Media Release

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Roche launches cobas TV/MG on the cobas 6800/8800 Systems in markets accepting the CE mark

- **New test allows simultaneous processing of any combination of four separate sexually-transmitted infections (CT, NG, TV and MG) from one patient sample**
- **First and only high volume molecular test on market with approval for combination TV/MG testing using meatal swab specimen**
- **Continues the rapid expansion of testing menu on the cobas 6800/8800 Systems since launching in 2015**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the CE-IVD launch of **cobas®** TV/MG, for use on the cobas 6800/8800 Systems for the direct detection of *Trichomonas vaginalis* (TV) and/or *Mycoplasma genitalium* (MG) DNA in both symptomatic and asymptomatic individuals.

cobas TV/MG offers labs the broadest set of specimen claims available in one test, including the ability to test for both TV and MG from one patient sample. This new flexibility can aid health care professionals in faster diagnosis and in reducing the testing volume for labs, while enabling fewer sample collections from patients.

“We are pleased to continue our commitment to expanding our portfolio for the detection of sexually transmitted infections,” said Uwe Oberlaender, Head of Roche Molecular Diagnostics. “By coupling cobas TV/MG with recently launched cobas CT/NG for the detection of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG), laboratories now have the most flexible, high throughput testing solution on the market today. Labs can now simultaneously process, from a single patient sample, any combination of CT, NG, TV and MG, which provides clinicians the valuable information they need to properly diagnosis STIs and improve patient care.”

cobas TV/MG has been validated for use with the same, full set of female urogenital

specimens available for use with cobas CT/NG.[1] In addition, the test has been validated for use with male urine and is the first CE-IVD molecular test to receive a claim for combo TV/MG testing using a meatal swab specimen.

The fully automated cobas 6800/8800 Systems offer the fastest time to results, the highest throughput and the longest walk-away time available among automated molecular platforms, providing laboratories with improved operating efficiency and the flexibility to adapt to changing testing demands.

About *Trichomonas vaginalis*

Trichomonas vaginalis is the most common non-viral sexually transmitted infection (STI) in the world. Roughly, 70% of people infected with TV do not have any symptoms. Those with symptoms may experience itching, burning, or irritation of the genital area, discharge of the penis for males and a change to vaginal discharge with an unusual fishy smell for females. Left untreated, TV can increase the risk of spreading or contracting other STIs such as HIV. Pregnant women with TV may experience complications such as preterm delivery and low infant birth weight.[2]

In 2008, there were an estimated 276.4 million cases worldwide. Global population based studies show rates ranging from 3.2% to 42.6%, depending on the geographic region studied.[3] Published rates are generally thought to be an underestimation because most of the studies have been from methods such as wet mount microscopy versus nucleic acid amplification tests (NAATs). Furthermore, as TV is currently not a reportable disease, the true estimation of prevalence is not currently known.

About *Mycoplasma genitalium*

Mycoplasma genitalium is a fastidious bacterium first isolated in 1980 from the urethral swabs of two symptomatic men with non-gonococcal urethritis (NGU).[4] Infections caused by this bacterium have been associated with male and female urethritis, balanoposthitis, prostatitis, cervicitis, pelvic inflammatory disease, and male and female infertility.[5] Additional complications, such as preterm delivery and extra-genital infections, have been reported. Prevalence has shown to be as high as 47.5% when testing using various molecular assays.[6]

About the cobas 6800/8800 Systems

The cobas 6800 and cobas 8800 systems are fully integrated, automated solutions that introduce a new standard for routine molecular testing in the areas of viral load monitoring, donor screening, women's health and microbiology. Based on Nobel prize-winning PCR

technology, the systems are designed to deliver full automation, increased throughput and faster turnaround time, providing users with greater flexibility to dramatically increase overall workflow efficiencies.

The systems provide up to 96 results in less than 3.5 hours and a total of 384 results for the cobas 6800 System and 960 results for the cobas 8800 System in 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) and four hours (cobas 8800) of walk-away time with minimal user interaction.

For more information about the systems, please visit www.cobas68008800.com or 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. Twenty-nine 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 eight 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.

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1. Roche launches cobas CT/NG on the cobas 6800/8800 Systems in markets accepting the CE mark
2. Trichomoniasis - CDC Fact Sheet
3. Kissinger P. Trichomonas vaginalis: a review of epidemiologic, clinical and treatment issues. BMC Infect Dis. 2015;15:307. doi:10.1186/s12879-015-1055-0.
4. Tully JG, Taylor-Robinson D, Cole RM, Rose DL. A newly discovered mycoplasma in the human urogenital tract. Lancet. 1981; Jun; 1(8233):1288-91.
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6. Daley GM, Russell DB, Tabrizi SN, McBride J. Mycoplasma genitalium: a review. Int J STD AIDS. 2014; 25(7):475-87. doi: 10.1177/0956462413515196.