NOTE OF THE THIRD MEETING OF THE AD HOC WORKING GROUP ON THE EVALUATION OF ANTI-HTLV III KITS, HELD AT DHSS ON 25 SEPTEMBER, 1985

1. Present:

Newcastle PHLS
Ruchill Hospital, Glasgow
Manchester BTS
Edinburgh BTS

Manchester BTS
Welsh Office
PHLS Virus Reference Laboratory
DHSS

- " (Chairman)
- " (Secretary)

Apologies were received from

and

- Minutes of the meeting held on 18 July 1985: These were taken as read.
- introduced the draft report of the evaluation of the з. Organon and Wellcome kits at Manchester and Edgware BTSs and indicated some corrections. The overall conclusion was that both kits were suitable for routine screening of blood donations. The Wellcome kit was, however, the easiest to use and the equipment supplied for use with it was better than that supplied by Organon. Wellcome's results were not easy to read by eye and the evaluators considered that computer-aided interpretation of data was necessary. The Apricot-based Sanguin package was under evaluation at Manchester BTC where Organon kits are to be used initially. The Sanguin package is only suitable for use with the Dynatech reader. Further automation of the Organon procedure was thought to be necessary. A Hamilton multi-injection syringe system was being used at the Manchester BTC. It was thought that both suppliers should provide larger sized kits for large scale users such as BTCs.

- 4. Organon plates had been replaced because QC values fell outside the manufacture's stated values. This kit had failed to identify some weak positive results and it was thought that adjustment of the cut-off or the use of 'plate-negative mean' method would bring an improvement. Organon did not require the control material supplied with the kit to be diluted. This was considered to be a bad practice and independent controls were advocated.
- 5. Two batches of Wellcome kits had been implicated in the production of false-negative results.

 agreed to send the sera agreed to ask Wellcome to provide

with samples of plates from the batches concerned.

Results of investigations would be circulated to members of the group as soon as possible. The Chairman would then seek members' views by telephone.

- 6. It was agreed that there was a need for a NEQAS-like scheme for anti-HTLV III assays and that there was a need for the Department to look at the manufacturers' qualtity assurance procedures.
- 7. reported that BTCs were on target for the start of routin screening for anti-HTLV III on 14 October. Supply contracts had been arranged by most BTCs and it was planned that training program would start on 1 October.
- 8. It was reported that a Scottish BTC had looked at the Abbott kit but had rejected it in favour of the Wellcome product. Whilst there had been offers to carry out full scale evaluations of the Abbott kit, using the protocol devised by and colleagues, in Wales and Scotland, it was considered that there was no indicati that further evaluations of the products examined by were necessary. However, the group would be interested in any evaluation data that was made available by BTCs. It was agreed that Stage 1 evaluations, at the Virus Reference Laboratory, of kits new anti-HTLV III/should continue.

introduced the final draft of the report of the evaluation of Abbott, ENI, Organon, Ortho and Wellcome kits. This had an appendix which dealt with the Western blot results obtained on most of the panel of sera and an appendix which gave immunofluorescence conclusions were that results obtained by it would be unwise to rely on the the use of Western blot alone to confirm positive results obtained in anti-HTLV III assays and that in experienced hands immunofluorescence assay would be a useful confirmatory procedure in conjuction with others. It was reported that the Lancet had accepted an article based on the evaluation In this article it would be stated that carried out by the full evaluation report-which will very soon be published by the Department-will be made available on application to the Department offered to carry out Western blot analysis on some of the sera examined by Biotech on behalf of the Department.

9.

10. The Chairman would contact members individually about the date of the next meeting which would be held when there was more data to consider.