Media Release



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Roche announces availability of the LightMix Modular Zika Virus Assay (CE) in markets accepting the CE mark

Roche (SIX: RO, ROG; OTCQX: RHHBY) and TIB MOLBIOL, GmbH, announced today the availability of the **LightMix Modular Zika Virus Assay** (CE) in markets accepting the CE mark for patients with signs and symptoms of Zika virus infection living in affected areas where the Zika virus is known to be present. The test is used for the qualitative detection of Zika virus in plasma samples, and can be run on the large installed base of Roche's MagNA Pure 96 system for nucleic acid purification and LightCycler[®] 480 or **cobas z** 480 instruments for real-time PCR.

"The LightMix Modular Zika Virus Assay (CE) provides healthcare professionals an immediate option to detect the virus," said Uwe Oberlaender, Head of Roche Molecular Diagnostics. "As the worldwide leader in molecular diagnostics, Roche is committed to providing diagnostic solutions for the world's most challenging health emergencies."

"Our knowledge and expertise in both Real-Time PCR and detection of emerging pathogens have enabled us to quickly respond to this international public health issue," said Olfert Landt, CEO, TIB MOLBIOL. "The LightMix Modular Zika Virus Assay (CE) is an easy-to-use molecular diagnostic test and was developed and produced in our ISO 9001 and ISO 13485 certified manufacturing facilities." Roche is the exclusive distributor of this test and other LightMix Modular products.

In addition to the LightMix Modular Zika Virus Assay (CE), Roche has also developed the recently announced cobas[®] Zika test for use with the cobas[®] 6800/8800 Systems. This test has been approved by the United States Food and Drug Administration to initiate collection and testing of blood samples for screening under an Investigational New Drug Application (IND) protocol. It is currently being utilized in blood centres in the United States.

About the LightMix Modular Zika Virus Assay (CE)

Manufactured by TIB MOLBIOL GmbH and exclusively distributed by Roche, the LightMix Modular Zika Virus Assay (CE) can be used for the qualitative detection of Zika virus in combination with a full process RNA control monitoring efficient extraction to PCR result. The end-to-end process from sample preparation to results for 96 samples can be performed in just 2 hours. The test was developed to run on the LightCycler[®] 480 or the **cobas z** 480 qPCR instruments, allowing the response to be most effective through utilization of a broad installed instrument base.

About TIB MOLBIOL, GmbH

Since 1990, TIB MOLBIOL has been providing high quality products used in the fields of life science research, medical diagnostics, product quality assessment and environmental analysis. Head Quartered in Berlin, Germany, TIB MOLBIOL has offices and production facilities in the USA, Italy, Spain and Poland. The company's presence in several countries has facilitated the support and cooperation with its customers and increased its potential to quickly respond to critical biological threats such as Ebola, SARS, Anthrax, Avian Influenza H5N1 and the novel Influenza H1N1 swine. For more information, please visit <u>www.tib-molbiol.com</u>

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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