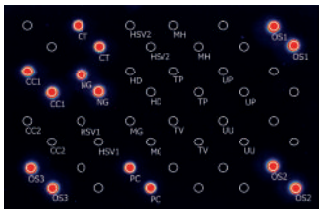
EUROArray STI



- **Detection of up to 11 sexually transmitted pathogens in one reaction**
- **Reliable identification of multiple infections (including asymptomatic)**
- **Fully automated and standardised evaluation with the EUROArrayScanner**

Technical data

Substrate	Single-stranded DNA probes, length: 15 to 50 nucleotides
Test procedure	PCR (approx. 60 min) / hybridisation (60 min) / fully automated evaluation Total working time approx. 1.5 min per sample (with 40 samples per run)
Reagents	Ready for use
Controls	DNA negative control and further integrated controls
CE IVD certificate	Complete process is validated
Test kit format	5, 10 or 20 slides, each with 5 reaction fields or 8 slides, each with 3 reaction fields
Order no.	**MN 2830-0505, -1005, -2005, -0803: EUROArray STI-11** (Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), herpes simplex virus 1 (HSV-1), herpe simplex virus 2 (HSV-2), Haemophilus ducreyi (HD), Mycoplasma genitalium (MG), Mycoplasma hominis (MH), Treponema pallidum (TP), Trichomonas vaginalis (TV), Ureaplasma parvum (UP) Ureaplasma urealyticum (UU)) **MN 2830-0505-1, -1005-1, -2005-1, -0803-1: EUROArray STI-7** (HD, MG, MH, TP, TV, UP, UU) **MN 2830-0505-2, -1005-2, -2005-2, -0803-2: EUROArray STI-CT/NG** (CT, NG) **MN 2830-0505-3, -1005-3, -2005-3, -0803-3: EUROArray STI-CT/NG/TP/TV** (CT, NG, TP, TV) **MN 2830-0505-4, -1005-4, -2005-4, -0803-4: EUROArray STI-6** (CT, NG, HSV-1, HSV-2, TP, TV) **MN 2830-0505-5, -1005-5, -2005-5, -0803-5: EUROArray STI-HSV-1/2** (HSV-1, HSV-2)

Clinical significance

The EUROArray STI test systems provide PCR-based direct detection of up to eleven sexually transmitted pathogens. Timely detec tion of these pathogens and subsequent treatment can prevent consequential damage, which can lead to severe chronic disease or infertility. In addition to the direct consequences for the patient, infection with most of the above pathogens during pregnancy can lead to intrauterine death, premature birth or damage to the foetus. Moreover, many pathogens can be transmitted to the newborn during birth, causing severe postnatal infections.

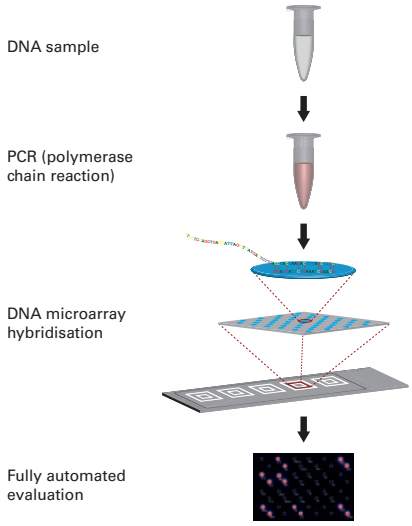
PCR-based direct detection is particularly useful for the detection of sexually transmitted pathogens that are difficult or impossible to cultivate (Chlamydia trachomatis, Mycoplasma, Ureaplasma, Treponema pallidum). Moreover, due to the amplification of the pathogen DNA, infections with a reduced pathogen number can also be reliably identified. The combined detection of all patho gens with the EUROArray STI test systems is especially useful for clarifying ambiguous clinical findings, identifying asymptomati infections as part of pregnancy healthcare, and identifying multiple infections with different sexually transmitted pathogens.

Diagnostic application

The EUROArray STI test systems enable simultaneous determination of up to eleven sexually transmitted pathogens in one reaction The detection is highly specific and sensitive and offers an enormous time advantage over detection by culturing. The EUROArray STI test systems therefore contribute substantially to improving diagnosis of infections with sexually transmitted pathogens.

Test principle

The EUROArray STI test systems are based on the multiplication of defined gene sections of the pathogens and subsequent determination through a hybridisation reaction with immobilised DNA probes in a microarray system. In the first reaction step, specific DNA sections from the pathogens present in the sample are amplified by polymerase chain reaction (PCR) using a multiplex primer system and, at the same time, labelled with a fluorescent dye. In a second step, the products are detected using an oligonucleotide microarray. The specific binding (hybridisation) of the fluorescence-labelled PCR product to the corresponding oligonucleotide probe is detected using a special microarray scanner (EUROArrayScanner). The EUROArrayScan software evaluates all spot signals automatically and deduces the test result.



Test performance

The PCRs are incubated in the thermocycler and then, using the TITERPLANE technique, on EUROArray slides containing microarray BIOCHIPs. Scanning and evaluation are performed using the EUROArrayScanner (incl. EUROArrayScan software). This provides fully automated evaluation of EUROArray analyses and detailed documentation of results.

Analytical sensitivity

The lower detection limit (limit of detection, LOD) of the EUROArray STI-11 depends on the pathogen and lies between 10 and 100 DNA copies/reaction. The LOD is the minimum detection limit. Usually fewer DNA copies of the pathgen are detected.

Analytical specificity

The specificity of the EUROArray STI-11 is ensured by the primer and probe design and by the defined PCR and hybridisation conditions. The PCR amplification products from the different pathogens do not show any cross reactivity with probes for other pathogens when template DNA is used at concentrations ranging from the LOD to 2 million copies. Further, it was experimentally verified that there are no cross reactivities with 28 microorganisms found in anogenital regions.

Evaluation

In an evaluation study, 325 smears and 134 urine samples were analysed using the EUROArray STI-11. There was a good agreement with the precharacterisation. In many cases, additional pathogens that were not included in the precharacterisation were detected. These additional findings were verified by independent tests.

Literature

1. Bignell C, Ison CA. Gonorrhoea. Sex Transm Inf 2006; 82: 6-9.
2. Marais NF, Wessels PH, Smith MS, Gericke A, Richter A. Chlamydia trachomatis, Mycoplasma hominis and Ureaplasma urealyticum infections in women. Prevalence, risks and management at a South African infertility clinic. J. Reprod. Med. Mar; 36: 161-164 (1991).
3. World Health Organization: Laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus. Geneva: World Health Organization; 2013.