cobas® 6800/8800 Systems
Fact Sheet

Fast Facts

- The cobas® 6800/8800 Systems are next generation molecular testing platforms, available in medium and high throughput models, designed for blood screening, viral load monitoring, women’s health, and microbiology testing.

- The cobas® 6800/8800 Systems offer the fastest time to results with the highest throughput available, along with the longest “work-away” time, enabling laboratory staff to drive increased workflow efficiencies, while evolving with their ever-changing testing demands.

- The current portfolio includes the cobas® 6800/8800 Systems; the cobas p 680 instrument to support the creation of donor sample pools; four next-generation assays for viral load testing: cobas® HIV-1, cobas® HCV; cobas® HBV and cobas® CMV and four next-generation assays for donor screening: cobas® MPX, cobas® DPX, cobas® WNV and cobas® HEV. Other assays currently in development will follow.

About the cobas® 6800/8800 Systems

Based on the Nobel-prize winning PCR technology, the cobas® 6800 System and the higher throughput cobas® 8800 System, are designed to be readily integrated into laboratory workflow from pre-analytic to post-analytic solutions, while transforming the way molecular testing is performed.

Key features of the systems include:

**Unparalleled Performance:** Delivering the fastest time to results, as well as greater throughput volumes, the cobas® 6800/8800 Systems enable users to rapidly complete daily testing requirements with trusted and reproducible results. In just an eight-hour shift, the systems can process up to 384* and 960* tests respectively, with up to 96 test results available in less than 3.5 hours.

**Absolute Automation:** The cobas® 6800/8800 Systems are designed to provide users with minimal and intuitive interactions, resulting in hours of “work-away” time, while also reducing the potential for human error. The systems offer eight and four hours of “work-away” time* respectively, allowing users to focus on more complex testing demands, in turn increasing productivity within the lab.

* May vary based on workflow demands
Unmatched Flexibility: With the cobas® 6800/8800 Systems, users can perform up to three molecular tests simultaneously, without the need to batch or pre-sort samples. Samples can be continuously loaded onto the system and up to three different tests can be performed from a single sample. These features allow users to run the tests they want, when they want with minimal user interactions.

The cobas® 6800/8800 Systems are not available in all markets, including the United States. For more information about the systems, please visit www.cobas68008800.com.

About the Assay Portfolio for the cobas® 6800/8800 Systems

The four viral load monitoring assays are quantitative nucleic acid tests used to detect and manage the viral load in patients. Viral load monitoring is essential to determine the effectiveness of therapeutic interventions.

- **cobas® HIV-1** is a quantitative real-time PCR test with an integrated dual target approach, focusing on two unique regions of the HIV-1 genome, gag and LTR, that are not subject to selective drug pressure.

- **cobas® HCV** is a quantitative real-time PCR test that uses a dual-probe technique designed to accurately detect and quantify HCV genotypes 1-6 while maintaining high sensitivity.

- **cobas® HBV** is a quantitative real-time PCR test designed to offer an expanded linear range with two input volumes coupled with broad coverage of all known HBV genotypes (A-H), including pre-core mutations with high sensitivity.

- **cobas® CMV** is a quantitative real-time PCR test designed to reliably monitor patients receiving antiviral therapy and is traceable to the first WHO International Standard for Human CMV.

**cobas® MPX, DPX, WNV and HEV** are nucleic acid tests for the detection of blood-borne viruses in donations of blood, blood components, tissues, and organs.

- **cobas® MPX** is a real-time PCR multiplex test covering five critical viral targets: HIV-1 Group M, HIV-1 Group O, HIV-2, HCV and HBV, from a single sample. It offers real-time detection and identification of HIV, HCV and HBV, eliminating the need for discriminatory testing. Plus, the dual-target approach with amplification of separate regions of HIV-1, and dual probes for HCV, improve coverage of new virus variants.

- **cobas® DPX** is a real-time duplex test designed to quantify parvovirus B19 (B19V) DNA with a broad linear range and simultaneously detect HAV RNA in a single test. It provides complete coverage of known B19V and HAV genotypes.

- **cobas® WNV** is a real-time PCR test for West Nile virus (WNV) that is highly sensitive for both WNV lineages 1 and 2. It also provides broad coverage of other flaviviruses that can cause transfusion-transmitted infectious diseases.

- **cobas® HEV** is a real-time PCR test for hepatitis E virus (HEV), providing broad coverage of all 4 major HEV genotypes.

Assays for women’s health and microbiology are also in development.

** Currently in development
About the Assays in Development

**Assays for other indications**

**cobas® CT/NG** is a qualitative real-time PCR test designed to accurately test CT and NG in a single sample.

**cobas® HPV** is a qualitative *in vitro* test designed to detect HPV DNA in human specimens, simultaneously providing results on high-risk genotypes while providing individual results on the highest risk genotypes (HPV 16 and 18).

