Y SWYDDFA GYMREIG
GWYDYR HOUSE
WHITEHALL LONDON SW1A 2ER
Tel. 01-233 3000 (Switsfwrdd)
01-233 6106 (Llinell Union)

Oddi wrth Ysgrifennydd Gwladol Cymru

WELSH OFFICE
GWYDYR HOUSE
WHITEHALL LONDON SW1A 2ER
Tel. 01-233 3000 (Switchboard)
GRO-C (Direct Line)

From The Secretary of State for Wales

18th October 1985

PERSONAL AND CONFIDENTIAL

Dear Secretary of State

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Since I wrote to you on 8 October on this subject, I have been given a detailed presentation by my officials. In the course of it, I was given the results of the evaluation by the National Blood Transfusion Service of the and test kits which have been recommended for use in the BTS. As the table I attach shows, 1 in 5 of "strong positive" test material was missed by the kit, and about half of the "weak positive" material was missed by the kit. I understand that the manufacturers have given assurances about future quality control but I cannot help wondering how realistic their promises are: I would have expected that firms producing kits for evaluation in the knowledge that a very lucrative contract lay in the offing would have done their utmost to ensure the highest possible degree of quality control in the material supplied.

Be that as it may, I accept that even unreliable testing is better than no testing at all. But clearly we must take every step to ensure that we get the system as foolproof as it can be. I am therefore surprised to learn that no further evaluation is planned of the other test kits which are available on the market. I believe this is because there were considerable doubts about the suitability of the other kits, such as However, the 4 October edition of the Journal of the American Medical Association (JAMA) reports (copy attached) that 5 months of experience with other kits

in the American ...

Secretary of State for Social Services
Alexander Fleming House
Elephant and Castle
London
SE1 6BY

in the American Blood Transfusion Services have shown a very high standard of performance. Whatever doubts we might have about their claims, it does seem to me that we would be in an indefensible position if, in a few months time, the earlier doubts about the systems we are using were not allayed and we had no alternative available which the BTS could immediately turn to. In short, I consider it essential that all kits should be put into an evaluation programme. A public comparison between the report of the BTS on our present kits with the JAMA report would make life very difficult for us all!

Yours sincerely

(Approved by the Secretary of State
and signed in his absence)

SECRETARY OF STATE'S OFFICE

For advice pl.

COPIES TO Health Ministers.

EXTRACT FROM "AN EVALUATION OF ANTI-HTLV III TEST KITS IN THE NATIONAL BLOOD TRANSFUSION SERVICE"

SUMMARY

1. General

In this evaluation there is evidence of problems affecting both test kits and testing centres which would be expected to be reduced with increasing experience. Thus, a substantial number of plates failed to meet the manufacturer's values for quality control parameters during testing. Also, plates were repeated because of excessive numbers of positive results probably attributable to lack of operator familiarity.

Thus, the conclusions drawn from the data must be qualified.

2. Detection of known positive coded control samples included in the study

See Summary Table A.

In both centres the Vironostika kits failed frequently to detect the weak positive sample.

In both test centres the Wellcozyme test failed to detect the strong positive sample on several occasions.

3. Numbers of initial screen positive, repeat screen positive and continued positive results

See Summary Table B.

4. Calculation of results

From the data in this study it is apparent that minor alterations to the method of calculating the cut-off value for the Vironostika kit would lead to the detection of almost all the weak positive coded control samples.

However, the failure of the Wellcozyme assay with one batch of kits to detect the strong positive coded control samples could not be remedied by simple adjustment of calculations.

In the three instances in which the Vironostika tests failed to detect the strong positive coded control, no adjustment to the calculations of the results would have resulted in the right results. It is possible that two instances could have been due to failure to add the sample.

5. The study emphasises the importance of some form of computerised interpretation of results, since a significant number of positive and borderline results were missed on first examination and detected only by subsequent computer analysis.

TABLE A

DETECTION OF STRONG AND WEAK POSITIVE CODED CONTROL SAMPLES

	Strong Positive Missed per Total Tested	Weak Positive Missed per Total Tested
Vironostika (Organon)	3/46	~~26/56~~ 26/52.
Wellcozyme (Wellcome)	9/48*	1/42

* One batch only (3252) accounts for all the missed strong positive coded controls.

Blood banks give HTLV-III test positive appraisal at five months

The nation's blood supply is measurably safer than it was five months ago—at least as far as the risk of transmitting the acquired immunodeficiency syndrome (AIDS) is concerned. This is the conclusion from experience to date with the tests for human T-cell lymphotropic virus type III (HTLV-III) antibody being used by blood banks to screen out potentially AIDS-infected blood.

