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Roche to initiate testing for Zika virus at US Blood Centres

01 April 2016 | News | By BioSpectrum Bureau

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Roche has announced that the US Food and Drug Administration (US FDA) has provided approval to initiate collection and testing of blood samples for screening with the cobas Zika assay under an Investigational New Drug Application (IND) protocol. The cobas Zika test for use with the cobas 6800/8800 Systems, is a qualitative in vitro nucleic acid screening test for the direct detection of Zika virus RNA in plasma specimens from individual human blood donors.

"The cobas Zika test has been specifically designed utilising the generic cobas omni Utility Channel on the cobas 6800/8800 Systems. These fully-automated high-volume systems provide solutions for blood services to detect the virus and ensure that potentially infected blood units are not made available for transfusion" said Mr Roland Diggelmann, COO Roche Diagnostics.

He added, "As a leader in diagnostics, Roche is committed to providing testing solutions for the world's most challenging healthcare emergencies. With the collaboration of the FDA on this IND, we are able to further expand our commitment to help keep the blood supply safe."

Initially, the cobas Zika test will be deployed to screen blood donations collected locally in Puerto Rico. It is expected that this testing will enable the reinstatement of the blood services in Puerto Rico and reduce the reliance of blood importation from other areas in the United States.

The second stage of deployment for the cobas Zika test will be to prepare for screening of blood donations collected by blood services in the southern United States, which will most likely be impacted by any spread in the virus.

Roche continues to work with regulators around the world to determine the path forward to implement the cobas Zika test for blood screening.