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FDA approves Roche cobas Zika as first commercially-available donor screening test for Zika virus

- **Zika virus infection is linked to neurological complications in adults, and brain defects in fetuses and newborn infants**
- **cobas Zika complements efforts to prevent the spread of Zika virus through blood donations in the U.S.**
- **cobas Zika expands Roche's industry-leading donor screening portfolio for blood-borne diseases**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received approval from the U.S. Food and Drug Administration (FDA) for the cobas® Zika test for use on the cobas 6800/8800 Systems.
The cobas Zika test is the first commercially available test for the detection of the Zika virus RNA in samples of human plasma intended for use in screening blood donations.

This approval marks an important milestone in the effort to protect the blood supply from Zika virus in the U.S. The newly approved cobas Zika test can now be used alongside other routine tests for the screening of blood and plasma donations in the United States.

"As the world's leading in-vitro diagnostics company, Roche is very proud to offer an expanding menu of solutions to protect the blood supply from emerging threats such as Zika," said Roland Diggelmann, Chief Executive Officer, Roche Diagnostics. "Since its development here at Roche, the cobas Zika test has been used under the Investigational New Drug Application (IND) protocol to screen more than 4 million blood donations from the United States and Puerto Rico. This broad testing has helped to identify and remove over 450 potentially infectious donations from the blood supply, a significant achievement in the rapid response to this global health emergency."

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Roche deployed the cobas Zika test in April of 2016 under the FDA's IND Protocol to screen blood donations collected in Puerto Rico. This initial testing protocol enabled the reinstatement of the blood services in Puerto Rico after concerns over the high rates of infection locally posed a significant threat to the blood supply. By the end of 2016, expanded deployment for the cobas Zika test supported donor screening efforts throughout the United States and Puerto Rico.

About the cobas Zika test

Manufactured by Roche, 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 is the newest addition to the testing menu for the cobas 6800/8800 Systems. These fully-automated, high-volume systems perform automated sample preparation (nucleic acid extraction and purification), followed by PCR amplification and detection. Automated data management is performed by the cobas 6800/8800 software, which assigns a test result for each test as non-reactive, reactive, or invalid. Together with the cobas 6800/8800 Systems, the cobas Zika test provides solutions for blood services to detect Zika virus and ensure that potentially infected blood units are not made available for transfusion.

About the Zika Virus

The Zika virus belongs to the Flaviviridae family of viruses, which includes dengue, yellow fever, Japanese encephalitis and West Nile viruses. Zika is mainly spread by the bite of infected mosquitoes; however, transmission through sexual intercourse and from pregnant mothers to fetuses has also been documented.[1] A growing body of evidence confirms the links between Zika virus infection and defects in fetuses and newborns, as well as neurological complications in children and adults.[2] Similar to other viruses in the Flaviviridae family, such as West Nile Virus, it is suspected that infected donor blood used for transfusions could serve as an additional transmission route for Zika virus.[3]

About Roche

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

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. Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty 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 nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 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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