HCV ASSAY Preliminary report No.2.

The results for the individual centres are shown in tables I,II and III. The total tested so far is 3,282 with 22 initial reactive (IR) [1:149] and 14 repeat reactive (RR) [1:234]. Not included in the 14 are samples from two donors (one from NLBTC and one from Manchester) which, while negative using Ortho's criteria, had an optical density that was clearly greater than the negatives.

Preliminary assessment indicates an equal ratio of positive male and females. The average age of the anti-HCV positives was 39 years. For comparison, the average age of HBsAg-positive donors at NLBTC is 31 years and the average age of the 3000 routine NLBTC donors in the National Study is 26.5 years. NLBTC is showing the highest rate of anti-HCV positive donors

NLBTC	1:172	{n=2063}
Bristol	1:480	{n=960}
Manchester	0:259	{n=259}

DH/JAB/rme 23.6.89

NLN/T0988

Table I

Date 20 June 89 Category NATIONAL DONOR STUDY (NBTC donors) Number Tested 2063 (18 initially anti-HCV reactive)

Donation Number	Age	Gender	HCV Result	ALT iu/l	AST	Anti-HBc
GRO-A	47	F	RR	23	25	neg
	37	F	RR	14	20	neg
	37	M	RR	55	46	neg
	51	F	RR	11	23	neg
	21	F	RR	23	26	neg
	36	F	RR	12	20	neg
	51	M	RR	17	24	neg
	37	M	RR	59	36	POS
	31	M	RR	14	23	neg
	55	M	RR	19	30	neg
	41	F	RR	132	90	neg
	23	M	RR	14	25	neg.
			TOTAL RR = 12			
[NB: GRO-A	37	M	on rpt: OD = 0.294; 0.502 cut off = 0.470	17	20	neg]

SYM/511

NLN/10989

Table II

Date 20 June 89 — Category NATIONAL DONOR STUDY (Manchester donors) — Number Tested 259 (1 initially anti-HCV reactive)

Donation Number	Age	Gender	HCV Result	ALT iu. per l.	AST	Anti-HBc
GRO-A Initially reactive, but not 'positive' on repeat.	27	F	on repeat: OD = 0.352; 0.361 cut-off = 0.485			

Table III

Date 20 Jun 89 — Category NATIONAL DONOR STUDY (Bristol donors) — Number Tested 960 (3 initially anti-HCV reactive)

Donation Number	Age	Gender	HCV Result	ALT iu./l	AST	Anti-HBc
GRO-A		F	RR	17		neg
		M	RR	39		neg.

SYM/512

NLN/10990

GENERAL COMMENTS

1. Test seems reproducible, robust and meaningful.
2. Confirmation of some sort is obviously required.
3. Correlation of specific activity with infectivity will require further extensive study.
4. A total test time of 3 hours will be inconvenient if 2 batches of donations are tested daily.
5. Approximately 2% of samples react below cut-off but with higher OD values (e.g. 0.2) than the rest.

UK NATIONAL DONOR STUDY

- Cross-section of donor panels from three regions:

  North London
  Manchester
  Bristol

- Donors screened for ALT
  anti-HBc
  anti-HCV

- ALT and anti-HBc positive donors, with controls, followed-up medically, and histories taken.