**cobas® MTB/MAI/r** is a qualitative real-time PCR test designed to detect mycobacteria including *Mycobacterium tuberculosis* (MTB) and to identify MTB organisms that harbor resistance mechanisms to first line therapies.

**cobas® HIV Qual** is a qualitative *in vitro* diagnostic, total nucleic acid amplification test for the detection and discrimination of HIV-1 and HIV-2 RNA in human EDTA plasma or dried blood spots (DBS).

About the Viruses Tested with the Assay Portfolio

The cobas® 6800/8800 Systems menu of next-generation assays provides detection and identification of some of the world’s most significant insidious viruses.

A major concern regarding the transfusion of blood and blood components is the potential for transmission of viral infections, particularly with Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2), Hepatitis C Virus (HCV), and Hepatitis B Virus (HBV). These agents are primarily transmitted by exposure to contaminated blood or blood and plasma products, exposure to certain body tissues or fluids, by sexual contact, or by an infected mother to her newborn child.

- **Human Immunodeficiency Virus (HIV-1)**
  HIV-1 is prevalent globally, with an estimated 34 million people living with HIV around the world in 2011 for overall prevalence of 1.1%. Persons infected with HIV-1 can experience a brief, initially acute, flu-like illness associated with high levels of viremia in peripheral blood within 3 to 6 weeks of initial infection.

  HIV-2 was first isolated in 1986 from patients in West Africa. Both HIV-1 and HIV-2 have the same modes of transmission and are associated with similar opportunistic infections and Acquired Immunodeficiency Syndrome (AIDS). The prevalence of HIV-2 in some African nations reaches more than 1%, and HIV-2 is a growing concern in certain parts of Europe and India.

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- **Hepatitis C Virus (HCV)**
  According to the WHO, every year, 3-4 million people globally are infected with the hepatitis C virus. About 130-150 million people are chronically infected, and many of those with chronic infections are at risk of developing liver cirrhosis and/or liver cancer. More than 350,000 people die from hepatitis C-related liver diseases every year.\(^9\)

  The hepatitis C virus is typically spread when blood from an infected person enters the body of a susceptible person. It is among the most common viruses that infect the liver. The disease can ultimately result in cirrhosis, liver failure and hepatocellular carcinoma, which together are responsible for hundreds of thousands of deaths each year.

- **Hepatitis B Virus (HBV)**
  According to the World Health Organization (WHO), an estimated 2 billion people worldwide have been infected with the hepatitis B virus, and more than 350 million are chronically infected.\(^10\) Over 1,000,000 people die every year due to the consequences of hepatitis B1. Because many HBV infections are either asymptomatic or never reported, the actual number of new infections is estimated to be tenfold higher.

  The hepatitis B virus is spread through having unprotected sex, by sharing needles or from an infected mother to her baby during child birth. Symptoms occur in about 70 percent of patients and include jaundice, fatigue, abdominal pain, loss of appetite, nausea and vomiting.

- **Hepatitis E (HEV)**
  Approximately 20 million people around the globe are infected with hepatitis E each year.\(^11\) The virus is transmitted primarily through contaminated drinking water. Although hepatitis E is usually a self-limiting infection and resolves within four to six weeks, occasionally, a fulminant form of hepatitis leads to acute liver failure, which can lead to death. Each year, there are over 3 million acute cases of hepatitis E and 56,600 hepatitis E-related deaths.

- **West Nile Virus (WNV)**
  Although nearly 80 percent of people who are infected with West Nile virus (WNV) will not show any symptoms at all or may experience several days of flu-like symptoms, WNV is a potentially serious illness, especially for those with compromised immune systems. In

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2012, the U.S. Centers for Disease Control (CDC) reported a total of 5,387 cases of WNV disease in people in the U.S., including 243 deaths.\textsuperscript{12}

In 2003, when blood transfusion-associated transmission (TAT) of WNV infection marked the emergence of a new threat to the U.S. blood supply, blood-collection agencies implemented new, investigational WNV NATs to screen all blood donations and identify potentially infectious donations for quarantine and retrieval.

- **Cytomegalovirus (CMV)**
  CMV is the most common and single most important viral infection in solid organ transplant (SOT) recipients. CMV can be transmitted through the donor organ resulting in CMV infection and leading to the development of CMV disease. Approximately 20–60% of all transplant recipients develop symptomatic CMV infection. CMV infection usually develops during the first few months after transplantation. CMV disease is defined by evidence of CMV infection with attributable symptoms similar to infectious mononucleosis or glandular fever, prolonged fever, sore throat, and a mild hepatitis. Once infected, the virus remains latent in the body for the rest of the person's life.

