Media Release

Pleasanton, CA 13 February 2018

Roche receives FDA clearance for Factor II and Factor V test on the cobas® 4800 system

- ***Provides a rapid workflow to aid in the diagnosis of patients with suspected thrombophilia***
- ***Uniquely addresses the needs of mid- to high- volume labs***
- ***Expanded assay menu enables labs to consolidate Genomics, Oncology, Microbiology, HPV and Virology on a single platform***

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received FDA clearance for the **cobas®** Factor II and Factor V Test for use on the **cobas®** 4800 system. The test enables laboratories to simultaneously assess Factor II and Factor V gene mutations from a single patient sample, which can reduce hands-on time when testing patients for inherited thrombophilia.

"Patients and their caregivers rely on genetic test results to accurately manage their risk for blood clots," said Uwe Oberlaender, head of Roche Molecular Systems. "With this test, Roche can help labs generate results faster and with less hands-on time."

Roche has been a market leader in inherited thrombophilia testing since the launch of the first FDA approved test for Factor V Leiden in 2003. The clearance of the new **cobas®** Factor II and Factor V Test demonstrates Roche's continued commitment to providing market-leading testing solutions for patients at risk of blood clots.

The **cobas®** Factor II and Factor V Test further expands the current menu of the **cobas®** 4800 system, enabling labs to consolidate genomics, oncology, microbiology, and virology[1] testing onto a single platform. The new test also complements the recent CE approval of the **cobas t** 511 and **cobas t** 711 coagulation analyzers for the central lab, making Roche a key partner for

[1] **cobas®** Virology assays on the **cobas®** 4800 System are not available in the US.

laboratories performing coagulation and thrombophilia testing.[2]

About the cobas® Factor II and Factor V Test for use on the cobas® 4800 System

The **cobas®** Factor II and Factor V Test is a multiplex test, with flexible reporting of both Factor II and Factor V gene mutations. The **cobas®** Factor II and Factor V Test represents a significant system and workflow efficiency upgrade for customers currently utilizing a LightCycler® system for Factor II and Factor V testing.

One key feature of the new assay is the user-selected sample preparation. The **cobas®** Factor II and Factor V Test allows labs the flexibility to select the extraction method that best fits their workflow needs.

Laboratories performing the **cobas®** Factor II and Factor V Test will be able report one or both Factor V and Factor II genotypes from one well, streamlining the testing workflow and minimizing additional testing. The efficient test design also allows laboratories to report up to 94 patient samples -and 188 results - per 90 minutes.

About Inherited Thrombophilia

Thrombophilia is a condition with a predisposition to develop thrombosis (e.g., blood clots) due to either an inherited or acquired defect in the coagulation system. Blood clots may form in either the venous or arterial vascular system and can lead to Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE). Collectively, DVT and PE are known as Venous Thromboembolism (VTE). VTE is the third most common cause of cardiovascular death after acute coronary syndrome and stroke.

Inherited thrombophilia is most frequently caused by Factor V or Factor II (Prothrombin) gene mutation. The Factor V Leiden mutation is a single point mutation (G to A at position 1691, or G1691A) of the human Factor V gene that results in substitution of arginine to glutamine at position 506 (R506Q) in the Factor V protein. Factor V Leiden mutation renders the protein partially resistant to inactivation by activated protein C (APC). APC resistance is regarded as the most prevalent coagulation abnormality associated with VTE. Genetic analysis has demonstrated that Factor V Leiden mutation, which has a relatively high prevalence in the general population (e.g. about 5% in Caucasians), may account for 85% to 95% of APC resistance cases. In addition to the Factor V G1691A mutation, molecular genetic

[2] the **cobas t** 511 and **t** 711 modules are not approved in the US.

testing for Factor II G20210A (G to A at position 20210) is recommended as this mutation is present in 1-3% of the general population and its involvement in VTE is well established. Evaluation of a patient's risk for hereditary thrombophilia through a Factor II and Factor V genotyping test is critical for diagnosis and clinical management of patients with thrombophilia.

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.

For media inquiries please contact:
Todd Siesky
1-888-545-2443