Data from experience with the tests were reported at a meeting held in Bethesda, Md, at the National Institutes of Health in association with the Food and Drug Administration (FDA), Rockville, Md, and the Centers for Disease Control, Atlanta. "The general impression is that, after the first five months, these tests are doing an extremely good job of screening potentially AIDS-infectious blood units out of the blood supply," said Harry M. Meyer, Jr, MD, director of the Center for Drugs and Biologics at the FDA.

The HTLV-III or lymphadenopathy-associated virus (LAV) is the agent generally held to be the cause of AIDS. When antibody to this virus is present in human blood, evidence indicates that the blood has the potential of transmitting the disease to persons transfused with that blood.

The first test for detecting the presence of the antibody to this virus in human blood was licensed by the FDA at the beginning of March to Abbott Laboratories of North Chicago, Ill. Since then, two other companies, Electronucleonics of Rockville, Md, and Litton Bionetics (now known as Organon Teknika) of Charleston, SC, have received licenses from the FDA to market their tests. All of the tests are based on an enzyme-linked immunoassay, known either as ELISA or EIA.

At the meeting, Joel N. Kuritsky, MD, of the FDA reported data from a preliminary survey of 1,128,166 units of blood gathered in 131 blood collection centers around the United States during a two-month period from April 22 to June 16, 1985. These units were screened by one or another of the ELISA tests and 9,629 were initially positive by the assay (0.85%). On repeat testing by the assay, the number of antibody-positive units fell to 2,831 (0.25%). Kuritsky did not report any data on results of Western blot analyses on these repeatedly positive units.

Blood banks collecting less than 10,000 units of blood a year were not included in the FDA's survey. Thus, the survey covers only about 70% of all blood collected in the United States during this period.

A similar overall picture came from a survey, conducted by the American Red Cross, of blood collected from March through June 1985 in its 57 blood centers. During that period, the Red Cross tested 1,593,969 units, reported Paul D. Cumming, PhD. Of these, 3,209 (0.2%) were repeatedly positive by the immunosorbent assay the Red Cross employs. *Repeatedly positive* is defined as units that have been tested at least twice by an ELISA and read as positive both times.

Because the Red Cross routinely furnishes its data on these tests to the FDA, the figures cited by Kuritsky necessarily include some of the units discussed by Cumming. Kuritsky could not be reached to clarify exactly how much of an overlap is involved, but Gerald Quinnan, MD, of the FDA agreed that there must be some "substantial" amount. However, he noted that the FDA's data also included experience from non-Red Cross blood collection centers, "so the summary is not simply a subset of the Red Cross data. It would include results from other sections of the country not represented by the Red Cross."

So far, reported Cumming, 2,552 of these repeatedly positive samples have been further tested by Western blot analysis and 587 were labeled as positive.

The Western blot is an immunoelectropheretic procedure for identifying antibodies to proteins of specific molecular weight, in this instance those associated with HTLV-III. The Red Cross is routinely requiring Western blot analysis of donor blood that is repeatedly positive by ELISA.

While some blood collecting organizations are doing Western blot analysis themselves, the Red Cross has a contract with Abbott Laboratories to perform this test. "It's a labor-intensive procedure that takes a fair amount of skill and is really only as good as the technicians who are doing it," comments Joseph P. O'Malley, MD, of the Red Cross's medical operations department. O'Malley said the contract with Abbott under which the Red Cross purchases its ELISA test kits includes the provision that Abbott perform whatever Western blot tests are needed. "The Red Cross is not passing along the charges for this test to its customers," O'Malley said; it is absorbing the cost. A spokesman for Abbott said in a recent telephone interview that his company's charge to perform the

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test at present is "about $100."

At present it takes about two weeks to get a Western blot test result back from Abbott's laboratory in North Chicago, according to the Red Cross's Cumming. "We've got it down from about eight weeks, where it was at the beginning of the phase-in period. I don't think we're going to get much better than that and, frankly, I don't see the need to," he said. He pointed out that the results of Western blot analysis had no effect on the chances of an AIDS-infected unit entering the blood supply.

The value, at least at present, of doing a Western blot on antibody-positive specimens was demonstrated by a laboratory study reported at the meeting by Roger Y. Dodd, PhD, and C.T. Fang of the Red Cross Research Laboratory, Bethesda, Md. Dodd and Fang took 73 specimens that had been identified in routine screening as repeatedly positive by one or another of the tests—39 by the Abbott test, 12 by the Electronucleonics test, and 22 by the Litton test.

They repeated the test in duplicate with each of the licensed ELISA tests. They found ten of the 73 specimens were negative by all three of the tests. They then tested the remaining 63 units by Western blot and found that 23 were positive and 40 were negative.

