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Roche receives CLIA waiver for cobas® Influenza A/B & RSV test for the cobas® Liat®

The first CLIA-waived, real-time PCR test that differentiates flu and RSV in 20 minutes is available now for use in physician offices and urgent care settings

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the US Food and Drug Administration (FDA) has granted 510(k) clearance and CLIA (Clinical Laboratory Improvement Amendments) waiver for the **cobas®** Influenza A/B & RSV test for use on the **cobas®** Liat® System. Roche is the first manufacturer to extend the value of highly accurate CLIA-waived molecular testing beyond flu A/B and strep A to include Respiratory Syncytial Virus (RSV), a cause of more than 80% of acute lower respiratory tract infections in infants under one year of age.¹

“For young children and the elderly, it is essential to have a differential diagnosis for RSV and flu to ensure appropriate treatment within a short time frame after symptoms strike,” said Uwe Oberlaender, Head of Roche Molecular Diagnostics. “This can be challenging with current turnaround times for lab-based test results. The **cobas®** Influenza A/B & RSV test provides lab-quality PCR results for flu and RSV in about 20 minutes, supporting a prompt, confident diagnosis to patients.”

In the US, an average of 58,000 hospitalizations and 2.1 million outpatient visits in children under five years are attributed to RSV. A significant number is also seen in adults over 65 years with 177,000 hospitalizations and 14,000 deaths per year². A quick detection and discrimination of flu and RSV enables clinicians to optimize patient management and antiviral treatment.

The **cobas®** Influenza A/B & RSV test is the third assay on the **cobas®** Liat® System to receive CLIA waiver, following the **cobas®** Strep A and **cobas®** Influenza A/B tests, which received CLIA waiver in May and September 2015, respectively. The **cobas®** Liat® Analyser and all three assays are FDA cleared and CLIA waived.

About the cobas® Influenza A/B & RSV test

The **cobas®** Influenza A/B & RSV test uses real-time PCR (polymerase chain reaction) technology to detect and differentiate influenza A virus RNA, influenza B virus RNA and respiratory syncytial virus (RSV) RNA in about 20 minutes. It targets well-conserved regions of influenza A, influenza B and RSV RNA to provide broad strain coverage and has been validated on over 40 commonly found strains of influenza A and B and seven commonly found strains of RSV.

About the cobas® Liat® System

Utilizing 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 influenza A/B, strep A and influenza A/B & RSV, 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.^{3,4}

More information is available at go.roche.com/cobasliat or www.cobasliat.com.

The **cobas®** Liat® System is not commercially available in all markets.

About Respiratory Syncytial Virus

RSV is one of the most contagious human pathogens, but with limited antigenic and strain diversity.⁵ It is the most common cause of childhood acute lower respiratory tract infection (LRTI), causing more than 60% of acute LRTI in children, and more than 80% in infants under one year of age.⁶ Symptoms of adults with RSV infection are usually consistent with an upper respiratory tract infection such as the common cold. Acute illness lasts 5–10 days, but the cough may be prolonged for several weeks.⁷ Mild RSV infections are resolved without treatment, but

infants and children with a severe RSV infection may be admitted to the hospital.⁸ Real-time PCR assays are recommended due to their high sensitivity, particularly since many patients may have low viral loads.⁹

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 worldwide every year. 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.¹⁰

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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