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Using the Stimulation Index (SI) of the SMARTube™HIV&HCV to identify recent infections and high incidence populations

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***Background*:** the last three years have ushered a fundamental change to the future handling of both the HIV and the HCV epidemics. In HIV the "Test & Treat" program has clearly established that treating all those infected with HIV, and especially those in the early days of infection, is beneficial for both the patient and society. In HCV, the new drugs, with a shorter duration of treatment, and less toxicity, can enable early treatment in HCV. The high prevalence, especially among the new HCV infections, of co-infection with HIV, and the shared risk factors in some populations, point to a need to identify the populations with high incidence of HIV and HCV infections. Identifying the populations with a high rate of transmission, and measuring their incidence rates, are important both for identifying populations for treatment (e.g. early infections) and for monitoring the efficacy of the treatment (e.g. prevention (HIV), and clearance (HCV)). Currently there are neither good tools for measuring incidence of HIV (or of HCV), nor for differentiating between recent and non-recent infections.

***Methods*:** Blood was collected from high risk populations in the USA, China, Turkey, and Kenya, transferred to the laboratory at room temperature, and one ml of whole blood was incubated in the SMARTube; plasma was kept from the remaining blood. After the incubation, the supernatant (SMARTplasma) was collected and the paired plasma and SMARTplasma were tested for HIV antibodies using ELISA. The ratio of antibody levels in the SMARTplasma versus in the plasma was determined as the SI for that sample. Based on the humoral immune response during HIV infection, it was expected that the SI will decrease over time, starting >1.0 at seroconversion, remaining at ~1.0 during most of the infection, and decreasing to <1.0 as the immune system deteriorates at late stages of HIV infection. In HCV, the SI is expected to be <1.0 only when the infection is cleared (spontaneously or via treatment).

***Results*:** Based on the SI, HIV infected individuals/samples could be divided into four groups. Three among the seropositives: SI>1.0, for recent seroconversions; SI~1.0, for non-recent infections; and SI<1.0, for late stage of HIV infection. A fourth group included those with SI=∞, representing those in the WP, i.e. infected yet still seronegative. The ratios of the different SI sub-groups, for both HIV and HCV, varied among the various populations and countries. Thus an epidemiological picture could be obtained, by the distribution of the SI in a cross sectional survey.

***Conclusion*:** The ability to detect persons, infected with HIV and/or HCV, who are in the WP, and to identify recent infections in seropositive individuals, provides a tool for identifying populations with high incidence, and for targeting appropriate treatment(s) to early/recent infections.