First test to detect Zika in blood donations approved

October 9 2017

(HealthDay)—The cobas Zika test has been approved by the U.S. Food

and Drug Administration—the first approved screening test to detect the Zika virus in blood donations.

The test is not designed to diagnose any particular individual's Zika infection, however, the FDA said.

In August 2016, the agency recommended that all U.S. states and territories screen blood for Zika, according to an FDA media release. "Screening blood donations for the Zika virus is critical to preventing infected donations from entering the U.S. blood supply," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research.

Some blood-collection centers had already been using the cobas test in order to comply with the 2016 edict. Data collected from this testing, in tandem with additional information provided by the test's manufacturer, were used to approve the diagnostic, the FDA said. The test has a specificity of more than 99 percent.

The cobas test is produced by Roche Molecular Systems, based in Pleasanton, California.

More information: More Information

Health News