# FDA clears new IMMY and University of Nevada, Reno life-saving blood test

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The Food and Drug Administration has cleared a new diagnostic test that will help save the lives of hundreds of thousands of AIDS patients stricken with cryptococcosis, a fungal meningitis. The test was developed through a collaboration between Tom Kozel, professor of microbiology of the University of Nevada School of Medicine, and Sean Bauman, president and CEO of IMMY (Immuno-Mycologics) of Oklahoma.

The new, rapid blood test known as the CrAg Lateral Flow Assay leads to early diagnosis of cryptococcosis, a leading cause of AIDS-related deaths in developing countries, by detecting the cryptoccocal antigen. Using an antibody developed by Kozel, the point-of-care product is a simple dipstick test requiring no equipment.

"Our goal is to save lives," said Bauman. "With the CrAg Lateral Flow Assay, a health-care provider can give the test, observe the results, and administer the first dose of oral medication, all within a few minutes…resulting in a life that has truly been changed for the better."

Current diagnostic tests for cryptococcosis are effective, but are not suitable for resource-limited settings. The tests require technical expertise, special laboratory equipment, and refrigeration for storage. All of these elements are difficult to come by for a rural clinic in a resource-limited country that lacks reliable electricity and proper infrastructure.

Kozel, who has been conducting AIDS research for more than 25 years, said studies have shown that early identification and treatment is essential to beat the disease; a late diagnosis means antifungal therapy will likely fail in resource-limited countries. Most patients in that setting are not diagnosed until they are very sick, and then it's too late.

The United States' Center for Disease Control and Prevention has published a fact sheet and established a "call to action" goal of having half of all AIDS clinics in Africa and Asia equipped by 2015 to do the testing and treatment. They estimate 50,000 to 100,000 lives will be saved every year.

The antibody used for the Cryptococcus test was developed in the lab at the Reno campus with grants from the National Institutes of Health. Bauman commercialized the technology to make it available at low cost to patients in developing countries with a licensing agreement established through the University of Nevada, Reno's Technology Transfer Office.

The IMMY product is now available in South Africa, Kenya and Uganda, and this FDA approval makes it available globally.

Provided by University of Nevada, Reno