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Comments on the draft flow-chart for the handling of anti-HTLV-III positive results

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1. Annotations of donor record cards

We are opposed to the annotation of '? positive' or 'awaiting repeat' comments on donor record cards. Such instructions will need to be explicit since confusion could be dangerous and/or embarrassing. If they are explicit, confidentiality is lost and furthermore, staff may refuse to rebleed or resample the donors concerned.

In our experience, annotating cards for microbiological purposes (especially if the comments are vague) requires considerable clerking/laboratory time if confusion (potentially disastrous in this situation) is to be avoided. Especially in the early stages of testing the numbers of 'query' results may be high.

In summary, we are opposed to any annotation regarding anti-HTLV-III testing on donor cards.

2. 'First-test positive, repeat test negative' samples

2.1. Re-testing the sample is a separate consideration to testing the pack; the latter enables cross-contamination or carry-over errors to be revealed. Discrepancies on retest of the tube sample may well be due to technical reasons concerned with the handling of the test. In our experience labelling errors are much <u>less</u> likely to be involved in discrepancies than are cross-contaminations or carry-over errors (especially with tests of high sensitivity).

2.2. Samples for reference testing

We would only send a virgin sample obtained from the pack of a 'screen positive, repeat tube-sample positive, pack sample positive' to the Reference Laboratory. If there is a discrepancy between tube and pack samples, then (if staffing and time allow) pack samples from all the specimens on the plate may require testing. This should be sorted out before the Reference Laboratory is encumbered with it. Otherwise, the test is being evaluated, rather than being used for screening.

3. At what stage should donations be 'held'?

This depends on how rapidly results are required, for issue of blood or components. It would be preferable if the release of blood could await repeat testing of the screen positive sample. 'Held' packs should be stored in a designated place. Donations from which samples have been taken for sending to the Reference Laboratory should be discarded or sent to a Research Laboratory.

4. Discarding packs

If a 'screen-positive' sample is not backed up by finding the pack positive, we do not understand why that donation has to be discarded; nor need the donor be specially singled out at the next donation.

When the Reference Laboratory confirms that a <u>pack</u> sample is positive, then further samples should be obtained from the donor for confirmation of the result. The information given to the donor at the time of obtaining this first follow-up sample remains to be decided.

Confirmed-positive donations may well be of value to certain laboratories and special arrangements should be made for delivery to such laboratories or for their safe disposal.

5. <u>Biological false-positives</u>

This term should be confined to cardiolipin reactions in syphilis serology as opposed to cross-reacting false positives in general.

6. Initial stages of screening

If the proposed flow-chart is fully implemented then in the early stages of screening, errors due to over complexity are likely. Much will depend on clerking and laboratory manpower. It would be a pity to erode the manpower needed for careful 'holding' and 'checking' duties on less essential activities.

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North London Blood Transfusion Centre Deansbrook Road Edgware Middx SUGGESTED FLOW-CHART

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screen sample: positive negative : release 'hold',or repeat test (if there is time) on same sample before holding positive negative: different options: ? release hold or (? quarantine pack) ? check adjacent (or whole plate?) tube (and/or pack) samples * test pack sample (? 'hold' all these donations from release) positive; hold 101 card negative: different options: 'virgin' pack sample to ? release Reference Laboratory and or or remove pack from circulation ? check adjacent (or whole plate?) samples* or ? retest pack sample and release if negative positive: negative Inform donor (how much Treat as negative for future donations information?) (discrepancies should have been sorted out by obtain new sample; the time sample sent to Reference Laboratory) withdraw 101 card; Send the new sample to Reference Laboratory → negative positive Inform and counsel donor; ? investigate for a) labelling/clerical error Confirm withdrawal of donor; b) changing HTLV-III serology 101 card to appropriate file; Incinerate or pass pack on to relevant laboratory;

Details may vary from one Centre to another, depending on the facilities available and the speed with which blood has to be available for release.

* May depend on staff availability