads @ 1/hr.

(5D) Volume 423 l; Na<sup>+</sup> 142 mmol/l PH 7.10 T.P. 46.6 g/l

Appearance of filtrate ..... 24 hrs ..... \* 36g NaCl, 50g NaOH  
 Volume of filter wash ..... 1  
 Handed to filling team at ..... hr.

Remarks & Variations from Standard Procedure

SMALL

41

Formulation of albumin concentrate

Batch: P1199/1195

Operator: GRO-C

Date: 9/5/83

1st Dilution

$$23 \text{ l Concentrate} @ 322 \text{ g/l} = \frac{23 \times 322}{52} \text{ l} @ 52 \text{ g/l}$$

$$= 142 \text{ l}$$

Washes to be added:

	Batch	Type	Volume	Conc. g/l	Total g
1					
2					
3					
4					
Total					

∴ Water to be added =  $142 - 23 = 119 \text{ l}$   
 less 10% = 112 l

(5A) Volume 135 l Na<sup>+</sup> 64 mmol/l (Total Na<sup>+</sup> 8.64 mol) T.P. 47.7 g/l

2nd Dilution

$$135 \text{ l solution} @ 47.7 \text{ g/l} = \frac{135 \times 47.7}{47.5} \text{ l} @ 47.5 \text{ g/l}$$

$$= 135.6 \text{ l}$$

∴ Water to be added =  $135.6 - 135 = 0.6 \text{ l}$

135.6 l @ 140 mmol/l = 18.97 mol

Na<sup>+</sup> present at 5A = 8.64 mol

∴ Na<sup>+</sup> to be added as NaCl = 10.33 mol = 603.14 g (58.44 g/mol)

(5B) Volume 135.6 l Na<sup>+</sup> 138 mmol/l pH 6.86 T.P. 47.2 g/l

Filtered through 34 x 40 cm WKS pads @ 1/hr.

(5C) Volume 423 l Na<sup>+</sup> 142 mmol/l pH 7.10 T.P. 46.6 g/l

Appearance of filtrate ..... *Clear* \* 15g NaCl, 80 mg NaOH

Volume of filter wash ..... 1

Handed to filling team at ..... hr.

Remarks & Variations from Standard Procedures

SPPS WASH VOLUME RECORD

88

The filter wash/unfilled volume is to be sterile filtered after the batch of SPPS has been completed and before the bubble point test is carried out. The can identification label must be carefully inspected for details of batch, type of wash and volume. The can is to be immediately transferred to the drying plant with this form and handed over to the technician.

Batch: P1145  
Volume: 32L  
Sterile Filter: Yes

Type of Wash: EKS  
No. of Cells: 1  
Signed: GRO-C Date: 22/4/83

Samples Taken: S. Mubson  
Protein Assay: ✓  
Colony Count: ✓  
Date and Time to -40°C Cold Room: 20/4/83 at 1450  
Signed: GRO-C

Protein Result (g/l) 27.4  
Colony Count (cols/ml) 21  
Limulus (dilution) 1/10  
Pyrogen (0.4°C) 0.2°C  
HB Ag Neg.

Microbiology Filtrate Added: ✓  
Volume: 4L  
Date: 22/4/83  
Signed: S. Mubson

After clearance, washes (maximum of 3 per batch) are removed from the -40°C Cold room the night before use.  
CLEARANCE TO USE   
CLEARANCE TO RETURN FOR RE WORK   
CLEARANCE TO DISCARD   
Signed: GRO-C

Removed from -40°C Cold Room: Date: 8/5/83 Signed: GRO-C

Added to Batch SPPS P1184/1145  
Date: 8/5/83  
Signed: GRO-C



SMALL

Analysis Request

Requested by: GRO-C

Date: 9/5/83

Return to: *Stark* / *Foley* if Urgent:

Special Requests:			Sample		
P1194/1195			5A	5B	5C
X	Total Protein	g/l	7.65	7.55	7.65
X	Fibrinogen	g/l	4.7	4.7	4.6
X	% Clot	%			
X	CAE	g/l			
X	% Alb	%			
X	Sodium	mmol/l	136	133	142
X	Potassium	mmol/l	3.7	3.5	3.5
X	Chloride	mmol/l			
X	pH		7.22	7.21	7.10
X	Conductivity	µmho			
X	Ethanol	g/l			
X	Citrate	mmol/l			
X	Phosphate	mmol/l			
X	PEG	g/l			
X	Lithium	g/l			

Special Requests:			Sample		
X	Total Protein	g/l			
X	Fibrinogen	g/l			
X	% Clot	%			
X	CAE	g/l			
X	% Alb	%			
X	Sodium	mmol/l			
X	Potassium	mmol/l			
X	Chloride	mmol/l			
X	pH				
X	Conductivity	µmho			
X	Ethanol	g/l			
X	Citrate	mmol/l			
X	Phosphate	mmol/l			
X	PEG	g/l			
X	Lithium	g/l			

Date Reported:

