

Dr A S M Rejman
Mr J Canavan

*Dr Rejman } 2 agree we should try to expand the study to include
Mr Canavan } new competitor kits, provided this does not cause
too long a delay
cc Mr Fuller.*

GRO-C 31.1.91
M Fuller MDD PG1C
Date: 29 Jan 1990
Copies: Dr J Metters
Dr D A Kennedy
Mr E Evans
Mr K Gill

*Pl see last
section.*

GRO-C

POLICY / COMMERCIAL - IN CONFIDENCE

**ORTHO - WELLCOME JOINT PROPOSALS FOR VIROLOGICAL SCREENING OF
BLOOD SUPPLIES - UKBTS UPDATE**

Andrzej / John

Summary

Informal discussions with Ortho representatives suggest that they are hopeful of getting a price of £2.30 per test for HCV Ab detection kits, based on **Regional** contracts. Wellcome are not in the field. Strong suggestions of competition are materialising. We should undertake to obtain equivalent evaluation data on products from UBI (a US company), and Organon Teknika (European) with all haste - I seek support for extending the previous study.

Background

I attended the Ortho/Wellcome "Roadshow" on Monday 28th, at North London RTC. The proposals are to add Ortho HCV to the range of Wellcome virological tests presently performed in RTCs "with the minimum disruption". **Nothing new is being offered.**

A range of purchase options is "on offer". This obviously begs the question: Do the RTCs need replacement equipment, and if so do they need it now?

There will be obvious pressure from RTC Directors to take advantage of this "package" if there is a perceived need to replace any capital equipment, even if on a "Reagent-lease".

The Ortho product under discussion was the "HCV 2". This has not been evaluated by us, yet. It claims greater specificity than the previous "First generation" product. Also being discussed was a new format RIBA supplementary product, again claiming greater specificity due to addition of new epitopes (C33-c and C22). The tone of the general discussion appeared to be to play down any progress that Abbott may have made.

A commercially available test panel (Boston Biomedical) appears to be used as "Industry standard" for determining sensitivity. All "clinical" samples referred to were single donors bled on weekly intervals and the game was to detect HCV Ab as soon as possible. This was not achieved before ALT peak was reached, nor were any results correlated with PCR result. RIBA results did suggest a reduction in "false positive" numbers from that obtained with the first generation screen.

Please copy
5 Mr Fuller
6.2.91
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Discussion with the head of R&D, Wellcome, suggested that the costs of kit manufacture had been stable for some considerable time, and had, in fact, been greatly reduced by use of recombinant technology. The single most expensive item, by far, was the plastics plate (NUNC, high quality polypropylene) - this at 5 pence per test in contribution.

Proposed progress

1. PD colleagues Eric Evans and Ken Gill have been in touch with competitors, who suggest prices as low as \$ US 2.00 for large volume contracts. These (UBI and AKZO - Organon) need evaluating, and the financial background of UBI must be ascertained.
2. These should be used now as leverage on Ortho. Abbott are a problem where "Commander" systems have tied-in RTCs, but the "national price" will have to be met by them.
3. We need to know the equipment status of the RTCs - Harold Gunson should be able to advise. I consider this an irrelevance.
4. The country can ideally be then split up to give a non-dominant share to each suitable product, all of the rest being bog-standard ELISA format.

I shall update you on any negotiations we anticipate setting up, and will stand by to be updated on progress of submission.

Please respond ASAP to request for extra evaluation funding, with backing of JSM, perhaps.

GRO-C

Mark Fuller PGIC

711 RSQ GRO-C

Andrey - wrt this PM, can I also have: - as well as

answer to (3) above;

- 1) Do PHL/NBTS have info /view of UBI and/or Organon Teknika kits?
- 2) Are they worth evaluating? - I think they may be "1st Generation" ?
- 3) If yes to (2), can they do it now?
- 4) How soon will we get answers?
- 5) How much will they charge us?
- 6) Do they see any need to "re-evaluate" Ortho "HCV-2". ?

GRO-C