Of the 40 Western blot-negative specimens, 22 were positive to only one of the assays—nine by the Electronucleonics test and 13 by the Litton test. The remaining 18 were positive in various combinations of the three tests.

The antigen for the licensed ELISA tests is cultivated on a malignant cell line known as H-9 cells. These cells are known to be positive for HLA class II antigens that can end up in the test reagent (*Lancet* 1985;1:1222-1223). In turn, this can lead to an ELISA being read as positive for HTLV-III in some persons.

One possible way of getting around the problem of false positivity is to include an uninfected control as part of the HTLV-III ELISA procedure. Comparing the two assays, it is argued, would enable one to separate the specimens that only contained antibodies to the contaminating proteins from those that contained antibody to the specific viral proteins.

"However, just because a specimen reacts to such a test for HLA antigens doesn't necessarily mean that a reaction that occurs in the licensed ELISA is nonspecific," notes the FDA's Quinnan. "The antigen preparation in an ideal control would have to contain the same nonviral proteins in identical concentrations that are in the specimen and none of the viral proteins, and there is no such test," he said. "So, based on the currently available data, you can't be sure that equivalent reactivity in the two tests means that the ELISA is truly negative.

"I think if there were a way to make the ELISA more specific and which was well understood, it would undoubtedly be implemented. But at the time the present tests were licensed, there were not enough good data available to use an uninfected control as a means of accomplishing this."

Persons who are most likely to be misclassified as positive for HTLV-III antibody by the present ELISA include those who have received blood transfusions or multiparous women. Some evidence that these may indeed be false positives was provided by the Red Cross's Dodd.

Of the 40 ELISA-positive, Western blot-negative specimens, he and Fang tested 26 for reactivity to HLA class II antigens and 24 of these were positive. Conversely, when a similar test was run using an ELISA developed on a different cell line, only one of the samples was positive.

This, pointed out Dodd, "supports the concept that most, if not all, of the units described as ELISA-positive and which turn out to be Western blot-negative actually represent false-positive results."

The second ELISA used by Dodd for this study is one developed by Genetic Systems Corp of Seattle. It employs the virus called LAV (isolated by the French group) and the assay is developed in a cell line called CEM (rather than H-9 cells). The system is currently under review by the FDA for licensure.

At the meeting, Lynn Goldstein, MD, of Genetic Systems, reported that—in specimens from 10,038 presumably normal blood donors—10,005 were negative by the company's ELISA, 33 were initially reactive, and 20 of the 33 were repeatedly positive. "If one assumes that all blood donors are negative, this is an overall specificity of 99.8%," she said.

(*Sensitivity* is defined as "the number of diseased individuals with a positive test result divided by the total number of diseased individuals." *Specificity* is defined as "the number of nondiseased individuals with a negative test result divided by the total number of nondiseased individuals" [*JAMA* 1984; 252:2418-2422]. This differs from the classical definition of these terms as used by immunologists.)

Genetic Systems' ELISA was evaluated by a radioimmunoprecipitation (RIP) procedure that involves radiolabeling the virus, complexing it with antibody in the specimen, and reading off the radiolabeled antigen that reacts with the antibody by autoradiography. A random sample of 542 ELISA-negative donor specimens were all confirmed negative by this test.

The performance of the company's ELISA was also evaluated by the RIP in 1,469 specimens from groups at high risk for AIDS. These included patients with AIDS, patients with AIDS-related complex, patients with the lymphadenopathy syndrome, and intravenous drug abusers. In all of these groups, the ELISA's sensitivity was 100%. In a group of 472 presumably healthy homosexual men, 205 were repeatedly positive by this LAV-ELISA, and 264 were negative. Three of

the specimens tested negative by the ELISA but were positive by the RIP test—a sensitivity in this group of 98.5%, Goldstein observed.

One of the major questions before the HTLV-III antibody tests were licensed was whether simply detecting the antibody in donor blood would actually identify infectious units. Two studies from the Centers for Disease Control, reported at the meeting, go a long way toward supporting the conclusion that the vast majority of those persons whose specimens are repeatedly ELISA- and Western blot-positive do, in fact, have virus in their blood.

The two studies involve two disparate groups. One is composed of heterosexual blood donors; the other of homosexual men.

