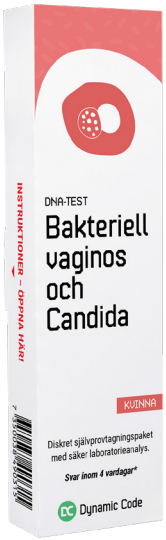
DNA test Bacterial Vaginosis and Candida



Dynamic Code wants to make healthcare safer, smarter, and more readily available for all. It is YOUR health we're talking about. Why should you need to worry unnecessarily, and have to wait passively to get help when you can take responsibility and get a definite answer in just a few days?

Many women experience problems including vaginal itchiness, or a discharge with a bad odour, without knowing that this could be caused by bacterial vaginosis or a vaginal yeast infection (Candida). The symptoms for these are similar, but the required treatment differs between the two. In order to get the correct diagnosis and treatment it is therefore important to get tested for both bacterial vaginosis and Candida.

It is estimated that 10-20% of all women of a fertile age will have bacterial vaginosis[1], and 75% of all women will have Candida[2], at some point in their life. In traditional healthcare practice, bacterial vaginosis and Candida are diagnosed through a clinical examination in accordance with the Amsel criteria, i.e. a KOH test, discharge type, pH value, and microscopy of the vaginal secretion. Often, a woman visiting her doctor will not be examined based on all of the Amsel criteria, and in most cases there will be no test for which particular bacteria and fungi may be present. In order to make the correct diagnosis, it is vital that the number of bacteria, and the relationship between these, are examined.

Untreated bacterial vaginosis can lead to complications. It increases the risk of premature birth and low birthweight, and it even increases the risk of infection following an abortion or a hysterectomy (removal of the uterus).[3] In addition, it increases the risk of contracting Chlamydia and HIV[4].

In order to ensure that you get the correct diagnosis and treatment, we have developed a test that identifies and quantifies the six most common bacteria present in bacterial vaginosis, as well as the four most common types of Candida.

This is how our overall solution works, from obtaining a sample, to meeting with your doctor, to treatment.

Order a test on or website or buy it via a chemist.

Follow the clear instructions and obtain the sample.

Return the sample to us, the packaging will be used for the return shipment.

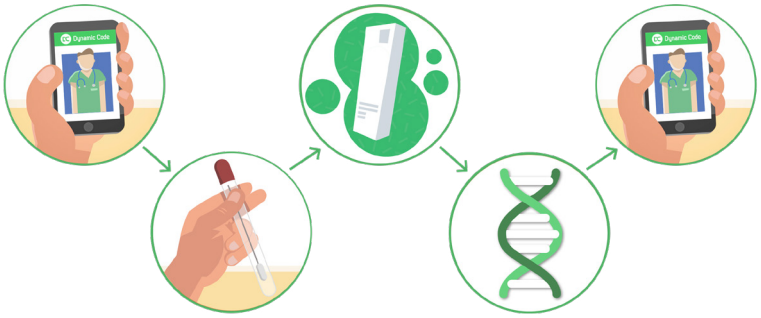
We analyse your sample in our quality-assured laboratory.

Retrieve the test result on our website, using your personal code.

When necessary, we will help forward you to an online healthcare provider.

Order – obtain a sample – send – get the result, and any required assistance, straight to your mobile phone!

With our overall solution, you get help when you need it, without having to visit a health centre. The test result, which is obtained with the help of medical experts, is retrieved on our homepage, and if you would like to see a doctor to discuss your test results, you can do so directly online. The doctor will provide a diagnosis and give you the correct treatment.



If you choose to get in touch with one of our online healthcare providers, with whom we collaborate, then it will be the doctor who orders the test for you. The cost of the test is covered by the patient fee. The test result will go directly to the doctor, who will then provide you with the correct diagnosis and treatment.

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Information on Bacterial Vaginosis and fungal infections in the genital area

Bacterial vaginosis results from an imbalance in the naturally occurring bacterial flora of the vagina. Normally, this bacterial flora is dominated by lactobacilli, but if other bacteria take over at the expense of these lactobacilli, then this can cause problems. A fungal infection is the result of fungal growth is the genital area. In most cases it is the fungus *Candida albicans*, and when fungal levels are high, problems can arise.

