STI & Women's health

Product Portfolio

Flexible:
Extensive portfolio – the right solution for every laboratory routine

Individual:
The right system for every sample throughput

Precise:
High sensitivity and specificity thanks to selected Technologies

More information:

https://r-b.io/sti-en

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What requirements does your laboratory have?

Flexible solutions for your molecular diagnostics laboratory

Highplex Alliance™ & Ultraplex Alliance™

Semi-automated

The multiplex tandem PCR offers outstanding sensitivity and specificity even in the highly plexed system

- Efficient processing through the parallel detection of viruses, bacteria and fungi; up to 30 pathogens in one run
- Suitable for multiple requirements in medium to high sample throughput ranges

RIDA®GENE

Manually

Direct detection of the target sequence using real-time PCR

- Efficient combination of all RIDA®GENE assays independent of the detection of RNA or DNA
- Adaptation to your individual routine with 100 reactions per product and 20 thaw/freeze cycles
- Suitable for specific requirements in low to high sample throughput ranges

Vivalytic

Fully automated

Fully automated molecular diagnostics at the point of care

- Flexibility through fully automated processing of single to multiplex applications
- Easy handling due to intuitive cartridges
- Connection to KIS possible
- Suitable for multiple requirement profiles with low sample throughput

BOSCH
Technik fürs Leben

Vivalytic

Microbix

Quality Controls

External Quality Controls from Microbix

- Can be used for ongoing external quality control
- For assay and device verification/validation
- Operator training

Challenges in STI diagnostics

Why is a comprehensive STI-diagnostic important?

STIs, mainly transmitted through sexual intercourse, are caused by multiple pathogens. The variety of symptoms, the often asymptomatic nature and the frequent multiple infections in sexually transmitted diseases emphasize the relevance of multiplex testing. This enables comprehensive detection of important sexually transmitted pathogens in one approach.

The recent emergence and rapid spread of a new Mpox variant (Mpox clade 1) is currently of particular interest. The focus of diagnostics here is on rapid detection and differentiation from common STIs in order to prevent global spread.

Detect multiple infections:
Multiple infections are common! In risk groups 29 % of patients show a double infection, three or more pathogens occur in approx. 16 % of all cases[1]. Specialist associations therefore recommend diagnostics with PCR multiplex tests.

Prevent the spread:
STI infections can be asymptomatic in up to 70 % of cases[2].
Recognition of asymptomatic infections is therefore essential!

Targeted treatment:
The choice of the right antibiotic depends on comprehensive diagnostics! Consequential damage can only be prevented if all pathogens to be treated are identified and their resistance status is known.

Use our extensive portfolio in the fight against STIs

Haven't found the right product yet?

We have a suitable solution for your diagnostic needs and will be happy to advise you!

Please contact us personally:
MDX@r-biopharm.de

[1] Epidemiologisches Bulletin 45/2023
[2] Kenyon et. al; Management of asymptomatic sexually transmitted infections in Europe: towards a differentiated, evidence-based approach; The Lancet Regional Health - Europe 2023;34: 100743

TandemPlex® Panels

TandemPlex® panels feature our proprietary multiplextandem PCR (MT-PCR) technology, a highly multiplexed molecular method that empowers users with the added capability to detect viruses, bacteria, parasites and fungi in a single run. MT-PCR enables comprehensive syndromic diagnosis and earlier medical intervention.

Multiplex Tandem PCR (MT-PCR)

MT-PCR is based on a two-step PCR, in which the gene fragments of interest are pre-amplified in a few copies before entering a second round of PCR using nested primers. Combining the unique primer design and consecutive PCR steps offers maximum sensitivity and specificity so that even the most minor nucleic acids are detected efficiently.

Reliable and efficient

Multiplexed molecular methods are becoming the gold standard for the detection of multiple pathogens due to their superior sensitivity, rapid turnaround time, security, and ability to identify multiple pathogens, some of which are slow growing or difficult to culture.