The blood donor study was done in association with Alfred J. Grindon, MD, medical director of the Atlanta region of the Red Cross blood services. It was reported at the meeting by John W. Ward, MD, of the Centers for Disease Control. The group found that 19 (56%) of 34 specimens of blood from donors who tested "strongly positive" for HTLV-III antibody were also found to be harboring the AIDS virus. On the other hand, two of 51 blood donor specimens described as being of low reactivity to the ELISA test yielded virus. "Thus, the interim recommendations by blood banking groups, such as the American Association of Blood Banks, that blood which is repeatedly ELISA-positive should not be used is prudent," noted Ward.

However, two of these virus-positive specimens were reported as Western blot-negative. One of these was in the high reactive group, the other in the low reactive group. Ward could offer no explanation for this finding. "We are repeating the tests on these specimens and we will just have to see what we get the second time around." He agreed that the finding highlights the need for better tests for HTLV-III antibody. "Certainly, the Western blot is no gold standard," he added.

The second study was done in association with the San Francisco Health Department and was reported at the meeting by James R. Allen, MD, of the Centers for Disease Control. In a group of 70 homosexual men, virtually all of whose blood samples were described as "strongly positive" to the HTLV-III ELISA antibody test, 42 (60%) had AIDS virus isolated from their lymphocytes.

"The sensitivity of the culture method used to assay for HTLV-III in lymphocytes has not been determined," Allen noted. But, he said that, based on the centers' experience, as well as on data from elsewhere, the 60% isolation rate of virus is high.

There are no commercially available assays for recovering HTLV-III infectious virions from specimens taken from patients with AIDS, although assays are done routinely in some research laboratories. Virus can be isolated from lymphocytes in patients with AIDS, but frequently it is difficult to get enough lymphocytes late in the course of the disease because their number is depressed by that time.

Tests for the virus involve treating lymphocytes collected from patients with T-cell mitogens, such as phytohemagglutinin, and cultivating them in the presence of interleukin-2 or T-cell growth factor. The cultures are monitored for virus either by assaying for reverse transcriptase (the enzyme that characterizes this group of viruses) or by using an immunofluorescent antigen test for the presence of virus, or by electronmicroscopy.

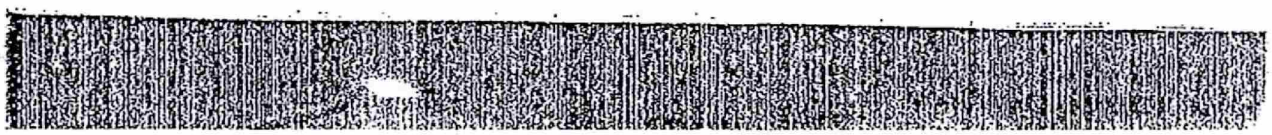
Summarizing these two studies, Allen said that the findings "clearly demonstrate the screening test is valid for antibody. We have found that in a group of blood donors—persons at low risk of HTLV-III exposure and with a low prevalence of infection—and in a group of gay men who are at high risk of HTLV-III exposure and with a high prevalence of infection with HTLV-III, that the ELISA is highly specific. It correctly identifies those in both groups who had a high probability of infection."

Commenting on the principal findings reported at the meeting, Walter R. Dowdle, PhD, of the Centers for Disease Control, pointed out that in April, when the testing of blood was getting under way, "we had no idea how the tests would perform. What we have seen now is that persons who have been donating blood—and who did not consider themselves to be at risk for AIDS and hence a potential source of transmitting the disease—are being picked up by this test. They had virus isolated from their blood and so were capable of transmitting disease. I think this is a tremendous accomplishment."

James Curran, MD, of the Division of Viral Diseases, Centers for Disease Control, was equally optimistic about the value of the present antibody tests for AIDS as a screening procedure. But he cautioned the audience not to expect any sudden fall in the number of transfusion-associated AIDS cases. "Because of the long incubation period, there will continue to be cases of AIDS occurring associated with blood transfusions," he said. "Most of these will occur in those who received blood prior to the antibody tests being introduced.

"How many there will be depends on the natural history of the infection, but I think it will be decreasingly important as a proportion of those who are reported with AIDS," he said. (Out of a total of 12,067 AIDS cases reported at the time of the meeting, there have been 202 cases [1.67%] associated with blood transfusions.) Some of these cases, Curran said, have occurred five or six years after exposure. On the other hand, he noted, there are instances of persons who have been exposed for six or seven years and who have remained healthy.

—by CHARLES MARWICK



AIDS
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1.

The attached draft, prepared in conjunction with has been seen and agreed by . If CMO is content;

2.

AIDS TESTING

I attach a draft reply to the Welsh Secretary's letter of 18 October. It also disposes of a related point raised in paragraph 4 of his letter of 8 October.

