

AIDS: The Safety of Blood and Blood Products
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Summary of Experience in France Regarding Screening and Confirmatory Tests*

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Routine screening of blood donations for antibodies to LAV/HTLV-III has been officially implemented in France since August 1985. Our group set up a study to evaluate the available test materials and methods. 1007 sera from blood donors found repeatedly positive or doubtful during the first months of this routine screening in 74 of the country's blood transfusion facilities were tested in the same laboratory by the three commercially available ELISA kits. Western blot analysis and RIPA served as confirmatory tests. The main conclusions of this study, details of which will be published elsewhere, are shown in Tables 1 and 2.

Commercially available ELISA kits have heterogeneous performances in terms of sensitivity and specificity. Performances may also vary according to

Table 1 Overall specificity and sensitivity of ELISA test materials for antibody to LAV/HTLV-III

Probability of confirmatory tests being	Kit A (%)	Kit B (%)	Kit C (%)
Positive if positive ELISA	91	73.6	89.4
Negative if negative ELISA	99.8	99.2	98.5

* This summary is based on an investigation carried out by the Retrovirus Study Group of the French National Committee on Transmissible Infections by Blood Transfusion.

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Table 2 Calculated probability of confirmation of anti-LAV/HTLV-III (CI 95%) by Western blot analysis and RIPA according to the reaction strength obtained by ELISA (analysis of 1007 ELISA-positive/equivocal sera from donors tested in parallel by three ELISA kits, Western blot and RIPA)

Absorbance ratio serum: cut-off	Kit A* (%)	Kit B (%)	Kit C (%)
< 0.6	0 (0-1)	0 (0-2)	0 (0-1)
0.6-0.7	0 (0-31)	1.7 (0.04-9)	8.3 (1.03-27)
0.8-0.9	0 (0-41)	3.2 (0.08-16.7)	19 (6.4-41.9)
1-2.9	32 (21-45)	15 (10-21)	46 (36-57)
3-4.9	94 (88-98)	53 (39-66)	91 (82-96)
> 5	99.6 (98-99.9)	93.7 (91-96)	98.9 (94-100)
<i>Maximum</i> (sample absorbance > 2)	98.9 (96-99.9)	100 (98-100)	98 (96-99)

* 43 samples with positive reactions both in test and control wells were excluded from these calculations.

batches and reading specifications such as the cut-off threshold. In addition, the probability of a positive confirmatory test increases with the strength of the ELISA reaction.

These variables explain some of the difficulties experienced in comparing the rate of positive ELISA tests in large series from different countries and institutions. Accordingly, at the present time, the prevalence of antibody to LAV/HTLV-III among blood donors can only be estimated on the basis of positive confirmatory tests.

Such an approach was applied to a nationwide survey conducted by this group among blood transfusion centres in France. During the first 6-month period of this surveillance scheme (July-November 1985) 1,438,717 donations were tested. These samples originated from 75% of the French blood transfusion facilities, and represented 90% of blood collected in France in that period. 972 donors were found to have confirmed antibody to LAV/HTLV-III (6.8/10,000). The principal epidemiologic features found in these donors are shown in Tables 3 and 4.

These data clearly indicate that measures self-deferral implemented to inform the public and to encourage self-deferral from blood donation of potentially at-risk donors were not fully efficient. The development of alternative sites for anti-LAV/HTLV-III testing outside of blood transfusion centres and continuing public educational efforts therefore remain issues of high current concern.

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Table 3 Epidemiologic features in donors with confirmed antibody to LAV/
HTLV-III

The 972 positive donors were predominantly:

Male: 837/972 = 86%

Age: 63% of males and 75% of females, under 30

Anti-HBc-positive: 238/369 = 65%

First-time donors: 41.3%, the proportion of first-time donations in general being 12%

Marked variations according to regions:

Auvergne: 0

Côte d'Azur: 11.8/10,000

Paris region: 19/10,000

Table 4 Risk factors among the 972 donors with confirmed antibody to LAV/
HTLV-III

	Males = 837 (%)	Females = 135 (%)
Homosexuality	43	-
Bisexuality	14	-
Intravenous drug abuse	25	51
Previous transfusions	3	4
Sexual contact with at-risk individuals	2	30
None documented	13	14