<u>UK-ACTTD</u> SUB-COMMITTEE ON LABORATORY ASPECTS

Terms of Reference

To examine and report on blood transfusion microbiology laboratory implications of policies and questions raised at the UK-ACTTD.

To seek advice from outside the ACTTD where appropriate and where specific expertise is required.

Proposed items for attention:

1. 'Confirmation' of reactivity

For: HBsAg, anti-HIV, syphilis, anti-HCV and other agents as they may arise.

Aim: To provide formal guidelines on confirmation of routine mandatory microbiological assays for the UK NBTS. These will be based on ACTTD policies. HBsAg will require re-examination in the light of the increased non-specificity of ELISA testing compared with RIA.

HBsAg: items to consider:

a) Neutralization: which species of antibody?

pre-dilution to avoid 'swamping'?

determination of titre (for dilution).

minimum titre of neutralizing antibody.

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- b) Value of anti-HBc, anti-HBc IgM, and 'e' testing to assist in confirmation.
- c) 'Indeterminate' neutralization results in relation to different test kits. Possibility of HBV variants.

HCV: items to consider: continuing review of the performance of screening and confirmatory assays as they develop. This is likely to be a rapidly evolving field for some time.

2. Formulation of QC samples and their promulgation.

e.g. current studies in conjunction with NIBSC on an HBsAg working standard.

Working standards for the other agents (HIV-1/2, syphilis, CMV, malaria) will also be required.

3. Assessment of specific assays for non-mandatory tests

e.g. ELISA for antibodies to malaria.

Preliminary work to assemble a panel of relevant samples has commenced at NLBTC/ABSD/Birmingham/Leeds, with the help of Drs. Chiodini and Voller. The results, when ready, will be presented to the subcommittee.

JB/mm

3 June 1991