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# Early Detection

A NEW BLOOD PRETREATMENT DEVICE MAY SMARTEN UP HIV AND HCV PREVENTION & TREATMENT

by Chael Needle

**E**arly detection of HIV and HCV offers individuals who are positive the opportunity to make decisions about their treatment and care that may often increase their chances to live longer and live better than those whose virus has progressed undetected. Established testing, however, still relies on a built-in delay because it must wait for antibodies to appear, a “window period” that can last anywhere from thirty to ninety days for HIV and eighty to 180 days for HCV from initial infection. (Rapid oral testing only shortens the testing turnaround time.) A new testing platform called SMART Technology, developed by SMART Biotech, promises to shut this window.

Part of this platform, SMARTube is a newly developed and unique early detection assay that enhances the levels of antibodies in a blood sample, making them detectable earlier than other established antibody assays. The presence of HIV and HCV can be detected within three to five days with SMARTube, which relies on a process called Stimmunology that involves initial immune priming.

“The virus is recognized by the immune cells as soon as it enters the body—priming the HIV-specific cells,” explains Tamar Jehuda-Cohen, PhD, CTO of SMART-Biotech. “However, the virus inhibits the immune response against it, silencing the primed cells and inhibiting them from developing into antibody producing cells. Thus, the ‘window period’ is a time when the immune system is inhibited from

making antibodies against the virus. It is as if the virus silences—gags—the immune cells from shouting against it.” A blood sample is taken and treated with a formulation based on Stimmunology, which stimulates the immune cells in vitro so that they are able to overcome this immune suppression and become active antibody-producing cells. Five days of incubation produces detectable levels of these antibodies. Explains Jehuda-

Cohen: “The primed cells, which saw the HIV and/or HCV in the body, are now un-gagged and are provided a megaphone to declare the presence of the virus loud and clear, that is, to make antibodies against it.”

SMART Biotech focused on HIV and HCV as a bundled technology because “both HIV and HCV are deadly epidemics. Both are diagnosed using antibodies (the virus is not consistently in the blood at detectable levels, especially not in the early days of the infection). Both have a very long ‘window period,’ leading to missed infections, especially in the most critical stage of the infection...,” shares Jehuda-Cohen.

“We started our research in the HIV epidemic. Then we realized that the ‘window period,’ and its personal, social, public health, and epidemiological implications were not unique to HIV, and that there is another silent epidemic—HCV—that infects eight times more people and kills at least as many as does HIV. The two applications were bundled due to the fact that both are transmitted by blood and there seems to be a high rate of coinfections of HIV and HCV in some [high risk] populations.”

Including SMARTube as part of the detection of HIV/HCV and the fight against AIDS in general first and foremost saves lives, says Jehuda-Cohen. “For example, the life of twenty-nine out of thirty babies can be saved by a short term ARV treatment [being given] to the pregnant mother. [But] the treatment is offered based on a positive HIV antibody test. All those mothers infected with HIV who are still in the window period at the possibly one time they are tested



during pregnancy will not be offered ARV, and their babies are at the highest risk of acquiring the HIV infection. Since the window period in pregnancy is longer, due to a general immune suppression to keep the fetus, the risk of testing negative in spite of being infected, and thus miss the chance for life-saving ARV is even higher.”

SMARTube could also improve the efficacy of prevention programs. He shares: “On both a personal and a public health level—the success of ‘test and treat’ programs for HIV is much dependent on the earliest possible diagnosis.

“On a personal level, the window period is a time of multiplied worry, in which the uncertainty of the accuracy of the diagnosis can cause more worry than the diagnosis itself. Using SMARTube eliminates this additional worry because [the accuracy of the diagnosis is more reliable than other tests].”

SMARTube is commercially available in some European and African countries, and under investigation in the U.S. SMART Biotech is currently dialoguing with the FDA, with the goal to bring it to this market as quickly as possible.

Chael Needle wrote about the ability of surfen to inhibit the infectivity of HIV in the February issue.

ILLUSTRATIONS BY TIMOTHY J. HAINES