Media Release

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Roche receives FDA clearance to expand testing menu on cobas 6800/8800 Systems for sexually transmitted diseases

- **The addition of the cobas TV/MG test to the testing menu provides the flexibility to process up to four sexually transmitted infections from one patient sample**
- **Laboratories now have the most flexible, moderate complexity high throughput testing solution on the market today for combination CT/NG and TV/MG testing**
- **This continues the expansion of the testing menu on the cobas 6800/8800 Systems**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced US Food and Drug Administration (FDA) 510(k) clearance for the **cobas®** TV/MG test for use on the **cobas®** 6800/8800 Systems for the detection of *Trichomonas vaginalis* (TV) and/or *Mycoplasma genitalium* (MG) DNA in both symptomatic and asymptomatic patients. Laboratories can now simultaneously process from a single patient sample a combination of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG), which provides clinicians the information they need to screen and diagnose sexually transmitted infections (STIs) and improve patient care.

The addition of the cobas TV/MG test continues the expansion of the testing menu on the cobas 6800/8800 Systems, supporting true consolidation and testing efficiencies. The cobas TV/MG test has been validated for use with broad specimen types, including sample types comparable to those available for use with the **cobas®** CT/NG test: male/female urine; endocervical swabs and vaginal swabs (both clinician collected and patient collected in a clinical setting).[1,2]

"The launch of cobas TV/MG continues our expansion of our STI menu, giving healthcare providers and their patients greater access to more information from a single sample," said Mario Torres, Head of Roche Molecular Diagnostics. "By coupling cobas TV/MG with the recently launched cobas CT/NG

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for the detection of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), laboratories have a highly flexible, moderate complexity, high throughput automated solution to support their testing needs."

"The addition of *Mycoplasma genitalium* (MG) and *Trichomonas vaginalis* (TV) detection to the cobas 6800/8800 Systems is an important step forward in the ability to diagnose sexually transmitted infections." said Barbara Van Der Pol, Associate Professor of Medicine, School of Medicine, University of Alabama at Birmingham. "These new analytes, in conjunction with the approved *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) molecular diagnostic assays, will support a more thorough assessment of the potential pathogens responsible for discharge-causing STI. As a result, clinicians can more easily identify co-infections and utilize appropriate treatment strategies earlier in the patient management process."

The fully automated cobas 6800/8800 Systems offer the fastest time to results with 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 (TV) is the most common non-viral sexually transmitted infection (STI) in the world. About 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.[3]

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] *Mycoplasma genitalium* infections are often asymptomatic. However, 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 ~40% when testing using various molecular assays in select patient populations.[6,7]

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 validated for molecular testing, providing users with greater flexibility to consolidate their IVD and LDT 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 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. 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. Moreover, for the tenth consecutive year, Roche has been recognised as the most sustainable company in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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.

Roche Molecular Solutions Media Relations

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References

1. Roche receives FDA clearance for cobas CT/NG on the cobas 6800/8800 Systems
2. Roche launches cobas CT/NG on the cobas 6800/8800 Systems in markets accepting the CE mark
3. Trichomoniasis - CDC Fact Sheet
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.
5. Jensen JS. Mycoplasma genitalium infections. Diagnosis, clinical aspects, and pathogenesis. Dan Med Bull. 2006; 53:(1):1–27.
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.
7. McGowin CL, Anderson-Smits C (2011) Mycoplasma genitalium: An Emerging Cause of Sexually Transmitted Disease in Women. PLoS Pathog 7(5): e1001324. https://doi.org/10.1371/journal.ppat.1001324