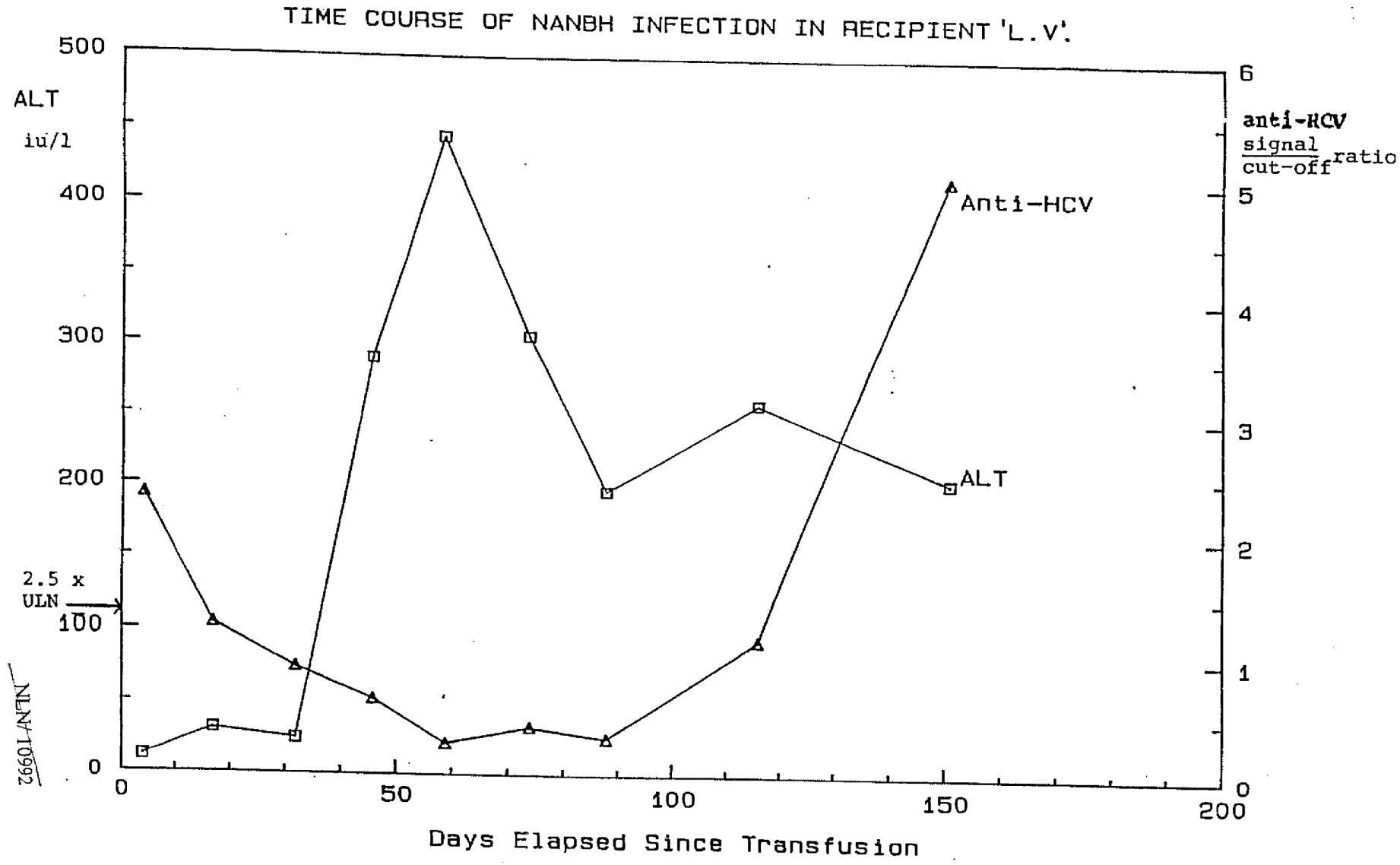
NLBTC RECIPIENT STUDY

- Approximately 1% NANB PTH by US criteria.
- Some ALT-normal recipients are anti-HCV positive. One of these (all samples, ALT ≤10 iu/l) became anti-HCV positive at 6 months. Follow-up will continue, for recipient and donors.
- 21/128 NANB PTH 'negative' recipients show <u>some</u> ALT elevations. All 21 are anti-HCV negative.
- <u>Recipient L.V.</u> (received 8 units of blood).

  A pre-transfusion sample was not available. One of 2 donors studied is anti-HBV and anti-HCV positive.

  The OD of the anti-HCV positive donor is >2.5. We will titrate donor and recipient samples to see if anti-HCV levels are consistent with passive transfer, allowing for dilution factors and antibody half-life.