Signature:

Result to follow:

Report complete:

Date: 9/5/83

Signature:

GRO-C

LARGE

Analysis Request

Requested by: GRO-C Date: 9/5/83 Return to: Danilo Pillay / If Urgent:

Special Requests:			Sample			
P1194/1196			5A	5B	5C	
X	Total Protein	Man. Licence No. 9.01	Unit g/l	760.57	760.54	760.86
X	Fibrinogen	9.01	g/l	49.90	46.8	46.6
	% Clot		%			
	CAE	9.02				
	% Alb		%			
	%		%			
X	Sodium	9.04	mmol/l	72	73	74
X	Potassium	9.04	mmol/l	0.44	0.39	0.50
	Chloride	9.05	mmol/l			
X	pH	9.06		6.94	6.89	7.10
	Conductivity	9.07	µmho			
	Ethanol	9.09	%			
	Citrate	9.10	mmol/l			
	Phosphate	9.11	mmol/l			
	PEO		g/l			
	Limulus	9.70	g/l			

Special Requests:			Sample		
X	Total Protein	Man. Licence No. 9.01	Unit g/l		
	Fibrinogen	9.01	g/l		
	% Clot		%		
	CAE	9.02			
	% Alb		%		
	%		%		
	Sodium	9.04	mmol/l		
	Potassium	9.04	mmol/l		
	Chloride	9.05	mmol/l		
	pH	9.06			
	Conductivity	9.07	µmho		
	Ethanol	9.09	%		
	Citrate	9.10	mmol/l		
	Phosphate	9.11	mmol/l		
	PEO		g/l		
	Limulus	9.70	g/l		

Date Reported: \_\_\_\_\_ Signature: \_\_\_\_\_  
 Result to follow: \_\_\_\_\_  
 Report complete:  Date: 9/5/83 Signature: GRO-C

Analysis Request

Requested by: GRO-C Date: 10-5-83 Return to: S/F Mung- / if Urgent:

Special Requests:				Sample			
<input checked="" type="checkbox"/>	Total Protein	9.01	g/l	1194			
<input checked="" type="checkbox"/>	Fibrinogen	9.01	g/l	1195 WASH			
<input type="checkbox"/>	% Clot		%				
<input type="checkbox"/>	CAE	9.02	%				
<input type="checkbox"/>	% Alb		%				
<input type="checkbox"/>	Sodium	9.04	mmol/l				
<input type="checkbox"/>	Potassium	9.04	mmol/l				
<input type="checkbox"/>	Chloride	9.05	mmol/l				
<input type="checkbox"/>	pH	9.06					
<input type="checkbox"/>	Conductivity	9.07	μmho				
<input type="checkbox"/>	Ethanol	9.09	%				
<input type="checkbox"/>	Citrate	9.10	mmol/l				
<input type="checkbox"/>	Phosphate	9.11	mmol/l				
<input type="checkbox"/>	PEG		g/l				
<input type="checkbox"/>	Limulus	9.70					

Special Requests:				Sample			
<input checked="" type="checkbox"/>	Total Protein	9.01	g/l				
<input checked="" type="checkbox"/>	Fibrinogen	9.01	g/l				
<input type="checkbox"/>	% Clot		%				
<input type="checkbox"/>	CAE	9.02	%				
<input type="checkbox"/>	% Alb		%				
<input type="checkbox"/>	Sodium	9.04	mmol/l				
<input type="checkbox"/>	Potassium	9.04	mmol/l				
<input type="checkbox"/>	Chloride	9.05	mmol/l				
<input type="checkbox"/>	pH	9.06					
<input type="checkbox"/>	Conductivity	9.07	μmho				
<input type="checkbox"/>	Ethanol	9.09	%				
<input type="checkbox"/>	Citrate	9.10	mmol/l				
<input type="checkbox"/>	Phosphate	9.11	mmol/l				
<input type="checkbox"/>	PEG		g/l				
<input type="checkbox"/>	Limulus	9.70					

Date Reported: \_\_\_\_\_ Signature: \_\_\_\_\_  
 Result to follow: \_\_\_\_\_  
 Report complete:  Date 12.5.83 Signature: \_\_\_\_\_ GRO-C

ALBUMIN : RESOLUTION AND VACUUM DISTILLATION

BATCH : P1194/1195 (C600/601)

RESOLUTION

DATE : 9/5/83

WEIGHT OF PASTE : 80.2 kg

RESOLUTION VOLUME : 190 L

FINAL VOLUME : 213 L

FINAL PH : 6.97

SIGNED

GRO-C

VACUUM DISTILLATION (CENTRIFERN) DATE 9/5/83

START VOLUME : 213 litres

NUMBER OF CENTRIFERN PASSES : 2

FINAL CONCENTRATG VOLUME : 73 Litres

CONCENTRATE TO : STERILE FILLING

VOLUME : 73 Litres

DATE : 9.5.83

TIME : 14.25

SIGNED

GRO-C

NOTES

100 mls of final concentrate to C Thimble (R&D)

