

Basel, 22 September 2015

## **Roche receives FDA CLIA waiver for flu A/B test for use on its cobas Liat PCR System**

**First CLIA-waived, real-time PCR tests for flu and Strep A now available for physician offices and pharmacies**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has granted CLIA (Clinical Laboratory Improvement Amendments) waiver for the **cobas**<sup>®</sup> Influenza A/B test for use on the **cobas**<sup>®</sup> Liat System. It is the first CLIA-waived, real-time polymerase chain reaction (PCR) test to detect influenza A and B in ~20 minutes. Coupled with the CLIA waived **cobas** Strep A test, the **cobas** Influenza A/B test can now be used by healthcare providers in non-traditional testing sites, including physician offices, emergency rooms, health department clinics, pharmacy clinics and other healthcare facilities.

“Today’s CLIA waiver for the **cobas** Influenza A/B test allows real-time PCR technology, the gold standard in molecular testing, to be utilized at the point of care to accurately and quickly detect and differentiate influenza A and B,” said Roland Diggelmann, COO, Roche Diagnostics. “Effective management of influenza relies on accurate detection within 48 hours of onset, which can be challenging with current turnaround times for lab-based test results. The **cobas** Influenza A/B test provides lab-quality PCR results in ~20 minutes, enabling health care providers in all settings to give prompt and confident diagnosis and treatment to patients.”

An estimated three to five million individuals develop influenza each year worldwide, and 250,000 to 500,000 die from the virus.<sup>1</sup> Patients at highest risk include children, the elderly and pregnant women. The CLIA waived **cobas** Influenza A/B test for the **cobas** Liat PCR System offers an effective, new diagnostic tool to clinicians for the upcoming flu season and provides faster diagnosis and treatment for patients in primary and urgent care settings.

The **cobas** Influenza A/B test is the second assay on the **cobas** Liat System to receive CLIA waiver, following the **cobas** Strep A test, which received CLIA waiver in May 2015. The **cobas** Liat Analyzer, **cobas** Influenza A/B test and **cobas** Strep A test are CE Marked, FDA cleared and CLIA waived.

#### **About the cobas Influenza A/B test**

The **cobas** Influenza A/B test uses real-time PCR technology to detect and differentiate influenza A virus and influenza B virus RNA in ~20 minutes. It targets highly conserved regions of the influenza A and B genomes to provide broad strain coverage of over 30 commonly found strains of influenza A and B.

#### **About the cobas Liat System**

Utilizing polymerase chain reaction (PCR) technology, the **cobas** Liat System fully automates the testing process, simplifies workflow and enables healthcare professionals to perform molecular testing in a variety of settings with speed, reliability and minimal training. Definitive results are generated in 20 minutes or less to aid a treatment decision. In addition to the existing tests for flu A/B and Strep A, assays for other infectious diseases are in development.

#### **About real-time PCR**

Real-time PCR is widely recognized as the gold standard for molecular testing. It is highly accurate and offers a low limit of detection (LOD) to detect viruses in patients with low viral load, such as some adults with influenza infection. PCR is also extremely versatile, offering capabilities with high multiplex testing (e.g. influenza A, influenza B and RSV in the same test), quantification (viral load count), and detection. Additionally, compared to physician clinical management, rapid antigen testing and other point-of-care testing methods, real-time PCR has demonstrated improved detection of influenza.<sup>23</sup>

More information is available at [go.roche.com/cobasliat](http://go.roche.com/cobasliat) or [www.cobasliat.com](http://www.cobasliat.com).

The **cobas**<sup>®</sup> Liat System is not commercially available in all markets.

#### **About influenza A and B (flu)**

Influenza is an acute respiratory illness caused by infection with the influenza virus. Influenza viruses consist of three types: influenza A, influenza B and influenza C. In the U.S., influenza A/H1N1, A/H3N2 and influenza B are the predominant seasonal viruses. Influenza A and B viruses are among the leading causes of respiratory infections, estimated to affect 5-10% of adults and 20-30% of children every year worldwide. Influenza is primarily spread by breathing in infected droplets formed when a person with the flu sneezes, coughs, or talks. Symptoms include fever,

cough, headache, fatigue, muscle pain, sore throat, and runny nose. Elderly people, young children, and people with weakened immune systems or chronic medical conditions can be at high risk for serious disease. Each year, approximately 3 to 5 million people develop severe illness and 250,000 to 500,000 people die from the flu.<sup>4</sup>

### **About Roche**

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. 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 chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. 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 [roche.com](http://roche.com).

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## References

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<sup>1</sup> World Health Organization. Influenza (Seasonal) Fact Sheet No 211. <http://www.who.int/mediacentre/factsheets/fs211/en/>. Accessed 25 Sep 2014.

<sup>2</sup> Hazelton et al. (2015) Detection of influenza A and B with the Alere™ i Influenza A & B: a novel isothermal nucleic acid amplification assay. *Influenza and Other Respiratory Viruses* 9(3), 151–154.

<sup>3</sup> Dugas et al. (2015) Clinical diagnosis of influenza in the ED. *AJEM* 33 (2015) 770–775. <http://dx.doi.org/10.1016/j.ajem.2015.03.008>

<sup>4</sup> World Health Organization. Influenza (Seasonal) Fact Sheet No 211. <http://www.who.int/mediacentre/factsheets/fs211/en/>. Accessed 25 Sep 2014.