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Early diagnosis of HCV infection, a double challenge in a coinfection with HIV, enabled by using SMARTube(TM) HIV&HCV

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***Background*:** The HIV and hepatitis C (HCV) epidemics are major public health concerns. While antiretroviral therapy options have markedly improved, the early diagnosis is still a challenge, due to the phenomenon of the seronegative window period (WP), with a duration of as long as several months from infection to seroconversion. An HIV/ HCV co-infections faces significantly increased diagnostic complications due to the immune suppression caused by those viruses. Thus, an HIV infection makes a person more susceptible to contracting HCV, while at the same time it could cause false negative results in HCV antibody tests, due to the reduced ability to produce antibodies, which also could lead to WP prolongation. An innovative technology – Stimmunology™ (ST) was developed to overcome the WP challenge and enable the detection of antibodies prior to seroconversion. Addition of the Stimmunology step, via the SMARTube™ HIV&HCV blood pretreatment device, to routine antibody testing, promotes the *in vitro* stimulation of HCV and/or HIV lymphocytes, primed *in vivo*, with concomitant enhancement of HIV/HCV specific antibodies synthesis, bringing them to detectable levels.

Methods: 5888 blood samples (mostly unlinked) were tested for anti-HCV and anti-HIV antibodies before (plasma), and after, SMARTube pre-treatment (SMARTplasma), at 37ºC, with 5% CO_2. Samples were collected in Russia, Israel, Kenya, China, Turkey, Hungary and Romania. The efficacy of the SMARTube was measured by comparing antibody levels, in parallel samples of plasma and SMARTplasma.

Results: Among the 5888 samples tested for HCV, 641 were HCV seropositive by routine serology testing, and all were positive in SMARTplasma too. In the high risk populations (HRG), 16% (Russia) - 61% (China) of HCV infected individuals were co-infected with HIV. Among the HRG, the SMARTube enabled the diagnosis of 10 additional HCV infected, who were still seronegative, i.e. in the WP. Most of the additional positives were detected among individuals who had a suspected, high risk, exposure 1-3 weeks prior to testing. While increasing diagnostic sensitivity for HCV, using SMARTplasma reduced the false positive results by as high as 100%. (This is of importance especially in low risk groups were false positive rates can reach >60% of all HCV-reactive results).

Conclusions: Stimmunology implementation leads to early detection of infected individuals, before seroconversion, and provides possibility for earlier (within days of infection) and more effective HCV treatment. While increasing diagnostic sensitivity; it also reduces the false positive rate, rendering all initial antibody results more true, both positive and negative. As a result, SMARTube based diagnosis can be applicable for changing the way we diagnose and treat both the infected individuals and the epidemic as a whole.