

# DNA Test for four STIs

[chlamydia, gonorrhoea, mycoplasma, trichomoniasis]



Dynamic Code wants to make healthcare safer, smarter and more accessible to everyone. It is YOUR health we are taking about. Why should you have to wait passively for help and worry unnecessarily, when you can take responsibility and obtain a safe result in just a few days?

Chlamydia, mycoplasma, gonorrhoea and trichomoniasis are some of the most common STIs in the world. The four STIs have many similarities, e.g. they all get transmitted through unprotected sex, the symptoms can be unclear and difficult to detect. That's why Dynamic Code has developed a test with which you can test for all four STIs at the same time, and thus find out, in one single test, if you have any of the diseases.

Symptoms in both women and men can be a burning sensation when urinating and itchiness in and around the genital area. Woman can have bleeding between periods, vaginal discharge and abdominal pain. Men can get urethral inflammation and discharges from the urethra. Untreated chlamydia, mycoplasma, and gonorrhoea in women can lead to pelvic inflammatory disease, which can lead to ectopic pregnancy (a fertilised egg implants and develops in the fallopian

tube) or impaired fertility<sup>1, 2</sup>. Furthermore, these infections can be passed along from the mother to the child during vaginal childbirth, causing eye infection and pneumonia<sup>3, 4</sup>.

Untreated chlamydia, mycoplasma and gonorrhoea in men can lead to epididymitis, prostatitis, urinary tract inflammation and impaired fertility<sup>1</sup>. The infections are contagious, even if no symptoms are experienced. That is why it is important to test for the diseases, both to avoid complications and to avoid spreading the infections.

Chlamydia, mycoplasma and gonorrhoea are caused by the bacteria *Chlamydia trachomatis*, *Mycoplasma genitalium* and *Neisseria gonorrhoeae*. Trichomoniasis is caused by the parasite *Trichomonas vaginalis*. All four infections are treated with antibiotics, but of different kinds. Today, many mycoplasma infections are resistant to the most common type of antibiotics, which is an increasing problem worldwide<sup>5</sup>. Dynamic Code has developed a test that establishes whether or not the mycoplasma bacteria is resistant, allowing the doctor to give you the correct treatment immediately!

This is how our comprehensive solution works, from test to doctor's appointment and treatment.



Order a test kit on our website or buy one from a pharmacy.



Follow the detailed instructions and collect the sample.



Return the test kit to us. Use the original packaging to return the sample.



Your sample is analysed in our quality reliable laboratories.



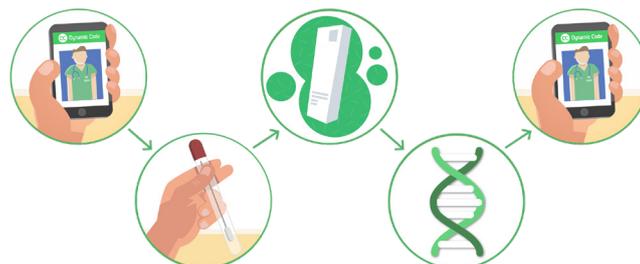
The result can be accessed on our website using your personal code.



If necessary, we will help you further.

## Order – take the sample – mail it – access the result and get help straight in your mobile!

Use our comprehensive solution to get help when you need it. Your test sample is analysed by medical experts and the results can be retrieved on our website. Should you wish to see a doctor to discuss the results, this will be done directly online. The doctor will provide the correct diagnosis.



If you decide to use one of the digital health providers we collaborate with, then the doctor will order the test kit on your behalf. The result is sent directly to the doctor, who will provide the correct diagnosis and the proper treatment.

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## Development of the test

The test has been developed in accordance with Dynamic Code's quality guidelines and is based on solid technical foundations with well-tested PCR methodology and on at least two of each other independent scientific studies supporting the link between diagnosis and genetic analysis.

