

Hologic - MediaRoom

Hologic Receives Additional CE-Marked Claims for Aptima® Combo 2® Assay for Chlamydia Trachomatis and Neisseria Gonorrhoeae in Europe

--Assay Now Cleared for Throat and Rectal Specimens for Use on the Panther System--

MARLBOROUGH, Mass. (June 20, 2017) – Hologic, Inc. (Nasdaq: HOLX) announced today that its Aptima® Combo 2® Assay for *Chlamydia trachomatis* (chlamydia) and *Neisseria gonorrhoeae* (gonorrhoea) has received new CE-marked claims in Europe. These additional claims for the world's leading chlamydia and gonorrhoea assay allow for testing of both clinician- and patient-collected throat and rectal swabs.



“We developed the throat and rectal claims for Aptima Combo 2 to help clinical teams accurately diagnose and treat these common, but potentially serious diseases,” said João Malagueira, VP Sales Diagnostics, EMEA. “These new samples, which can now be collected by the patient or the clinician using the Aptima® Multitest Swab Specimen Collection Kit, broaden the range of patient-collected samples available and allow us to offer the widest range of collection options.”

The excellent performance of the assay across sample types is reflected in throat and rectal samples, where Aptima Combo 2 demonstrates up to 100% sensitivity and specificity in detecting chlamydia and gonorrhoea.[\[1\]](#)

About Aptima Combo 2

The APTIMA Combo 2 Assay can be used to test endocervical, throat, rectal, and male urethral swab specimens; female and male urine specimens; and cervical samples collected in PreservCyt Solution from symptomatic and asymptomatic individuals. The Aptima Combo 2 assay provides an upfront biological advantage compared to assays that detect DNA – up to 1,000-fold more rRNA than DNA per cell.² The assay can be run as a standalone test or run simultaneously with other assays, providing clinicians with more flexibility.

About Chlamydia and Gonorrhoea

Chlamydia and gonorrhoea are the most common notifiable sexually transmitted infections, and most chlamydial infections in the throat and rectum are asymptomatic. The European Centre for Disease Prevention and Control (ECDC) reported that in 2013, 384 555 cases of chlamydia infection were reported in 26 EU/EEA Member States, translating into an overall rate of 182 notifications per 100 000 population.[\[2\]](#) Two-thirds (67%) of all chlamydia infections were reported in young people between 15 and 24 years of age, with the highest rates reported among women aged 20 to 24 years (1,717 cases per 100,000 population). The study also stated that the true incidence of chlamydia is likely to be considerably higher than the reported rates due to the asymptomatic nature of the infection.

The ECDC also stated that in 2013, 52 995 gonorrhoea cases were reported in 28 countries of the EU/EEA, with three times more cases in men than in women. Nearly half of all gonorrhoea cases in 2013 (43%) were reported in men who have sex with men. Incidences of gonorrhoea have increased 79% since 2008, a trend seen in most EU/EEA Member States.

About Hologic, Inc.

Hologic, Inc. is an innovative medical technology company primarily focused on improving women's health and well-being through early detection and treatment. For more information on Hologic, visit www.hologic.com.

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This information is not intended as a product solicitation or promotion where such activities are prohibited. For specific information on what products are available for sale in a particular country, please contact a local Hologic sales representative or write to womenshealth@hologic.com.

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[1] Package insert leaflet for Aptima Combo 2. Updated May 2017 502183EN Rev. 004

[2] European Centre for Disease and Prevention Control. STI trends in Europe: chlamydia rates stabilise while gonorrhoea numbers go up. Sept 15
http://ecdc.europa.eu/en/press/news/_layouts/forms/News_DispForm.aspx?ID=1285&List=8db7286c-fe2d-476c-9133-18ff4cb1b568#sthash.R2cLK8XY.dpuf

² Chernesky M, Jang D, Luinstra K, et al. High analytical sensitivity and low rates of inhibition may contribute to detection of *Chlamydia trachomatis* in significantly more women by the Aptima Combo 2 assay. *J Clin Microbiol*. 2006;**44(2)**:400-405

<http://media.hologic.com/news-releases?item=123054>