RESULTS OF FDA EVALUATION OF HTLV-III ANTIBODY SCREENING TESTS

US DHHS STATEMENT TO BLOOD AND PLASMA COLLECTING AGENCIES
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Summary of Contents Reported by Phone By Dr Jack Gillon
D B L McClelland 13th February 1985 (for EAGA Testing WP 15th February 1985)

METHODOLOGY

Kits for HTLV-III detection from 5 suppliers have been evaluated. 30,000 donor samples were made available. Each supplier received approximately 3,000 samples from donors in commercial plasma centres, and a similar number from voluntary whole blood donors. The samples were obtained from regions across the U.S. and distributed so that there should be no regional bias in the samples received by any one manufacturer.

Each manufacturer received samples from a different set of donors so that direct comparison cannot be made of results obtained by the different tests.

All samples found positive on first testing were retested by the initial screening procedure. All samples were further tested by a Western blotting procedure. These 'confirmatory' tests were done by the manufacturers.

RESULTS

Samples from Donors at Plasma Centres

Test Manufacturer	% Positive on First ELISA	% Positive on Repeat ELISA	% Positive on Blot	% of ELISA Pos Also pos on Blot
1	4.8	2.9	1.8	37.2
2	0.8	0.3	0.1	17.4
3	3.4	1.7	1.1	32.9
4	0.3	0.3	0.2	85.7
5	0.7	0.4	0.4	60.0

Samples from Voluntary Whole Blood Donors

Test Manufacturer	% Positive on First ELISA	% Positive on Repeat ELISA	% Positive on Blot	% of ELISA Pos Also pos on Blot
1	8.1	5.9	5.1	63.6
2	0.3	0.2	0.1	12.5
3	2.8	1.3	0.4	12.9
4	0.8	0.4	0.1	12.5
5	0.6	0.3	0.2	41.7

FURTHER POINTS

I understand no data are available on the repeat testing of samples found negative on the first screening test.

Studies in several US blood centres apparently show that positive results are found with equal frequency in female and male donors, and a study at the Community Blood Centre in Kansas City has revealed positive results in stored donation samples laid down in 1975.

IMPLICATIONS AND RESULTS OF FDA TRIAL FOR UK TRANSFUSION SERVICE USE OF THE SCREENING PROCEDURES EVALUATED

1. Even without sight of the complete date it seems very unlikely that the initial U.S. studies will provide an adequate basis for planning the introduction of antibody screening of donors in the U.K.

2. Applying the American trial data (on voluntary whole blood donors) to a region collecting 100,000 donations per year, the possible consequences appear to be:-

Test	% Donors with positive repeat ELISA	Number of Donations to be Blot tested	% of Blots positive	Number of "confirmed positive" donors
1	5.9	5,900	64	3776
2	0.2	200	12.5	25
3	1.3	1,300	12.9	169
4	0.4	400	12.5	50
5	0.3	300	41.7	126

3. Conclusion and Recommendation

In view of these results, before planning for the introduction of any of the present commercially available screening tests, a substantial comparative evaluation must be carried out among representative groups of UK donors.

This should be designed to:

- Allow comparison of the available screening procedures.
- Establish the prevalence of positive test results in the selected groups.
- Assess the resources required to undertake both the initial screening test and all necessary confirmatory procedures within an acceptable timescale.

In designing such a study, decisions will be needed on several difficult questions. In particular:

- Will the samples be coded so that the donors' indentity is totally uncoupled from the results of the test?

- If this is not done, what actions will be taken when a positive result is obtained, and do these action make it essential to obtain prior consent from the donor before the screening test is carried out on his sample?

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