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Carluke

RM/AH

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IN STRICT CONFIDENCE
NOT FOR PUBLICATION

Dr D B L McClelland
Director
South-East Scotland
Blood Transfusion Service
Royal Infirmary
EDINBURGH

Dear Brian

ABBOTT V WELLCOME ANTI-HTLVIII TESTING

Archie Barr has now returned from the Newcastle meeting. I have discussed with him the problem that you posed following the Nibsac discussions. I attach a table showing the parallel running which we have done on the Abbott test since we introduced the Wellcome system (Wellcozyme).

You will note that from 18-25 September we were using a manual diluting method using doubling dilutions of 1:20 followed by 1:20 and then tested. The initial positives were high and repeat positives were high. From 26-30 September we used the Eppendorf diluter, ie an automatic diluter but similar stepwise dilution and it seems as if we picked up only 1 out of 219 tested that were positive and repeatable positive.

We then proceeded to routine screening using random donors from 1-20 November using the Eppendorf diluter. We found that out of 3,473 tests 71 were initial positive and 27 repeat positive (2% and 0.8%). At that time it was found that the proquantum was not washing properly beyond the eighth plate in the series, most of our initial positives were found after the eighth plate. The proquantum was repaired by Abbott and from 22-29 November we tested 2,900 samples with 9 initial positives and 4 repeat positives (0.3% and 0.14%). With the repaired proquantum the problem (breakdown) returned on 29/11/85 and we were supplied with a new proquantum from Abbott. We then tested, from 2-9 December using the Eppendorf diluter, 1,825 samples with an initial positive for 24 and a repeat positive for 4 (1.3% and 0.22%). This would suggest that with the new proquantum the repeatable positives were apparently stabilizing at approximately 0.2%. In the remainder of December 1985, using the Eppendorf diluter at a dilution of 1:100 this time, we tested 1500 samples and found 16 initial positives and 3 repeatable positives (1.0% and 0.2%).

The table shows the aggregate of these various testing procedures and it would seem that out of a total of 11,201 we have found 136 initial positives and 44 repeat positives (1.2% and 0.39%). Obviously these initial positives and repeat positives are higher than one would expect with the Wellcozyme test, almost certainly due to washing problems with the proquantum and the less specific (IgG) nature of the Abbott test system. Of the 44 samples found to be repeatable positives, 42 were available for further examination by our Reference Laboratory. They have found 15 to be positive by Abbott, but all are confirmed negative by Wellcozyme. The 15 samples are being further investigated by Immunofluorescence and Western Blot technique. We have included a further table showing 4-month testing using Welloczyme test for comparison purposes.

What is perhaps more interesting is the result of the DMRQC anti-HTLVIII performance assessment of panel A which we have already sent to Colindale. You will see that in the primary screening test using Wellcozyme batch no. K413510 and using the level of sensitivity which we previously reported in which we have persuaded Wellcome to retain for us exclusively, we have no difficulty in detecting the positive samples in DRMQC panel. Using the Abbott system we have certainly been able to detect the LP1. What worries us about this is that looking at the figures published by Dr Rawlinson it would seem that many of the Blood Transfusion laboratories are struggling to detect the LP1 DMRQC sample. That does not concern us since we are operating at a level of sensitivity which was later changed by the Wellcome people to take account of the initial reports from Dr Rawlinson that many laboratories were detecting what I would call "hum". In order to reduce their level of "hum" the Wellcome people decided to reduce the overall level of sensitivity.

You will recall that was a matter which was discussed and circulated among Directors and I later reported that the matter had now been resolved. As far as we were concerned it was resolved to the satisfaction of other BTS users but would not entirely satisfy the rigid criteria of our own Centre. What concerns us about the figures published by Dr Rawlinson is that some of the other Centres may be living in a "fools paradise" and we understand that although the LP1 is not always detectable in certain Centres that somehow or other the inability to detect this level of sensitivity is being ignored.

I am sure you already have copies of my correspondence with Wellcome about the problem which was resolved, in our view, by reducing the sensitivity so as to avoid too many false positives in other RTCs and make life tolerable for them. Nevertheless, as I have indicated, we are working at the original sensitivity levels which were set at the onset of routine testing and we have stuck to our original thesis. The other important aspect of

this is that it would appear that the Abbott and the Wellcozyme test are not dissimilar in our hands in their level of sensitivity. I hope these observations are helpful to you.

I believe that a poster demonstration of this is being prepared for the Scotblood meeting 1986 and if we can be of any further help to the Expert Advisory Group then of course we would be prepared to assist in any way. We have also been asked by Abbott Laboratories if we would be prepared to publish our results and we have agreed to this and we would only wish to indicate that we had tested a fairly large number of donors in parallel with the Wellcome system. All that Abbott wish to achieve at this stage is the fact that they have not gone away and that they are still in the market. You will understand that I have no particular remit to act for Wellcome or for Abbott and we would be guided by the Expert Advisory Group although, as I have said, we have not accepted the change in sensitivity as agreed with Wellcome for other users.

Kind regards, best wishes.

Yours sincerely

Director

cc Mr A Barr