

Comparative Testing

Bosch Vivalytic versus Standard RT-PCR-Diagnostic Test

Performed at Kinderwunsch Praxisklinik Fleetinsel in Hamburg (Feb. 17, 2023)

Screening for Sexually Transmitted Infections (STI)

Background

Involuntary childlessness can have different etiological reasons. Female or male factors may contribute to infertility. Among others, sexually transmitted infections (STI) are known as a risk factor for infertility. To detect or exclude acute infections, screening for STI is important, so that any infection can be treated. According to the guidelines of the German Medical Association, such screening should be performed, in addition to a test for HIV and hepatitis B and C, before starting assisted reproduction. This makes microbiological testing of a vaginal swab sample mandatory – which is also recommended by the ESHRE guideline (European Society of Human Reproduction and Embryology) for assisted reproduction. From a medical point of view, testing of a very broad spectrum of pathogens is useful, so that possible infections can be cured before pregnancy. This will also minimize the risks of subsequent transmission from mother to child.

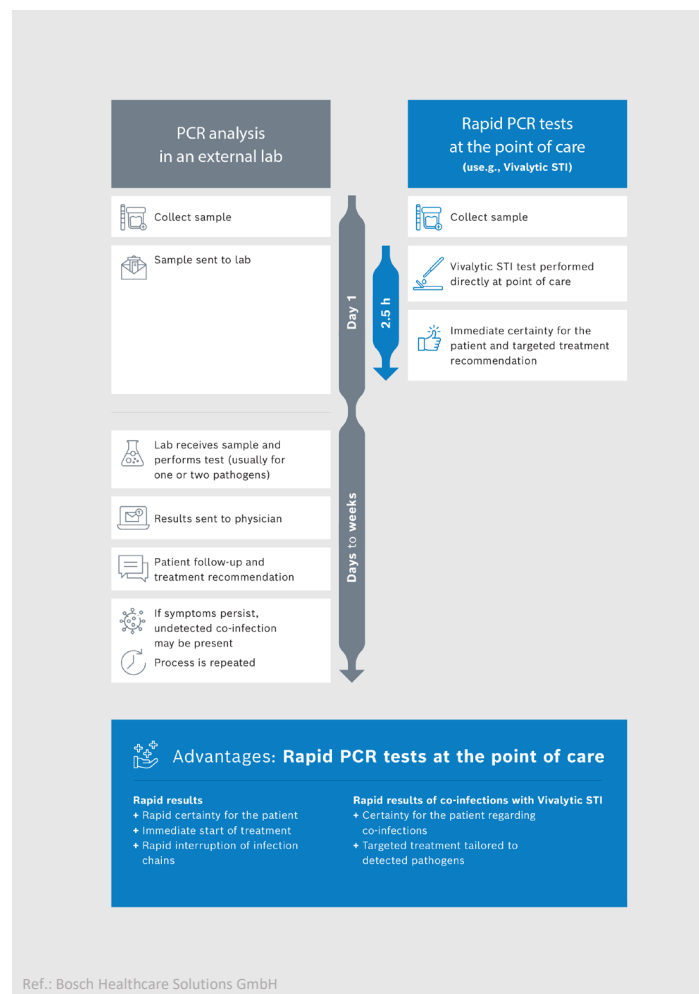
Screening for STI is easy with a point-of-care testing device which allows a rapid PCR test to be performed on site, e.g. at a fertility clinic. This kind of rapid PCR test screens for several different pathogens simultaneously, which offers many advantages: On the one hand, the result is available on site after a very short time. On the other hand, a broad range of pathogens can be tested within a single test, so co-infections can be found or excluded that would remain undetected with individual tests. This significantly increases the efficiency of diagnosis. Targeted treatment can immediately be initiated; sexual partners can be informed and, if necessary, their treatment can be initiated simultaneously. This is a very effective way to prevent the spread of infections and to accelerate recovery.

Test performance

A comparative test was performed at the Kinderwunsch Praxisklinik Fleetinsel in Hamburg in order to assess the applicability and performance of the Vivalytic PCR Analyser compared to a commercially available high-throughput RT-PCR diagnostic test in the laboratory. 61 samples (swabs and urine samples) from asymptomatic individuals were evaluated. First, the samples were tested for sexually transmitted infections on site, using the Vivalytic STI microarray PCR test. Subsequently, the frozen samples were taken to the Dr. Fenner & Kollegen MVZ laboratory and screened for the same pathogens using standard RT-PCR (Seegene Allplex™ Genital ulcer Assay and Allplex™ STI Essential Assay).

Testing included the following pathogens:

- *Chlamydia trachomatis*
- *Neisseria gonorrhoeae*
- *Trichomonas vaginalis*
- *Treponema pallidum*
- Herpes simplex virus I (HSV-1)
- Herpes simplex virus II (HSV-2)
- *Mycoplasma hominis*
- *Mycoplasma genitalium*
- *Ureaplasma urealyticum*
- *Haemophilus ducreyi*



Results and conclusion

Out of the 61 tested samples, a total of 8 samples tested positive: *Ureaplasma urealyticum* was detected in 5 samples, 2 samples tested positive for *Mycoplasma hominis*. One sample showed a positive result for HSV-2.

The Vivalytic Analyser showed high consistency with the standard PCR test. In the described testing, the concordance rate was at 98.36%. The sensitivity of the Vivalytic test was at 100%, which was as high as that of standard PCR testing in the laboratory. The specificity of the Vivalytic system in this test series was at 98.18%.

"The Vivalytic Analyser appears suitable to provide reliable diagnostics for detection or exclusion of sexually transmitted diseases, for example in fertility clinics. Thus, targeted treatment of patients can quickly be initiated, reducing follow-up costs and time." (Priv.-Doz. Dr. Kay Neumann, Head of Kinderwunsch Praxisklinik Fleetinsel)

Reference: Bosch Healthcare Solutions GmbH, STI Whitepaper; https://www.bosch-vivalytic.com/media/images_1/documents/tests/rz_bosch_whitepaper_sti_doppelseiten.pdf