NLN/10991



SYM/514

NLN/10992

NHBT0000017_006_0005

Group 1

COUNTRY : UK
PRINCIPAL INVESTIGATOR : Dr. John Barbara
LOT N° : 89-as-067

BLOOD DONORS

POPULATION GROUP	N = TOTAL TESTED	INITIALLY REACTIVE n =	Rate %	REPEATABLY RE. n =	Rate
Random donors * TOTAL	3282	22	0.67%	16	0.48%
NLBTC	2063	18	0.87%	14	0.67%
BRISTOL	960	3	0.31%	2	0.20%
MANCHESTER	259	1	0.38%	0	(0% I
Blood donors selected for.: ANTI-HBc POSITIVITY					
1) NLBTC	39	2	5.1%	1	2.5%
2) BRISTOL	24	0	0%	0	0% IN
3) MANCHESTER	26	0	0%	0	0% IN
Blood donors selected for:: ALT 1) NLBTC	132	1	0.75%	1	0.75%
2) BRISTOL	168	3	1.78%	1	0.59%

* : Random donors = Regular donors
Low risk population
Presumably healthy donors
Normal donors

SERUM or ☑ FRESH ☐
PLASMA ☐ FROZEN ☑
ANTICOAGULANT

SYM/515

NLN/10993

COUNTRY : U.
PRINCIPAL INVESTIGATOR : Dr. John Barbara
LOT N°: 89-AS-067

Group 2

TRANSFUSIONAL RISK
Prevalence of Anti-HCV

UPDATED
(to 23 June

Population Group	N = Total Tested	n = Anti-HVC + Reactive	Rate %	Sérum	Froze
Example : Thalassemics	48	22	46	Plasma	Fresl
Renal Dialysis					
Haemophiliacs (A) FVIII VARIOUS (UNINACTIVATED)	18	18 (RPT-REAC. 18)	IR 100% RR 100%	SERUM	FROZEN
FVIII Y (BPL): 80°C, 72H	32	0	0%	SERUM	FROZ
I.V. Drug Abusers					
Polytransfused					

SYM/516

NLN-10994

Group 4

COUNTRY : UK
PRINCIPAL INVESTIGATOR : DR. JOHN BARBARA
LOT N° : 89-AS-067

RECIPIENT

TABLE I

Follow-up of recipients : at 6 months.
All the implicated donors are available.

Classified with the ALT levels during the follow-up (PRELIMINARY CLASSIFICATION ONLY)	Recipients N = Total of Subjects tested	HCV result on the last sample n = % Reactive	n = % Negative
with NANB Hepatitis	1	(& REPEATED) 1 100%	0 0%
without NANB Hepatitis	128	1 0.8%	127 99.2%

SYM/517

NEN/1099S

COUNTRY: UK
PRINCIPAL INVESTIGATOR : DR. JOHN BARBARA
LOT N° : 89-AS-067

Group 5

TABLE III

HCV Proficiency Panel

Sample	Reactivity	2 SD Range	Isolated Results
1	-	0,007 - 0,039	.043
2	++	> 2,500	'OVER REACTIVE'
3	+	1,277 - 2,377	1.528
4	(+)	0,471 - 1,187	.745
5	(+)	0,509 - 1,065	.898
6	-	0,011 - 0,035	.048
7	(-)	0,624 - 1,036	.990
8	+	0,990 - 1,938	1.661
9	++	> 2,500	'OVER REACTIVE'
10	-	0,011 - 0,039	.038
11	-	0,013 - 0,045	.075
12	+	1,235 - 2,307	1.815

++ = Highly reactivity
+ = Moderate reactivity
(+) = Low risk
Cutoff :

NLN/ 10996

SYM/ 518

COUNTRY : UK
PRINICPAL INVESTIGATOR : DR. JOHN BARBARA
LOT N° : 89-AS-067

Group 5

Reproducibility Panel

TABLE IV

Specimen	Essai	N = Total Tested	Average Value	S.D. (c.v.)
Non reactive	Inter Plate	27	0.126	0.023 (18.1%)
Weakly reactive	Inter Plate	27	0.742	0.115 (15.5%)
Strongly reactive	Inter Plate	27	1.749	0.138 (7.9%)

NLN/ 10997