2. The reaction of Mr Edwards is understandable. He has been shown the draft report of the evaluation in the BTS of two screening tests. The purpose of the evaluation was to look hard for problems. As expected it found some. The report is a highly technical document needing expert interpretation. A group of experts examined the findings. The Welsh Office were represented on this group. The group were able to put the problems found in their proper context. They had no hesitation in recommending the general use of these tests. The performance of the tests since introduction has been monitored. Experience to date suggests they are satisfactory.

3. A fairly robust response is proposed. The introduction of a screening test, after a rigorous two stage evaluation, is one of the Government's most notable achievements in response to the challenge of AIDS. It is highly undesirable that another member of the Government should have such a negative perception of this achievement. Private attitudes can easily become reflected in the tone, if not the content, of public statements and correspondence. Damning the test by faint praise could lead to the very failure in public confidence which Mr Edwards wishes to avoid.

HS1
1209 HAN H
X. GRO-C

31 October 1985

Copies to:

15B

DRAFT REPLY TO SECRETARY OF STATE FOR WALES

Thank you for your letter of 18 October.

I am concerned that you have obtained from your officials such a negative impression of the Government's achievements in this area. This is the more surprising since your officials have participated fully in the forums which gave us the medical and scientific advice on which our policy has been based.

Perhaps the most worrying misconception is the statement "unreliable testing is better than no testing at all". This is the complete opposite of our thinking. We have based policy on the firm conviction that unreliable testing would be disasterous and would engender a false sense of security. This was the reason why we delayed the introduction of screening until we were satisfied that the tests to be used were sufficiently reliable. To achieve this objective the tests now in use have been subjected to a rigorous two stage evaluation, which to our knowledge surpasses what has been done elsewhere. The first step of the evaluation, which was carried out on a limited number of sera, identified 2 diagnostic kits particularly suitable for use in the BTS. The trials of these 2 kits carried out in the BTS was on a much larger scale and gave us a very clear indication of how the tests would perform in the field.

The first draft of the report of this evaluation did of course identify problems. This was the whole point of the exercise. The reasons for the apparent failures to which you draw attention were by no means clear cut and more work is being done to pinpoint the cause. The evaluation results were considered in detail by an "ad hoc panel" of leading experts (on which Welsh Office were represented). They had no hesitation in agreeing that routine testing of all blood donations should start, using these two test kits.

You mention the problems of quality control. Both manufacturers were called to meetings with officials and after lengthy discussions officials were satisfied with the assurances given. In addition a visit was made to Wellcome's premises. This was not a full quality audit. However nothing was found to alter our views on their ability to routinely produce satisfactory kits. In fact officials felt that the procedures used were good. The difficulties of ensuring that no batch variation occurs in such tests can perhaps be best illustrated by the fact that two other manufacturers (Abbott and ENI) had to substitute fresh batches for the ones initially supplied to the PHLS for their evaluation since these had proved faulty. We are not of course depending solely on assurances from the manufacturers. The performance of kits in the NBTS is being closely monitored and comparative data collected. Furthermore the PHLS have supplied quality control sera to Transfusion Centres so that they can be used as a daily independent assessment of the kits performance. (You were advocating some such approach in paragraph 4 of your letter of 8 October.) A number of centres have been using the test for a few weeks. Data has not yet been quantified but preliminary indications suggest that the kits are satisfactory.

You raise the issue of the evaluation of other tests. It has never been an objective to establish a general scheme for testing all available kits in order to "approve" them. Evaluation is a very expensive business. We had the narrower objective of identifying one or two tests which could be used confidently by the NHS. This we have achieved. It is not our intention to do more formal evaluations in the BTS until tests become available which appear to offer significant additional advantages. However we are funding the PHLS both this year and next to carry out evaluations. When appropriate we shall ask them to look at specific kits. (Several "Mark II" tests are known to be in preparation.) The "JAMA" article to which you drew my attention is not a full evaluation report. It concentrates solely on the level of positives and how many of these are "true" positives. It is however completely silent on the crucial issue of how many positives are missed ie the number of "false negatives".

I apologise for replying at such length. However the introduction of mass screening of blood donations is a significant achievement for the Government in its fight against AIDS. It is important that within Government misunderstandings do not detract from this achievement.

NORMAN FOWLER

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NORMAN FOWLER

PERSONAL AND CONFIDENTIAL

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Pse let me see a draft [illegible] SofS [illegible] analyses the reply [illegible]

DEPARTMENT OF HEALTH & SOCIAL SECURITY

Alexander Fleming House, Elephant & Castle, London SE1 6BY

Telephone 01-407 5522

From the Secretary of State for Social Services

GRO-C

The Rt Hon Nicholas Edwards MP
Secretary of State for Wales

November 15

Dear Nick..

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

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