



# Mobile Units

AN HCV RAPID TEST CANDIDATE MAY HELP EMERGENCY BATTLEFIELD HEALTHCARE AND BEYOND

by Chael Needle

**A**n evaluation by the Walter Reed Army Institute of Research of the still-in-development OraQuick HCV Test found that it had higher sensitivity (99.4 percent) than and highest specificity (99.7 percent) of other hepatitis C tests evaluated. The OraQuick HCV Test detected HCV antibodies approximately three days sooner than available laboratory-based enzyme immunoassays and approximately sixteen days earlier than the next most sensitive rapid HCV test, the evaluation indicated. In the end, the OraQuick HCV test was selected as the preferred test based on all facets of the evaluation.

“The impetus for the evaluation came from Walter Reed, who was very interested in the potential use of the test and its application for use in theaters of war,” says Ron Ticho, vice president of marketing and communications at OraSure Technologies, which is developing the test. Blood that is donated to commercial or hospital blood banks is subjected to extensive testing for various blood-borne pathogens before it can be released for use in transfusions. Emergency battlefield conditions dictate that soldiers who do not need medical attention, or Walking Blood Bank Donors, as the military calls them, can donate on the spot, without necessarily the normal safety precautions.

The test, which can be used with blood and oral fluids, shares the same technology platform as OraSure Technologies’ FDA-approved OraQuick HIV Test, which relies on oral fluid collection to test for HIV-1 and HIV-2 antibodies. The OraQuick HCV Test is not yet approved by the FDA, but OraSure Technologies is soon submitting results of completed clinical trials to obtain FDA approval for the test utilizing multiple specimen types including oral fluid, finger-stick and venous whole blood, plasma, and serum.

Of course, the test could impact the treatment and care of those of us who don’t wear fatigues. Early detection of hepatitis C (HCV) is arguably

as important as the early detection of HIV, especially when coinfection of the two viruses often go hand in hand. Although a vaccine exists for hepatitis A and B, one for hepatitis C does not. Early detection and treatment could have a positive impact on the sometimes fatal liver damage that hepatitis C infection causes.

One benefit of the rapid test “is that you are able to immediately learn your HCV status and have access to treatment right away if necessary...There is a very high percentage of individuals who will get screened or tested but, especially in public health settings, never come back for their results,” says Ticho about the impact the test may have on current testing limitations. “And it certainly will provide a testing opportunity for a number of high-risk populations. Hepatitis C is a critical disease state that individuals who have HIV need to know about.”

OraSure currently markets its HIV test by working with community partners to promote rapid testing. “We are especially active during all of the National HIV Awareness Days as well as National HIV Testing Day! This past year we were able to get the commitment of over seventy mayors across the country to encourage and promote testing. Many of the mayors actually got tested for HIV and launched major initiatives for others in their cities to get screened for HIV,” says Ticho about the general effort to make HIV screenings as commonplace as other screenings. “Without the support from the National Black Leadership on AIDS and the Latino Commission on AIDS, and from truly the entire AIDS-affected community in the United States, I don’t think as many people would be stepping forward to get tested and get screened for HIV.”

Asked what kind of impact OraQuick’s HIV test, the only saliva-based rapid test available in the U.S., has had on the AIDS community, Ticho mentions that the test is useful in patients who may be needle-phobic, as well as in settings



**At the National Latino AIDS Awareness Day kickoff in NYC, Miss Universe (Dayana Mendoza) swabs her mouth with the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test.**

where taking a blood sample is not easy and in settings beyond traditional health-care sites. Significantly, “prior to the introduction of our test, more than a third of all patients who came into public health settings to get screened for HIV never returned for their results. Thousands upon thousands of positive test results were never communicated to the individuals,” notes Ticho. “This made it very difficult for counselors and health-care providers, who were spending a majority of their time trying to track down individuals as opposed to being able to give them the results right there on the spot and get those who needed treatment into treatment right away. Greater than 99.8 percent of the time, patients are now getting their results, and they are able to act upon those results right away. We do feel that our test has helped get people get diagnosed sooner rather than later. The sooner you know about your HIV status the greater the chances are that you will live a longer and healthier life because of the treatment that is available and the ability to know that you need to monitor your healthcare.”

Chael Needle wrote about a new delivery technology for DNA-based HIV vaccine candidates in the October issue.

PHOTO COURTESY LATINO COMMISSION ON AIDS

[ TREATMENT HORIZONS ]