

Pleasanton, CA 08 January 2014

## **Roche announces launch of the **cobas**<sup>®</sup>HSV 1 and 2 Test for herpes simplex virus in markets accepting the CE mark**

*New test expands menu for sexually transmitted infections testing on the **cobas**<sup>®</sup> 4800 System*

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the CE-IVD launch of the **cobas**<sup>®</sup> HSV 1 and 2 Test for the direct detection of HSV-1 and HSV-2 DNA in anogenital specimens. With dual target detection and automation, the **cobas**<sup>®</sup>HSV 1 and 2 Test provides laboratories with the capability to report up to 94 results in significantly less time than traditional methods and provides a simplified workflow for sample handling in the laboratory.

Treatment guidelines cite the importance of sensitivity for HSV detection, and that Polymerase Chain Reaction (PCR) has demonstrated superior clinical performance to culture techniques<sup>1</sup>. Using one of the fastest, most advanced real-time PCR detection available today, the **cobas**<sup>®</sup>HSV 1 and 2 Test offers accurate and reliable results through the use of simple and reliable sample collection technology and automated processing.

“Clinical management of patients infected with HSV type 1 or type 2 requires a clear understanding of the virus, and as resistance to anti-viral agents continues to evolve, there are increasing concerns about the plasticity of the HSV genome,” said Dr. Raj Patel FRCP, Consultant GUM/HIV Physician and Senior Lecturer, University of Southampton, UK. “The innovative dual target approach of **cobas**<sup>®</sup>HSV 1 and 2 Test allows the detection of two distinct, conserved regions of the HSV genome, providing accurate detection of the virus and peace of mind when managing patients.”

“The **cobas**<sup>®</sup>HSV 1 and 2 Test provides labs with a highly sensitive and specific test for the detection of herpes simplex virus,” said Paul Brown, head of Roche Molecular Diagnostics. “This not only allows for optimal patient treatment and management decisions, but it also

expands the menu of our **cobas**<sup>®</sup>4800 System which enables labs to experience increased efficiency.”

The test is performed on the **cobas**<sup>®</sup>4800 System, currently the only CE-IVD marked system which offers the flexibility to run sexually transmitted infection and HAI tests, in the same run, on a single platform. The streamlined workflow can help labs reduce costs, improve turnaround time and enable staff to spend time on other critical tasks.

### **About Herpes Simplex Virus**

Clinical presentation for Herpes Simplex Virus infection is variable, and frequently signs and symptoms can be easily confused with other conditions. Most HSV-1 infections occur early in childhood and often go unrecognized, while HSV-2 infection rates remain low until the age of sexual maturity. Approximately 70 to 90% of patients with reactive serology for HSV-2 have not been diagnosed with genital herpes. Laboratory confirmation is recommended for all patients with suspected genital herpes, using methods that directly demonstrate the virus in genital specimens. The type of HSV a patient is infected with has an impact on management and treatment decisions, as HSV-2 recurrence is considerably higher than that of HSV-1. Molecular testing by PCR is the most sensitive method of direct detection for HSV-1 and HSV-2.

### **About the cobas<sup>®</sup>4800 System**

The **cobas**<sup>®</sup>4800 System offers true walk-away automation of nucleic acid purification, PCR set-up and real-time PCR amplification and detection to help laboratories achieve maximum efficiency. The expanding system menu currently includes the **cobas**<sup>®</sup>MRSA/SA Test, **cobas**<sup>®</sup>CT/NG Test (chlamydia/gonorrhea), **cobas**<sup>®</sup>HPV Test, **cobas**<sup>®</sup>BRAF V600 Mutation Test and the **cobas**<sup>®</sup>EGFR Mutation Test.

### **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, infectious diseases, inflammation, metabolism 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 diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 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 [www.roche.com](http://www.roche.com).

1. Patel et al. 2010 European guidelines for the management of genital herpes.

All trademarks used or mentioned in this release are protected by law.

# # #

For media inquiries please contact:

Bob Purcell

888-545-2443