
Hologic Launches First Fully Automated, Sample-to-Result Molecular Assay in Europe



-- The CE-marked Aptima® Mycoplasma genitalium Assay on the Panther® System Identifies a Prevalent, Often Misdiagnosed Sexually Transmitted Infection --

Hologic, Inc. has announced the European launch of the CE-marked Aptima Mycoplasma genitalium assay, adding to the growing menu of molecular tests available on the fully automated Panther system.

"Until now, a fully automated, sample-to-result nucleic acid amplification test (NAAT) had not been available to detect *M. genitalium*, a common sexually transmitted infection (STI) that is frequently misdiagnosed," said Claus Egstrand, Hologic Group President, International. "Now, clinicians and laboratories can test for this STI alone or from the same sample used for other STI testing."

M. genitalium was originally isolated in 1980.¹ Since then, many studies have explored the prevalence of the infection, which can be present in up to 6% of men and women visiting STD clinics.² It is associated with urethritis in men and women, and with cervicitis and pelvic inflammatory disease in women.³ Data also supports a correlation between *M. genitalium* infection and increased HIV-1 infection and transmission.⁴ Until now, identifying this elusive pathogen has been difficult because of its symptomatic similarities to other STIs, and due to limitations associated with traditional diagnostic approaches.

Accurate identification of *M. genitalium* is essential for successful treatment, as the infection can become resistant to antibiotics used to treat similar STIs.⁴ The Aptima Mycoplasma genitalium assay on the Panther system allows healthcare providers to diagnose and more effectively treat this STI.

The Aptima Mycoplasma genitalium assay further expands the test menu available on the Panther system, joining assays for HCV, HIV-1, HBV, HPV, chlamydia, gonorrhea and trichomoniasis. The assay may be used to test multiple sample types, including vaginal swabs, urine, unisex swabs or ThinPrep® Pap test vials, and will soon be available for use with multitest swabs for male meatal samples.

The Aptima Mycoplasma genitalium assay, Aptima HCV Quant Dx assay, Aptima HIV-1 Quant Dx assay and Aptima HBV Quant assay are not available for sale in the United States.

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