

Pleasanton, 16 April 2018

Roche receives FDA clearance for cobas® CT/NG for cobas® 6800/8800 Systems

- **First moderate complexity molecular test for sexually transmitted infections on fully automated, high throughput platform**
- **Broad set of urogenital sample claims ensure greatest flexibility for patient access**
- **New test for most common sexually transmitted infections complements existing menu that includes tests for viral load monitoring and donor screening**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has provided 510(k) clearance for **cobas® CT/NG** for use on the **cobas® 6800/8800 Systems** for the direct detection of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) DNA in both symptomatic and asymptomatic individuals.

“**cobas CT/NG** on the **cobas 6800/8800 Systems** provides clinicians with results in which they can have high confidence given the excellent sensitivity and specificity of the assay for all relevant sample types,” said Barbara Van der Pol, international expert on STIs and Associate Professor of Medicine, School of Medicine, University of Alabama at Birmingham. “For the laboratory, the platform provides a tech friendly solution that minimizes hands-on time while maximizing the flexibility of incorporating sexually transmitted infection screening with other assays that are currently available on the system.”

cobas CT/NG is the first assay available in the US for the testing of sexually transmitted infections on the **cobas 6800/8800 Systems**. It is cleared for use with male and female urine specimens, clinician-instructed self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected vaginal swab

specimens, endocervical swab specimens (all collected in **cobas**® PCR media) and cervical specimens collected in PreservCyt® Solution.

“Sexually transmitted infection rates are rising worldwide and the **cobas** CT/NG helps labs meet increasing testing volumes with highest throughput solution on the market today,” said Uwe Oberlaender, Head of Roche Molecular Diagnostics. “With exceptional performance, exemplary workflow and a flexible testing solution, the CT/NG helps labs free up staff to perform other tasks while still ensuring clinicians receive accurate and rapid results to aid in patient management.”

Other STI assays are in development and will further allow laboratories to consolidate high volume STI testing on a single platform. In addition to **cobas** CT/NG, **cobas** 6800/8800 Systems menu in the US includes viral load monitoring tests for HIV, HBV, HCV and CMV, as well as MPX, WNV, DPX and Zika for use in screening blood donations. Since its introduction in 2015, the fully automated cobas 6800/8800 Systems have offered labs the fastest time to results with the highest throughput and the longest walk-away time available among automated molecular platforms.

About Chlamydia

Chlamydia trachomatis is the most common bacterial Sexually Transmitted Disease (STD), with the highest prevalence among youth. Routine screening for chlamydial infection in young women has been demonstrated to reduce infection rates and the long-term consequences of untreated disease, as well as lowering the financial burden on the healthcare system. The Centers for Disease Control and Prevention (CDC) recommends annual *Chlamydia trachomatis* screening for all sexually active females under 25 years old and additional testing for pregnant women and those with risk factors.¹

About Gonorrhea

Neisseria gonorrhoeae is the second most commonly reported bacterial STD in the United States. Infections in males are generally symptomatic, motivating infected patients to seek evaluation by a clinician for

identification and treatment before the onset of serious complications. Gonococcal infections in women are often asymptomatic and may not be immediately recognized, which can progress to pelvic inflammatory disease, tubal scarring, infertility and ectopic pregnancy. Screening of sexually active women under the age of 25 and those at high risk for infection is the focus of successful detection programs in the United States.

About the cobas 6800/8800 Systems

Since 2014, the cobas 6800 and cobas 8800 Systems have established the new standard for routine molecular testing by delivering fully integrated, automated solutions that serve the areas of viral load monitoring, donor screening, sexual health and microbiology. Based on Nobel prize-winning PCR technology, the systems deliver proven performance with full automation, increased throughput, fast turnaround time and complete track connectivity, providing users with greater flexibility to consolidate their testing to a single system while increasing overall workflow efficiencies.

The systems provide up to 96 results in about 3 hours and a total of 864 results for the cobas 6800 System and 1,824 results for the cobas 8800 System from an eight-hour shift. Both make it possible for labs to perform up to three tests in the same run with no pre-sorting required. The systems also enable up to eight hours (cobas 6800 System) and four hours (cobas 8800 System) of walk-away time with minimal user interaction.

For more information about the systems, please visit <http://molecular.roche.com>.

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 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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. All trademarks used or mentioned in this release are protected by law.

Roche Molecular Diagnostics Media Relations

Todd Siesky

1-888-545-2443

References

1. Recommendations for the Laboratory-Based Detection of Chlamydia trachomatis and Neisseria gonorrhoeae — 2014, Recommendations and Reports / Vol. 63 / No. 2
March 14, 2014, 10-11.