

INTERIM REPORT TO MR. DAVID KENNEDY, DISS ON:-

THE 'KARPAS AIDS CELL TEST KIT' (Puji Chemical Industries Ltd).

This kit was evaluated on 3, 4 June, 1986 using a panel of 98 sera (defined in a previous report).

The results of the evaluator can be briefly summarised as follows:-

- 1) The thirty normal blood donors' sera gave negative results.
- 2) One of the twenty potentially false positive sera gave an equivocal result (repeats also equivocal); the remainder were negative.
- 3) One of the fifteen weakly anti HIV positive sera was negative on th initial test run (repeat was positive); the remainder were positive
- 4) All strongly anti HIV positive sera were clearly positive.
- 5) The series of dilutions showed that this test was able to detect antibodies in 1:200 and 1:400 dilutions of one anti HIV positive serum, but did not give good positive signals for dilutions of two other positive sera.

The results suggest that very low levels of HIV 1 antibody are not detected by this test. The sensitivity of this test is similar to that of Organon and superior to that of the Dipstick and Olympus tests.

COMMENT

The Karpas test is rapid and straightforward, and the only equipment needed for it is a domestic refrigerator and a bench microscope.

In the evaluator's hands the test was specific (one false positive result only) and, apart from tests on high dilution of positive sera, fairly sensitive (one false negative). However, when another worker read the

slides he gave seven false positive results and two false negative ones, suggesting that in the hands of a less experienced reader of cell-based tests the assay would be less specific.

In the instructions for the test (pink version) for the test the description of the washing procedure was loose. The test might possibly perform better if several washes rather than a single wash were used.

A separate 'confirmatory' test is available which is based on slides to which uninfected as well as infected cells are fixed. These slides would be needed to investigate positive reactions, both true positives and those due either to non specific effects or to reader error. An inexperienced worker would often need to use these slides. It is, perhaps, incorrect to refer to this as a 'confirmatory test' - this is an epithet usually applied to an assay with a different methodology used to investigate positive findings in a screening test. Any positive reactions 'confirmed' by the Karpas test ought if possible be tested by a different method before a positive report is given.

Finally, the instructions suggest that specimens containing anti HIV 2 may react in this assay; however slides to which HIV 2 infected cells have been fixed would obviously be preferable and might be made available.

Dr. Gary Bayliss

Dr. Philip Mortimer

8th June, 1987

copy to Mr. Wickland (WHO, Geneva)

Dr. Karpas (Cambridge)