

*New Serial as INCREP02.0LD.*

Report prepared by: T. SNAPE (HQC)      Batch : HL 3186  
 Report reference : INCREP02      Report from: Dr.D.S.Smith - Wessex  
 Distribution (PFL): Dr. Lane      RTC (by telephone)  
                          Mr. Mallory      On : 2nd October, 1984  
                          Mr. Vallet      Received by: Dr.T.J.Snape  
                          Dr. Smith

Donor admitted to Bournemouth Hospital with skin rash consistent with Kaposi's sarcoma, leukopenia and anaemia. Biopsy results awaited. Donor admits to homosexual activity but was VDRL negative when he donated blood several days ago (this donation was separated at Wessex RTC but plasma was not despatched to BPL).

00335388

Plasma donation number ~~3358~~ was collected into an IPP on 27th March, 1984 and despatched to BPL on 6th April in box No.SF4333. This pack was used in the manufacture of batch HL3186.

No factor IX was recovered from the cryosupernatant.

No fraction II was recovered from the A + I precipitate.

Fraction V was recovered and is presently held as L938 and L939.

Factor VIII batch HL3186 was distributed as follows :

Wessex RTC	485 vials (sent 10th August)	
Cardiff RTC	400 vials (sent 15th August)	150 in stock
<i>Cardiff:</i>	<i>150 in stock</i>	<i>Conwayton 40 still held</i>
	<i>101 returned from Heph. Park (6 patients)</i>	<i>Horv. 60 - 37 returned</i>
	<i>51 returned from Horv. (2 patients)</i>	<i>(2 patients)</i>
	<i>36 returned from Conwayton (1 patient)</i>	<i>Wessex 150 - still in clear recall</i>
	<i>338 recovered in all.</i>	<i>providing 6 patients</i>

#### Actions

1. Dr.Smith (Wessex) was informed of implication of HL3186 (telephone 2.10.84, TS) and was asked to recall all vials including any held by patients for home therapy.

Dr.Napier (Cardiff) was unavailable but Mr.Booth (Sen.Ch.MLSO, Cardiff) was informed (telephone 3.10.84, TS) and was asked to recall all vials of HL3186, including home therapy issues.

Both telephone conversations were confirmed in writing (3.10.84, copies attached).

2. Fraction V concentrate L938 and L939 were secured and labelled 'HELD' - although PPF might be argued safe in respect of viral transmission it is not considered that the risks possibly associated with further processing could be justified. These fractions are to be held against the possibility of development of suitable test methods.
3. The process of locating and reconciling all samples of intermediates and finished products (held in house) has begun - SH to append a report on this activity when complete.

4. Dr. Smith (Wessex) was asked to report any plasma from this donor despatched to BPL (or PFL) within the last 5 years (blood given by the donor on 7.9.83 and 21.11.82\* was not used to supply plasma to BPL). Dr. Smith was also asked to determine whether the donor had a history of attendance at local special clinics for venereal disease.
  5. Dr. Tedder (Middlesex) was consulted but indicated that he did not wish at the moment to receive samples of plasma fractions since he did not feel test methods presently in use were appropriate. He did however ask to receive a sample from the most recent donation (September, 1984) and this was arranged with Dr. Smith (Wessex).
  6. Dr. Craske (PHLS, Manchester) was consulted and asked to be supplied with a list of haemophilia centres supplied with HL3186 in order to initiate follow-up studies on patients treated with the batch. TS to comply once data is received from Wessex and Cardiff, and given confirmation of donor's condition.
  7. Medicines Division informed of situation (Dr. Fowler and also 'Defects Report' section). TS to supply Dr. Fowler with a copy of the summary report for the Director.
- \* Late telephone note from Dr. Barnes (Wessex) : the donation of 21.11.82 was taken at Leeds. Time expired plasma from this donation was sent to BPL on 11/1/83 in pool number C 3162TK. Information on this to be appended by SH.

Went into L825

No Fraction II made

Fraction V concentrate sent into AD1305 & AD1315

AD1305 labelled ; sent to Bulland - no further action yet

AD1315 due for inspection on 4.10.84 ; heated product to proceed as normal ; unheated samples to be recovered.