21194

Analysis Request CENTRAL THERM P1194/1195 20

Requested by GRO-C Date 9/5/83 Return to Original Plant  if Urgent

Special Requests:				Sample			
X	Test	Man. Licence No.	Unit	3B I	1C	3A	3B II
X	Total Protein	9.01	g/L	7605.1	7615	7616	7617
	Fibrinogen	9.01	g/L	322.0	99.0	158.0	288.0
	% Clot		%				
	CAE	9.02					
	% ALB		%				
	%		%				
	Sodium	9.04	mmol/L	428	135	226	442 372
	Potassium	9.04	mmol/L	2.84	0.86	1.5	3.02 2.0/6
	Chloride	9.05	mmol/L				
	pH	9.08					
	Conductivity	9.07	µmho				
X	Ethanol	9.09	g/L	2.42	97.8	16.0	2.35
	Citrate	9.10	mmol/L				
	Phosphate	9.11	mmol/L	2.25			
	PEG		g/L				
	Lipiduria	9.20					

[7.57 mg ETOH / g PROT]

Special Requests:				Sample			
X	Test	Man. Licence No.	Unit	ID	22		
X	Total Protein	9.01	g/L	7618	7619		
	Fibrinogen	9.01	g/L	7CA			
	% Clot		%				
	CAE	9.02					
	% ALB		%				
	%		%				
	Sodium	9.04	mmol/L				
	Potassium	9.04	mmol/L				
	Chloride	9.05	mmol/L				
	pH	9.08					
	Conductivity	9.07	µmho				
X	Ethanol	9.09	mg/L	217.0	254		
	Citrate	9.10	mmol/L				
	Phosphate	9.11	mmol/L				
	PEG		g/L				
	Lipiduria	9.20					

Date Reported: \_\_\_\_\_ Signature: \_\_\_\_\_  
 Result to follow: \_\_\_\_\_  
 Report complete:  Date 9.5.83 Signature: \_\_\_\_\_ GRO-C

P1195

C601

CENTRITHERM BATCH

PASTES FROM PROCESS

NO.	TYPE	% ALB	WT.	SOURCE PLASMA
14035-05	1V <sub>2</sub> 4V	80	11.7	Ny 750, 757
14034-05	"	93	16.0	Ny 750, 757
14033-05	"	72	13.2	Ny 750, 757
			40.9	

74

70

9194  
C. G. W.

CENTRITHERM BATCH

PASTES FROM PROCESS

NO.	TYPE	% ALB	WT.	SOURCE PLASMA
4033-05	N <sub>1</sub> VV	58	11.9	N <sub>1</sub> 755, 756 D: 100, 701
4032-05	"	43	12.1	N <sub>1</sub> 755, 756 D: 701
4035-05	"	40	15.5	N <sub>1</sub> 756, 757
			39.5	

A7)

REQUISITION FOR PRODUCT IDENTIFICATION MATERIALS

PRODUCT Albumin

BATCH NO. P14W

FILLING DATE 10-5-83

	Number Requested	Initial	Number Issued	Date	Initial	Number used	Number Spoiled	Number Returned for Destruction	Date	Initial
In House Labels										
Final Labels	Bottle					522	96	-	-	-
	Carton									
Boxes	VIAL A OUTER B									
Leaflets										
Albumin Tags										
Pyrogen Agg. Labels			62	8/15/83	DB	65	-	-	10/8/83	GRO-C

Check list for final finishing of product

LABELS	{	Labels printed correctly	<u>Initial</u>
		Checked	<u>AS</u>
	{	Batch information correct	<u>AS</u>
		Checked	<u>AS</u>
BOTTLES/ VIALS	{	Card Check on cages (SPPS only)	<u>✓</u>
		Number of units on filling sheet	<u>596</u> *
		Number of units labelled	<u>470</u> *
	{	* Account for difference below <i>10 samples 1 potency 100 Reagents</i>	Signature
	Signature		

Affix batch label(s) in space below

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE  
**STABLE PLASMA PROTEIN SOLUTION**

450 ml. of 45g/l protein of human venous plasma origin  
Contains 8mmol/l caprylic acid, 130-150 mmol/l sodium,  
3-10 mmol/l citrate and <0.05 mmol potassium per gram of protein.  
The contents should be used or discarded within 4 hours of opening.

STORE AT A TEMPERATURE BELOW 28°C, PREFERABLY  
IN A COOL, DARK PLACE.  
DO NOT FREEZE.

DO NOT USE UNLESS SOLUTION IS CLEAR  
AND FREE FROM DEPOSIT.  
PLEASE ENTER BATCH NUMBER IN PATIENT'S NOTES.

Protein Fractionation Centre  
Eliott's Green Road, Edinburgh EH17 7QY.

**STABLE PLASMA PROTEIN SOLUTION**

PH 8.0-8.5

Batch No. 1184

Expiry Date MAY 1988

R.O.M.

