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Roche receives FDA clearance for the cobas® HSV 1 and 2 Test for the detection of herpes simplex virus

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

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has provided 510(k) clearance for the **cobas**® HSV 1 and 2 Test for the direct detection and differentiation of HSV-1 and HSV-2 DNA in anogenital specimens from symptomatic patients. With dual target detection and automation, the **cobas**® 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. This can help labs reduce costs, improve turnaround time and enable staff to spend more time on other critical tasks.

“Accurate diagnosis of genital herpes infections, whether caused by HSV-1 or HSV-2, has important personal and public health implications,” said Edward Hook III, MD, Director, Division of Infectious Diseases and Professor of Medicine, Epidemiology and Microbiology, University of Alabama. “Many genital herpes infections present with non- ‘classical’ genital lesions. Culture is clearly inferior to nucleic acid amplification testing and use of polymerase chain reaction (PCR)-based tests will lead to improved etiologic diagnosis and better patient care.”

“The addition of the **cobas**® HSV 1 and 2 Test expands the menu for the **cobas**® 4800 System, enabling labs to experience increased efficiency with innovative testing solutions,” said Paul Brown, head of Roche Molecular Diagnostics. “This highly sensitive and specific new test for the detection of herpes simplex virus delivers reliable results to physicians for optimal patient treatment and clinical management decisions.”

Treatment guidelines cite the importance of sensitivity for HSV detection, and that PCR has demonstrated superior clinical performance to culture techniques¹⁻². Using one of the fastest, most advanced real-time PCR detection methods available today, the **cobas**® HSV 1 and 2

Test offers accurate and reliable results through the use of simple and reliable sample collection technology and automated processing. The test is performed on the **cobas**[®] 4800 System, currently the only FDA-cleared system which offers the flexibility to run sexually transmitted infection and healthcare-associated infection tests, in the same run, on a single platform.

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 presence of 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[®] 4800 System

The **cobas**[®] 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 in the U.S. currently includes the **cobas**[®] CT/NG Test (*Chlamydia trachomatis/Neisseria gonorrhoeae*), **cobas**[®] HPV Test, **cobas**[®] MRSA/SA Test, **cobas**[®] Cdiff Test, , **cobas**[®] BRAF V600 Mutation Test, **cobas**[®] EGFR Mutation Test and **cobas**[®] KRAS 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, 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-four 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.

1. Patel et al. 2010 European guidelines for the management of genital herpes.
2. Workowski et al. 2010 Sexually Transmitted Diseases Treatment Guideline, MMWR 59

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