## Medical expert

Dynamic Codes Test for Four STIs (chlamydia, gonorrhoea, mycoplasma, trichomoniasis) is reviewed by our medical expert Anders Selbing, specialist physician in obstetrics and gynaecology.

## Analysis methodology

Dynamic Code's Test for Four STIs (chlamydia, gonorrhoea, mycoplasma, trichomoniasis) uses a proprietary analysis methodology to detect *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Mycoplasma genitalium* and *Trichomonas vaginalis*. Two markers are used to detect the respective bacteria to determine mutation reliability. Positive mycoplasma samples go through an identification of resistance via a proprietary PCR-based method for the mutations that cause macrolide resistance in *Mycoplasma genitalium*: A2058T, A2058C, A2058G, A2059G.

## Test validation

Dynamic Code's method of analysis for the four STIs (chlamydia, gonorrhoea, mycoplasma, trichomoniasis) has been validated by comparing the obtained results with PCR performed at an external laboratory.

The validation for chlamydia was performed on 414 samples and yielded 100% compliance. Based on the validation results, sensitivity was thus obtained: 100%, specificity: 100% and reliability: 100%. The validation for gonorrhoea was performed on 200 samples and yielded 99.5% compliance. Based on the validation results, sensitivity was thus obtained: 100%, specificity: 99% and reliability: 99.5%. The validation for mycoplasma was performed on 200 samples and yielded 100% compliance. Based on the validation results, sensitivity was thus obtained: 100%, specificity: 100% and reliability: 100%. Identification of resistance of *Mycoplasma genitalium* was validated by comparing obtained results with sequencing performed at an external laboratory. The validation was performed on 81 samples and yielded 96% compliance. Based on the validation results, sensitivity was thus obtained: 100%, specificity: 94% and reliability: 96%. The validation for trichomoniasis was performed on 200 samples and yielded 99% compliance. Based on the validation results, sensitivity was thus obtained: 99%, specificity: 95% and reliability: 99%.

## Quality

Dynamic Code is responsible for the production of the sampling packages, which are CE-marked in accordance with IVD directive 98/79/EC, MDD directive 93/42/EEC and all subsequent legislative amendments. Dynamic Code's CE-marked products are further certified by international inspection body DEKRA. Dynamic Code's Test for Four STIs (chlamydia, gonorrhoea, mycoplasma, trichomoniasis) is registered with the Swedish Medical Products Agency and is thus included in the EUDAMED database. Dynamic Code's laboratories are accredited by SWEDAC in accordance with the ISO17025 standard.

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

<sup>1</sup> <https://www.folkhalsomyndigheten.se/folkhalsorapportering-statistik/statistikdatabaser-och-visualisering/sjukdomsstatistik/gonorre/>

<sup>2</sup> <https://www.folkhalsomyndigheten.se/contentassets/345ad3e05ad945becdba42d0a0150c9/faktablad-rad-fakta-sti-mycoplasma-genitalium-svenska.pdf>

<sup>3</sup> <https://www.folkhalsomyndigheten.se/smittskydd-beredskap/smittsamma-sjukdomar/klamydiainfektion/>

<sup>4</sup> <http://www.cdc.gov/std/gonorrhea/stdfact-gonorrhea.htm>

<sup>5</sup> <https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance>



Scan the QR code to access the product page on our website.

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## Om Dynamic Code

Dynamic Code vill hjälpa människor att ta kontroll över sin egen hälsa och utveckla meningsfulla hälso- och diagnostest baserat på DNA-teknik. Testerna erbjuds i en digital kommunikations- och logistikplattform som håller på att revolutionera medicinsk provtagning och diagnostester. Tester som tidigare krävt provtagning hos kliniker och av vårdpersonal och ibland tagit månader och år, kan patienterna nu göra själva och få svar och behandling på några dagar. Utan att tumma på kvaliteten – Dynamic Codes tester uppfyller alla medicinska och regulatoriska krav.