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Track 1; Category C

Enhanced HIV diagnostic sensitivity and detection of acute HIV infection in high risk populations using SMARTube technology.

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Background: The efficacy of HIV testing is reduced by the seronegative window period (WP), since during that time infected individuals test negative by the current HIV antibody tests. New infections are only a small fraction of the total HIV positive population, yet these are the most critical to identify as they are the most infectious. Identifying them is important in the effort to curtail the epidemic.

Methods: The SMARTube is designed to overcome, in-vitro, the immune suppression which causes the window period in-vivo, thus enabling, during a short incubation of 1ml whole blood, the production of antibodies to detectable levels in the current antibody assays (e.g. EIA, rapid tests). Thus an infected person, during the seronegative WP, will test positive, in the routine laboratory, using SMARTplasma (the supernatant in the SMARTube after the incubation) as the sample with local kits and testing algorithms. High risk populations, from both South Africa (SA) and USA were tested.

Results: Blood was collected from high risk individuals in USA and in South Africa (602 and 1137 respectively), and their plasma and SMARTplasma pairs were tested for HIV antibodies using Rapid and EIA tests. All plasma positive samples were also positive using SMARTplasma (75 and 240 respectively). One WP (1.3%) sample was found in the USA, and three (2.1%) in the SA population. Further studies of these individuals included western blot and PCR, confirming the early diagnosis using SMARTplasma. Follow-up study in SA detected additional two WP samples and showed seroconversion after 1-4 months of four of them (one not followed up).

Conclusions: Using the SMARTube blood pre-treatment step enables the detection of HIV infected individuals, using the available antibody assays, weeks and months prior to seroconversion. This increase in the testing efficacy, is simple to achieve and critical for identifying the most infectious individuals.