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Roche to initiate testing for Zika virus at U.S. Blood Centres under FDA Investigational New Drug Application protocol

*New **cobas**® Zika test will screen blood samples on the **cobas**® 6800/8800 Systems*

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (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 Roland Diggelmann, COO Roche Diagnostics. “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.

About the **cobas® Zika test**

Manufactured by Roche, the **cobas**® Zika test is based on fully automated sample preparation (nucleic acid extraction and purification) followed by PCR amplification and detection. The **cobas**® 6800/8800 Systems consist of the sample supply module, the transfer module, the processing module and the analytic module. Automated data management is performed by the **cobas**® 6800/8800 software which assigns test results for all tests as non-reactive, reactive, or invalid.

About IND Status

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA for use under a specific protocol by US Blood screening laboratories.
- All Testing Laboratories will need to be enrolled in and contracted into the clinical trial as specified and agreed with the FDA Center for Biologics Evaluation and Research.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in *in vitro* diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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