- **Human Parvovirus B19**
  Human parvovirus B19 (B19V) is normally transmitted by the respiratory route but transmission by plasma products has also been reported. B19V has a worldwide distribution and serological studies have indicated that at least 50% of adults have circulating B19V antibodies, indicating a past infection.\textsuperscript{13,14} Infection with B19V is often asymptomatic or may result in a mild illness including fifth disease in children or arthropathy in adults. However, B19V may cause severe disease in individuals with hematological disorders and fetal death in pregnant women. The prevalence of B19V in blood and plasma donors can vary from 0.003-0.6% depending on whether the collection is done during an epidemic or nonepidemic period.\textsuperscript{15,16}

- **Hepatitis A virus (HAV)**
  Hepatitis A virus (HAV) is transmitted by close personal contact. HAV infections in humans range from asymptomatic infections, mainly seen in young children, to acute liver failure, which in some cases may lead to death. In Northern Europe, Japan, Canada, and the USA, the prevalence in the general population is very low (about 0.01%) and outbreaks are associated mainly with risk groups, such as travelers to endemic regions.\textsuperscript{17} There are reports in the literature of transmission of HAV through plasma products.

- **Human papillomavirus (HPV)**

\textsuperscript{12} Centers for Disease Control and Prevention. \url{http://www.cdc.gov/ncidod/dvbid/westnile/} accessed 3May 2013.
Human papillomavirus (HPV) is a common infection transmitted during sexual contact and those affected often do not show symptoms. Almost all cervical cancers – more than 99 percent – are caused by HPV. There are more than 118 genotypes of HPV and 14 are considered high risk for cervical cancer. Two of these, HPV genotypes 16 and 18, are considered the highest risk and responsible for approximately 70 percent of cervical cancers. In an overview of more than 60,000 women, HPV testing was substantially more sensitive in detecting cervical disease than cytology (96.1% vs. 53.0%). By finding precancerous lesions early, clinicians can prevent cancer from developing. For more information about HPV screening, please visit www.hpv16and18.com.

- **Chlamydia trachomatis (CT)**

*Chlamydia trachomatis* (CT) is the most frequently reported bacterial sexually transmitted disease (STD) in the United States as well as the second most leading cause of sexually transmitted diseases worldwide, with approximately 89.1 million cases occurring annually. The Centers for Disease Control (CDC) Sexually Transmitted Disease Surveillance 2008 Supplement reports 1,210,523 CT infections from the 50 states. The U.S. National Health and Nutrition Examination reports that 2,291,000 U.S. civilians ages 14-39 are carriers of CT.

CT is the causative infectious agent for a variety of diseases in men: urethritis, proctitis, conjunctivitis, epididymitis and Reiter’s Syndrome. Among women, the consequences of chlamydial infections are severe if left untreated. Since approximately half of these infections are asymptomatic, many cases go undetected and untreated, leading to additional problems, particularly with pregnant women. In addition, re-infections are frequent if the sex partners are not treated. CT infection can cause urethritis, cervicitis, proctitis, conjunctivitis, endometritis, salpingitis (with subsequent infertility or ectopic pregnancy) and perihepatitis. Infants from infected mothers can develop conjunctivitis, pharyngitis and pneumonia.

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Neisseria gonorrhoeae (gonococci) (NG)

Neisseria gonorrhoeae (gonococci) is the causative agent of gonorrhoeae. *N. gonorrhoeae* are gram-negative diplococci, cytochrome oxidase positive, non-motile and non-spore forming. A total of 336,742 cases of NG infection have been reported to the CDC in 2008, and it is estimated that more than 700,000 persons get new infections each year. After several years of stable infection rates, a 5.4% decrease to 111.5 cases per 100,000 persons in the U.S. since 2007 has been noted.

Tuberculosis (TB)

Tuberculosis (TB) is a contagious disease. Like the common cold, it spreads through the air. Only people who are sick with TB in their lungs are infectious. When infectious people cough, sneeze, talk or spit, they propel TB germs into the air. A person needs only to inhale a small number of these to be infected. Overall, one third of the world's population is currently infected with the TB bacillus. Of the people who are infected with TB bacilli, 5-10% become sick or infectious at some time during their life. It is estimated that 1.7 million deaths resulted from TB in 2004. As with cases of disease, the highest number of estimated deaths is in the South-East Asia Region, but the highest mortality per capita is in the Africa Region, where HIV has led to rapid increases in the incidence of TB and increases in the likelihood of dying from TB. WHO targets, ratified by the World Health Assembly in 1991, are to detect 70% of new infectious TB cases and to cure 85% of those detected by 2005. Eighteen countries had already achieved these targets in 2002.

Contact Information:
Roche Molecular Systems
Bob Purcell
Vice President, Corporate Communications
Phone: +1.925.730.8114
Email: Bob.Purcell@roche.com

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Roche Molecular Diagnostics
4300 Hacienda Drive
Pleasanton, CA 94588
USA
http://molecular.roche.com

29 Centers for Disease Control Fact Sheet *Gonorhoeae*, 2006.
30 World Health Organization Fact Sheet Nº 104 Revised April 2005.