Development of the test

The test is developed in accordance with Dynamic Code's guidelines for quality, and it has a solid technical foundation, with a thoroughly tested PCR-methodology and at least two independent scientific studies supporting the connection between diagnosis and the genetic analysis.

Medical expert

Dynamic Code's test for bacterial vaginosis and Candida is examined by our medical expert Dr Per-Göran Larsson, professor of obstetrics & gynaecology.

Methodology for sample taking

In accordance with IVD-directive 98/79/EC and MDD-directive 93/42/EEC, studies have been carried out to ensure that the instructions given on the test's packaging is understood by laypeople. The studies show that the instructions provided with Dynamic Code's test for bacterial vaginosis and Candida are both clear and safe. The instructions cover how the sample is obtained, how it is sent back, and how the result is retrieved.

Method of analysis

Dynamic Code's test for bacterial vaginosis and Candida uses a self-developed method of analysis that is based on PCR and detects six different types of bacteria (*Gardnerella vaginalis, Atophobium vaginae, Leptotrichia/Sneathia spp., Megaspaera spp. Mobiluncus spp.* and *BVAB2*), in relation to *Lactobacillus spp*. Determining the likelihood of bacterial vaginosis is based on so-called "likelihood ratios" for each respective bacteria. A likelihood of >70% is determined as a positive test result. The test can also detect four different types of fungus, belonging to the Candida family (*C. albicans, C. glabrata, C. parapsilosis* and *C. tropicalis*).

Test performance

Dynamic Code's method of analysis has been validated by comparing the results with microscopic analysis of vaginal secretions. The validation was carried out on 289 samples, by an independent laboratory, and the results corresponded in 94% of cases. Based on these results, it is established that the test provides 95% sensitivity, 94% specificity and 94% confidence. Dynamic Code's method of analysis has been compared to that of general diagnostic practice in clinics. It has been discovered that the Amsel criteria are commonly not followed in traditional practice, clearly showing that there is a need for a secure, objective method of analysis for the diagnosis of bacterial vaginosis and Candida, and this is what Dynamic Code offers.

Quality

Dynamic Code is responsible for the manufacturing of the test packages, which are CE-marked in accordance with IVD-directive 98/79/EC and MDD-directive 93/42/EEC, and any additional law changes. Dynamic Code's CE-marked products are also certified by the international organisation DEKRA. Dynamic Code's test for bacterial vaginosis and Candida is registered with the Swedish Medical Products Agency and is therefore included in the EUDAMED database. Dynamic Code's laboratory is accredited by SWEDAC in accordance with ISO17025 standard.

Read more about the quality and validation of Dynamic Code's tests on our website: https://www.dynamiccode.com/se/kvalitetspolicy

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[1] Moi H. Prevalence of bacterial vaginosis and its association with genital infections, inflammation, and contraceptive methods in women attending sexually transmitted disease and primary health clinics. Int J STD AIDS. 1990;1:86-94

[2] Sobel JD. Vulvovaginal candidosis. Lancet. 2007 Jun 9;369:1961-71.

[3] Larsson P-G et al. Clue cells in predicting infektions after abdominal hysterectomy. Obstet Gynecol. 77:450,1991.

[4] Taha TE, Hoover DR, Dallabetta GA, Kumwenda NI, Mtimavalye et al. Bacterial vaginosis and disturbances of vaginal flora: association with increased acquisition of HIV. AIDS. 1998 Sep 10;12:1699-706.

Scan the QR-code to get to the product page of our website.

CE IVD

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About Dynamic Code

Dynamic Code wants to help people take control of their own health, and we develop meaningful health- and diagnostic tests based on DNA technology. The tests are offered on a digital communication and logistics platform, which is revolutionising medical testing and diagnostics. Tests which previously required samples to be taken at clinics by healthcare professionals, which sometimes took months or even years, can now be carried out by patients on their own, and they can receive answers and treatment within days. Without compromising on quality, Dynamic Code's tests fulfil all medical and regulatory demands.

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