WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

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Prière de rappeler la référence :

TO WHOM IT MAY CONCERN

The RED DOT HIV-1&2 (Cal-Test Diagnostics; distributed by Catalina) has been evaluated by WHO in the fourth quarter of 1994. From this evaluation we made the following conclusions:

The RED DOT HIV-1&2 is a dot immunoassay test for the detection of antibodies to HIV 1 and 2. A volume of 25 µl of serum or plasma is required to perform the test. The test is very easy to perform and does not require sophisticated equipment. Reading of the results can be done visually. This type of assay can be performed in laboratories with limited facilities.

In this limited evaluation on a panel of 600 samples from different origin (African, Asian, European, Latin American), including HIV-1 and HIV-2 positive specimens we found a sensitivity (95% CL) of 100% (99.89% - 100.0%) and a final specificity (95% CL) of 94.88% (92.51% - 97.25%). In this study, 1.8% of the results were recorded as indeterminate.

Results were interpreted independently by three technicians, the inter-reader variability was 9.5%.

In addition, 8 commercially available seroconversion panels (BBI) were screened with the RED DOT HIV-1&2. The RED DOT HIV-1&2 became positive, on average, 0.6 days later than the reference test (Abbott HIV-1/HIV-2 3rd gen EIA).

The detailed data of this evaluation will be published in the WHO report 10 of the Operational characteristic of commercially available assays to detect antibodies to HIV-1 and/or HIV-2 in human sera.

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