

Safe diagnostics for women tested HPV-positive

Greiner Bio-One starts international marketing of the cervical cancer triage test GynTect®

Jena / Frickenhausen, xx.01.2016 – With the start of 2016 the distribution of the cervical cancer triage test GynTect® by Greiner Bio-One has started. For this purpose the internationally active company had closed a marketing and distribution partnership with oncgnostics GmbH, who has developed and produces the GynTect® test, prior to Medica 2015. The CE IVD mark which GynTect® received in October 2015 allows the utilization of the test in laboratories in whole Europe.

GynTect® is a molecular biology test based on so-called epigenetic biomarkers, which yields early, fast and reliable results in the area of cervical cancer diagnostics. The test was developed and is produced by oncgnostics GmbH (www.oncgnostics.com), which is a spin-off from the University women's hospital Jena, Germany, founded early in 2012.

Epigenetic biomarkers yield fast and reliable results in cancer diagnostics.

The development of cancer cells from regular tissue cells is preceded or accompanied by modifications in the DNA, especially methylations. These epigenetic changes can be reliably detected in diagnostic labs by specific molecular biology methods such as the so-called methylation-specific PCR. With GynTect® oncgnostics has developed a molecular test which allows to clarify early if a patient with an abnormal Pap smear result or an infection with high-risk human papillomavirus (HPV), causative agent of cervical cancer, develops or has a cervical disease that requires treatment. Early and reliable diagnostics constitutes the specific potential of GynTect®.

Since GynTect® yields fast and reliable results, it also allows a fast and reliable detection of those women who have a disease that requires treatment. This facilitates the risk assessment during cervical cancer screening: the possibilities for a successful early treatment are improved, while unnecessary, over-hasty surgeries can be avoided.

Marketing and distribution of GynTect starts in several European countries

Greiner Bio-One GmbH (www.gbo.com) is a professional, international distributor, established as a partner of many diagnostic laboratories. With its own PapilloCheck® HPV test the company is already internationally active in the area of cervical cancer screening since several years. As a triage test for women tested HPV-positive, GynTect® is also a triage test for PapilloCheck®. Not only due to the current changes of the cervical cancer screening market towards implementation of HPV-testing in screening scenarios in several European countries as well as the USA, this market is highly attractive and competitive.

“In fact, this is a classical win-win situation. With GynTect® Greiner Bio-one strengthens its position in diagnostics, and we get the ideal partner for national and international distribution of our test. With its long-lasting presence and experience in the relevant diagnostic field Greiner will promote and establish GynTect® within the right target group”, Dr. Alfred Hansel, CEO of oncgnostics, says.

With its internal controls, GynTect® is a reliable test, which is easy to handle and compatible with cervical smear material obtained by different devices and stored in different media.

GynTect® is now available for distribution in Germany, Austria, Switzerland, France, England, Belgium, the Netherlands and Luxemburg. Further European countries as well as Northern America and different Asian states may follow soon.

Further Information:

Obtain GynTect® through Greiner Bio One:

<https://shop.gbo.com/de/germany/articles/catalogue/articles/0140/>

Further information about GynTect® as well as the test procedure, are found here:

<http://www.oncgnostics.com/gyntect-cervical-cancer/information-for-physicians/gyntect-test-procedure/?lang=en>

Find cost-free picture material concerning this press release, the test and the company here:

<http://oncgnostics.com/downloads>

About oncgnostics GmbH:

Oncgnostics GmbH is a spin-off from the research unit of the gynaecology department of the university women's hospital Jena and was founded early in 2012. As a molecular diagnostic company oncgnostics is specialized on cancer diagnostics. Oncgnostics tests target epigenetic changes, so-called DNA methylations, that typically occur in cancer cells. The patented biomarkers which are evaluated using a specific algorithm are the core of the products and provide thus the basis for the company's activities. Prominent investors have already invested into the market potential of the biotech startup, thus enabling the spin-off of the company and the development of the first product (High-Tech-Gründerfonds, Stiftung für Technologie, Innovation und Forschung Thüringen, bm-t Beteiligungsmanagement Thüringen GmbH and further investors).

About Greiner Bio-One GmbH:

Greiner Bio-One specializes in the development, production and distribution of high-quality products for the laboratory market made from synthetic materials. The firm is a technology partner for hospitals, laboratories, universities, research institutes, the diagnostic products and pharmaceutical industry, and biotechnology. Greiner Bio-One is divided into four lines of business: Pre-analytics, BioScience, Diagnostics, and OEM. The Greiner Bio-One Diagnostics Division develops, produces and markets products for human diagnostics, biopharmaceutical production, the food sector, and OEM products for the specialty areas of dental and veterinary medicine. Its two product families "oCheck" and "Genspeed" meet the requirements for mass analyses (high throughput) as well as for individual analyses in acute diagnostics. Its test procedures are used to monitor vaccine safety and to detect sexually transmitted diseases and hospital pathogens, among others. In addition to its head office in Rainbach (Austria), the company's sales and marketing headquarters are located in Frickenhausen (Germany).

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Short description: Distribution of the cervical cancer triage test GynTect® starts through Greiner Bio-One. Oncnostics GmbH, Jena, is legal manufacturer of the test.