

Indianapolis, January 5, 2017

Roche gains FDA Clearance for 18-Minute Anti-Müllerian Hormone Test to Assess Ovarian Reserve

New blood test measures the remaining egg supply of women who are planning to become pregnant

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it received clearance from U.S. Food and Drug Administration (FDA) via Direct *de novo* decision on their Anti-Müllerian (AMH) assay, making it the first approved fully automated AMH test available in the US to doctors looking to help women who are planning to become pregnant or struggling with infertility.

“Our new assay will help more doctors incorporate AMH testing into their routine clinical practice, ensuring that more women who have questions about their fertility can get answers, faster,” explained **Dr. Alan Wright**, Chief Medical Officer, Roche Diagnostics Corporation. “With over 7.4 million women in the U.S. who have ever used fertility services and 1 in 8 couples having trouble getting or sustaining pregnancy, the need for a consistent, reproducible and robust fertility measurement for women has never been greater.”

With a simple blood test, measurement of serum AMH may now be used for the clinical assessment of ovarian reserve. The Elecsys[®] AMH blood test produces standardized results for assessing ovarian reserve as compared with the use of vaginal ultrasound in which the result is often dependent on the operator or clinic.

The assay is designed for use on all Roche immunoassay systems for low-, mid- and high-volume testing environments, including the **cobas e 411**, **cobas e 601**, **cobas e 602** and **MODULAR ANALYTICS E170** analyzers. Roche currently offers an extensive menu of fertility assays that process in 18 minutes, allowing clinicians to evaluate patients quickly during their office visit.

About Anti-Müllerian Hormone:

In women, Anti-Müllerian hormone (AMH) is exclusively produced by granulosa cells of ovarian follicles during the early stages of follicle development. After an initial increase until

early adulthood, AMH concentrations slowly decrease with increasing age until becoming undetectable before menopause. Individual AMH serum concentration accurately reflects the size of the pool of antral follicles, representing the quantity of the remaining primordial follicles.

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 eight 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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