

14 Russell Square, London, WC1B 5EP Telex 883669 DHSSHQ G Fax 071-637 8990 Telephone 071-636 6811 Ext.

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Your reference:

Dr H H Gunson
National Director
National Blood Transfusion Centre
The National Directorate
Piccadilly South
Manchester M60 7LP

Our reference:

SEV/43/3B/08

Date:

21 March 1991

Dear Dr Gunson

## IN-CONFIDENCE

COMPARATIVE EVALUATION OF HEPATITIS C KITS - PHASE II - AGREEMENT NO: 35/91

- 1. The Department has agreed that there should be a 'second-round' comparative evaluation of Hepatitis C kits at the Newcastle, North London and Glasgow Regional Transfusion Centres (RTCs) with confirmatory testing to be carried out at the University College and Middlesex Hospital School of Medicine. The protocol is as per phase 1 trials, Section 1.
- 2. The work to be carried out by the NBTS should start in February for the North London RTC and March for the other centres and be completed by the end of April. After this any repeat positive samples previously not identified will be sent to the reference laboratory for additional (and confirmatory) testing.
- 3. (a) In consideration of the work to be carried out in Phase II the approved limit of expenditure, to cover sample archiving (including consumables) and distribution, testing, administrative, reporting and overtime costs shall be by quotation to Mr Fuller, from each of the centres. An invoice should be submitted upon completion of the NBTS portion of the work to Mr R Collins in Room 293 at the above address quoting Agreement No 35/91 SEV 43/38/08. It should be signed by a duly authorised official of the NBTS and should give full details of expenditure incurred under the categories mentioned above.
  - (b) The screening kits involved in the evaluation have been ordered from Ortho Diagnostic Systems, Organon Teknika and UBI by the Department's Project Officer, Mr M Fuller, and invoices will be sent to the Department for payment. Tests from Abbott Laboratories will be done at Newcastle & Glasgow when available, the other tests being only done at North London. Riba II supplementary testing to be carried out at Middlesex/UMDS under Dr R Tedder.
  - (c) In consideration of the confirmatory (PCR) testing to be carried out, the Department will also reimburse the NBTS for payments made to the reference laboratory. As soon as it is known exactly how many samples will need to be forwarded to the reference laboratory,

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the NBTS shall inform the Department so that a further letter authorising the extra expenditure may be sent.

- 4. An interim report should be submitted to the Department upon completion of each RTC portion of the work and a final report should be sent within 6 weeks of the completion of the entire evaluation.
- 5. Mr M Fuller and Dr A Rejman are the Department's Technical and Medical Project Officers for this evaluation. They, and other representatives of the Department, should be afforded reasonable access to the RTCs to discuss progress and inspect the work being done.
- 6. The programme of work shall be subject to the following Standard Provisions:-
  - (a) All stores or apparatus purchased from funds supplied for the work shall become the property of the Secretary of State as soon as they are purchased. The Evaluation Centre shall ensure that werever practicable, the property of the Secretary of State is clearly marked as such as that any loss, or damage to it from whatever cause, is properly notified.
  - (b) The Evaluation Centre undertakes not to enter into any arrangement with a third party which would affect any of the provisions of this Agreement except with the prior consent of the Secretary of State.
  - (c) No liability shall rest on the Secretary of State or his representatives for damage to any property airlising out of the conduct of the evaluation.

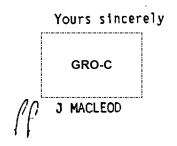
## ARBITRATION

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(d) Upon all matters which, in this Agreement, are subject to the approval, consideration or determination, of the Secretary of State, the decision of the Secretary of State shall be final and conclusve. All other disputes, differences or questions between the parties to the Agreement, in respect of any matter or thing arising out of or relating to this Agreement shall be referred to the arbitration of two persons (one to be appointed by the Secretary of State and one by the Evaluation Centre) or their Umpire, in accordance with the provisions of the Arbitration Act 1950, as amended by the Arbitration Act 1979.

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I should be grateful if you would confirm that these arrangements are acceptable to the National Blood Transfusion Service.



cc:

Dr M Contreras Dr J Barbara Dr M Brennan

Dr R Mitchell Dr R Doughty Dr R Tedder

North London BTS, Colindale North London BTS, Colindale North London BTS, Colindale Glasgow & West Scotland BTS North East Region BTS, Newcastle

Middlesex and UMDS



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