

rjp.imm (SOP)

1 September 1987

To: Transfusion Directors

Dear

*in the light of  
ALT introduction*

**CRITERIA FOR RELEASE OR RECALL OF FINISHED PFC PRODUCT OR INTERMEDIATE MATERIALS WITH POSSIBLE VIRAL CONTAMINATION**

I wrote to you recently outlining what I believe to be the current procedures in operation within the commercial blood product sector with regard to ALT and Anti-Core Antibody testing of plasma donations. With this information in mind and following a report (WBTS) of demonstrably infective (Hep B) donations (HBsAg negative core antibody positive) which have led to recent product recalls, I have taken the opportunity to re-examine our SOP (No 84 111 0004 03) on this topic. The following points emerge.

- (a) Our (SNBTS) criteria for potentially hepatitis B infective donations are more severe than those operated in the commercial sector (see Section 2.1). The reasons for this are simply that commercial fractionators do not have the ability to follow-up recipients of cellular components and as a result avoid the need for expensive product recalls or batch failures of the type that we have hitherto experienced.

|| We should therefore review whether or not there is any justification in changing our SOP bearing in mind our now stringent heating conditions for coagulation factors. ||

- || (b) We (SNBTS) are not ALT testing although it seems likely that such testing will be in place in the near future and we need to address ourselves to the relevance of such test results to PFC product recall and release in readiness for this testing. I would make the following preliminary proposals:

- (i) donations with abnormal elevated ALT will not be sent to PFC.  
(ii) donations which are retrospectively identified as having elevated

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ALT's will not be traced to product batches and accordingly no PFC action will be taken.

- (iii) Individual screening failures or reporting failures by RTC's which result in inclusion of ALT elevated donations into plasma pools will not be acted upon.

I believe it would be appropriate to discuss this topic at a forthcoming Co-ordinating Group.

With kind regards

Yours sincerely

DR R J PERRY  
Director

cc Professor J D Cash  
Or B Cuthbertson