

Copy to R. [unclear] & E. Love.

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21 December 1998

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P. Hansin
GRO-C

Phil Mellor
Contingency Downy.

RECEIVED
24 DEC 1998

Valuable to Calmorphic
event - cont 2nd Lab
- Commitment to Cont. Policy
- in 4 months set up Lab at Brentwood
Leeds - Brentwood
T.S.'s message

Dear Angela

I write to you about my concerns over the security of the NBS mini-pool testing project.

My principal concern is that we are now held hostage to our own success. A year ago, in light of the Hagen data and the American Red Cross data, many people would have said that NAT testing would be unemployable in routine transfusion medicine. I know Peter Flanagan was firmly of this view at the time but felt constrained to push the project forward in order to comply with CPMP recommendations. Fortunately, we have been able to validate manual and semi-automated methods for extraction of RNA from plasma, coupling these successfully with a commercial assay, and achieving sensitivities which were virtually unheard of a year ago. Coupled with the operational security of these developments it has been possible for the NBS to develop mini-pool testing strategies in collaboration with testing undertaken at BPL and to do so successfully. I fear that this has led to the belief in many people's minds that the roll-out of HCV mini-pool testing in the NBS project will be easy and without anything other than the odd simple operational problem.

Whilst I would not wish to belittle in any way the effort, skills and sheer hard work put in by everybody who has been involved in achieving the present position, I wish to go on record as saying that we are in danger of pushing the system too hard too soon. By sheer luck we have been able to take the project from running at the relatively limited testing of a few 480 sample-pools, down to a short-term turnaround of testing mini-pools of 96 samples. There is a reasonable expectation, which may be deliverable, that on a single testing laboratory facility the NBS will be able to comply with the MSBT directive that frozen material with a long-shelf life should only be held in stock or used for transfusion from 1 April 1999 onwards from a donation known to have been screened in mini-pool testing and to be free of detectable HCV RNA. In order to do this the goal posts have been changed. The removal of anonymisation for the project at a time at which the project remains fragile and the requirement of PULSE involvement for release increase greatly the stress on the system. Please realise, no matter how well intentioned these decisions are, they do by their very nature increase greatly the potential for damage. This will relate to individual donors, inventory handling and the availability of product for clinical use. The recent demonstration that a 'resolution' plate prepared at Brentwood was flawed for the most recent pick-up must alert you to the general fragility of the system.

single pool
plate
- implicated in
- all wells tested
- 1 NBS
- [unclear]

need more
info

eg/rst/14dec98

Professor of Medical Virology and Head of Department The Hon. Richard S. Tedder MA, MB, BChir, MRCP, FRCPath

We do not yet have sufficient security on the performance of the production of mini-pools and resolution plates to roll out the study in any substantial way. This surely is why the initial phase from early January 1999 to 1st April was always seen as a proving period. The system simply has not been proven.

Much more worryingly, there is only a single testing laboratory which makes reliance on NAT results for release extremely dangerous. Disaster recovery could take months and this simply appears to have been ignored. The possibility of a catastrophic contamination event is hopefully unlikely because of the use of aracil in amplicon production, however it is possible that if this were to occur recovery in a single laboratory would be difficult if not impossible. Until at least two sites are able to run at the level necessary to serve the NBS I do not think we should link the NAT release into PULSE. The potential for fouling up the system is too great. Please consider these comments as put forward with the very best of motives. I want neither the NBS nor BPL nor PCR to get a bad name.

Seasonal Greetings.

Yours sincerely

GRO-C

Richard S Tedder
Head of Department of Virology

RST/eg