THIS WEEK

AIDS test found suspect in African trials

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THE first quick test approved in the US for detecting the AIDS virus in blood came fourth out of five such tests assessed for their sensitivity in 1987 and 1988. The maker of the test, Cambridge BioScience in Worcester, Massachusetts, disputes the results, however, arguing that the tests were not run properly.

According to scientists who reviewed the tests during field trials in Kinshasa, Zaire, the version of the quick test offered by Cambridge BioScience showed a sensitivity for the human immunodeficiency virus in blood samples of 86 per cent. That means that if 100 samples of infected blood are tested, 14 will slip through as "false negatives"—seemingly free of the virus.

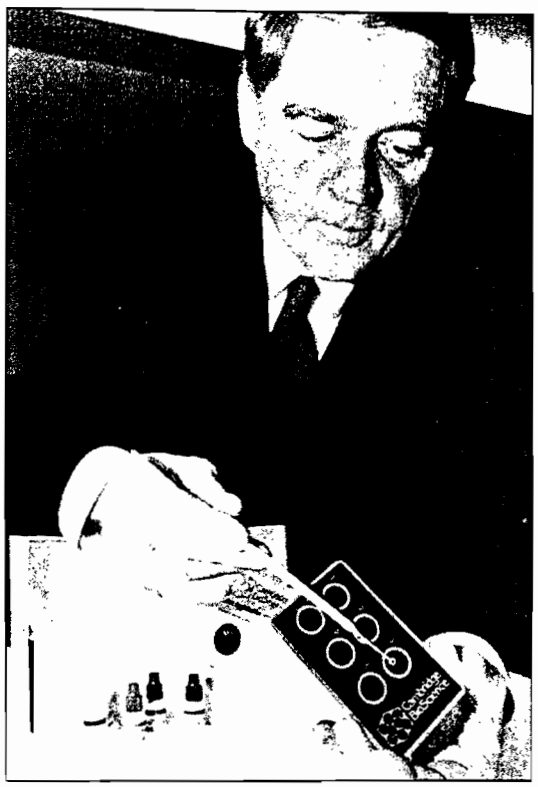
Jeff Harris, who is assessing HIV test kits for the US Agency for International Development, which provides aid to developing countries, says all but one other test kit tried in Kinshasa performed far better.

Last month, the Food and Drug Administration approved Cambridge BioScience's kit (This Week, last issue), the first quick test cleared for public sale in the US. At the time, the company said its test was accurate more than 99 per cent of the time. The FDA reviewed the data from Kinshasa, says a spokesman for the agency, but dismissed them as results from a product "in development" rather than from the final version.

Governments and pharmaceutical companies are vying to produce a quick and easy test for the human immunodeficiency virus (HIV). One large market is likely to be developing countries that lack the money, training and equipment to use the standard ELISA and Western blot procedures.

Scientists at the Program for Appropriate Technology in Health (PATH) in Seattle, Washington, carried out the trials in Kinshasa from October 1987 to spring 1988. Besides Cambridge BioScience's kit, PATH tested kits from Du Pont, Fuji Rebio of Japan, Salck Industry of Brazil, and the University of California at Davis.

Du Pont's test performed at a sensitivity of more than 99 per cent. Checks using the most accurate test, the Western blot, revealed that it missed less than 1 per cent of positive samples. Fuji Rebio's test also scored 99 per cent, while the test from Davis scored 92 per cent. The Brazilian test scored 85 per cent, and Cambridge BioScience's kit came in at 86 per cent.



Buck insists his test has a 99-per-cent success rate

"In clinical practices, the difference between 99 per cent and 86 per cent is a big deal," says Harris. If a test that scored accurately 86 per cent of the time were used to screen blood supplies, adds Milton Tam, a biologist with PATH, "that would worry me". Moreover, Harris told *New Scientist*: "All our conditions [in Kinshasa] were more controlled than they are going to be in most labs in the Third World."

The Cambridge test involves adding a small blood sample to a card coated with microscopic latex beads. The beads are covered with proteins from HIV. If, after about five minutes, the samples start to clump, the blood is infected. "If you have a room with relatively low humidity, you'll find that these drops dry out on the edges, and you might see some clumps that you should exclude," says Tam, who has performed the test. Sometimes the clumping is "very subtle".

Gerald Buck, chief executive of Cambridge BioScience, says that in trials at American hospitals and laboratories, its test performed at sensitivities above 99 per cent. Moreover, other trials in Africa run by Thomas Quinn of Johns Hopkins University scored in the "98-per-cent range".

Buck says that the PATH team failed to follow the directions for performing the tests that are included with the kit. "Each card has a spot for a negative control and a positive control," he explains. The negative control is known to be free of virus, while the positive does contain virus. Four samples of blood are added to other spots on the card and the results are compared with the controls.

Scientists from Cambridge BioScience have reviewed PATH's data. PATH's technicians, says Buck, sometimes lined up four to six cards at a time, assessing 24 to 36 samples with only one or no controls for the lot. He adds that all tests for HIV involve some skill in interpreting results.

Both Harris and Tam agree that quick tests such as Cambridge BioScience's are a welcome development to testing in developing countries. In many places, they said, 86 per cent is better than having no test at all. Tests should also be quick: often blood is drawn on the spot at a transfusion centre and cannot be kept for more than an hour or two.

Du Pont's test, however, takes about as long as Cambridge BioScience's test, from one to two minutes, says Tam. Furthermore, it is more "objective", requiring less judgment and less training to read the results. "I think one or two weeks' training would be necessary" to read skilfully the results of Cambridge BioScience's test, known as Recombigen, Tam says, "and you need experience and a little bit of talent". But Rod Raynovich, vice president of Cambridge BioScience, told *New Scientist* that "anyone can be trained" to perform the test in two hours.

Du Pont has been selling its test, HIVCheck, in Europe, Africa and South America. The company has not applied to the FDA for approval in the US, says Ken Koziak, HIVCheck's product manager at Du Pont. Physicians told the company that they were not enthusiastic about delivering results to patients within five minutes. Hospitals test blood in large batches using the ELISA method and do not need quick tests, says Koziak. □