

Pleasanton, 14 May 2018

## FDA approves additional claim for Roche cobas Zika test

- **New claim allows for streamlined screening of pooled blood or plasma donations**
- **Approved claim follows updated industry recommendations for screening the US blood supply for Zika virus**
- **Zika virus infection is linked to neurological complications in adults, and brain defects in fetuses and newborn infants**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today FDA approval of an additional claim for the **cobas**<sup>®</sup> Zika test for use on the **cobas**<sup>®</sup> 6800/8800 Systems. The newly approved claim allows for the streamlined screening of multiple individual blood or plasma donations that have been pooled together.

The new claim follows the screening recommendations made at the December 1, 2017 meeting of the Blood Products Advisory Committee (BPAC), an appointed group of key medical & scientific advisors to the FDA. In addition to supporting the most recent BPAC recommendations, the extended claims for **cobas**<sup>®</sup> Zika facilitate a simplified testing workflow for blood screening laboratories utilizing the **cobas**<sup>®</sup> 6800/8800 Systems with the **cobas**<sup>®</sup> Synergy software solution in the United States.

“More than 6 million blood donations from the United States and Puerto Rico have been screened with the **cobas**<sup>®</sup> Zika test since its initial release under the Investigational New Drug Application (IND) protocol in 2016 and subsequent commercial approval in 2017,” said Uwe Oberlaender, Head of Roche Molecular Diagnostics. “Roche is pleased to offer additional screening options that support BPAC recommendations for the US market.”

Roche deployed the **cobas**<sup>®</sup> 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. The **cobas**<sup>®</sup> Zika test received commercial approval from the FDA in October of 2017, enabling routine use of the **cobas**<sup>®</sup> Zika test to support individual donor screening efforts throughout Puerto Rico the continental United States.

### **About the cobas Zika test**

Manufactured by Roche, the cobas Zika test for use with the **cobas**® 6800/8800 Systems and **cobas**® Synergy software, 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 in the US market. These fully-automated, high-volume systems perform automated sample pooling, 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 primarily spread by the bite of infected mosquitoes; however, transmission through sexual intercourse and from pregnant mothers to fetuses has also been documented.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup>

### **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](http://www.roche.com).

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### **Additional information**

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### **References**

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<sup>1</sup> World Health Organization (WHO). Zika Virus Fact Sheet, <http://www.who.int/mediacentre/factsheets/zika> [Last accessed: September 2017].

<sup>2</sup> Rasmussen S.A., Jamieson, D.J., Honein, M.A., Petersen, L.R. Zika Virus and Birth Defects – Reviewing the Evidence for Causality. *New England Journal of Medicine* 2016;374:1981-7.

<sup>3</sup> Motta I.J., Spencer B.R., Cordeiro da Silva S.G., et al. Evidence for transmission of Zika virus by platelet transfusion. *New England Journal of Medicine* 2016;375:1101-3.