STI TandemPlex® Panels

Urinogenital 8-well

Art. Nr. 27113

Major STI
Chlamydia trachomatis
Neisseria gonorrhoeae
(2 Zielgene)
Trichomonas vaginalis
Mycoplasma genitaliu

Conditionally pathogenic flora
Mycoplasma hominis
Ureaplasma parvum
Ureaplasma urealyticum

Urinogenital and Resistance 12-well

Art. Nr. 87123

Major STI
Chlamydia trachomatis
Chlamydia trachomatis LGV
Neisseria gonorrhoeae
(2-assays)
Trichomonas vaginalis
Mycoplasma genitalium

Conditionally pathogenic flora
Mycoplasma hominis
Ureaplasma parvum
Ureaplasma urealyticum

Ceftriaxon resistances
Neisseria gonorrhoeae penA-60 (RUO)

Fluoroquinolon resistances
Mycoplasma genitalium parC

Makrolid resistances
Mycoplasma genitalium 23S

STI 16-well

Art. Nr. 27112

STI Screening
Chlamydia trachomatis
Mycoplasma genitalium
Neisseria gonorrhoeae
(2 Zielgene)
Trichomonas vaginalis

Conditionally pathogenic flora
Mycoplasma hominis
Streptococcus agalactiae (GBS)
Ureaplasma urealyticum
Ureaplasma parvum

Genital ulcer
Chlamydia trachomatis LGV
Haemophilus ducreyi (RUO)
HSV 1 (Human herpesvirus 1)
HSV 2 (Human herpesvirus 2)
Treponema pallidum

Thrush
Candida albicans
Candida glabrata
Candida krusei
(*Pichia kudriavzevii*)

LGV: *Lymphogranuloma venerum*

Your advantages

Sample material:
- Various swabs, urine, semen

Panel compositions:
- Large panel to avoid retesting and for Time-saving diagnostics
- Reliable *Neisseria gonorrhoeae* diagnostics through determination with dual target
- Integrated differentiation of *Chlamydia trachomatis* LGV
- Time-saving diagnostics thanks to integrated resistance determination
- Detection of Group B streptococci included
- Can be partially processed without extraction

Sexual Health TandemPlex® Panels

Viral and Syphilis 12-well

Art. Nr. 87095

HSV 1 (Human herpesvirus 1)
HSV 2 (Human herpesvirus 2)
VZV (Human herpesvirus 3)
EBV (Human herpesvirus 4)
CMV (Human herpesvirus 5)
HHV 6 (Human herpesvirus 6)
Treponema pallidum
Enterovirus
Parechovirus types 1-8
Adenovirus group B, C, and E

Your advantages

Sample material:
- Various swabs, urine, CSF, plasma/serum, EDTA blood, BAL

Panel compositions:
- Laboratory optimization through bundling of patient samples
- Combination of targets requested in small quantities
- Standardization of the laboratory routine

Vaginitis and Vaginosis (Universal) 12-well

Art. Nr. 87124

Bacterial Vaginosis
Gardnerella vaginalis
Atopobium vaginae
Lactobacillus crispatus
Lactobacillus iners
Lactobacillus jensenii
Lactobacillus gasser

Trichomonas vaginalis
Trichomonas vaginalis

Candidiasis
Candida albicans
Candida tropicalis
Candida glabrata
Candida krusei
(Pichia kudriavzevii)
Candida parapsilosis

Your advantages

Sample material:
- Vaginal swabs

Panel compositions:
- Time saving through simple PCR diagnostics
- Simple interpretation through automatic evaluation of the vaginal flora analysis (normal, intermediate, bacterial vaginosis)
- Additional safety by highlighting high *Lactobacillus iners* concentrations
- Comprehensive diagnostics through included *Trichomonas* and *Candida* detection
- Can be partially processed without extraction

High-Risk HPV Genotyping 8-well

Art. Nr. 23201

HPV16
HPV18
HPV31
HPV33
HPV35
HPV39
HPV45
HPV51
HPV52
HPV56
HPV58
HPV59
HPV66
HPV68

Your advantages

Sample material:
- Liquid based cytology

Panel compositions:
- Reliable determination of the most common high-risk HPV genotypes

Research Use Only/Not for *in-vitro* diagnostic use

HPV (High-Low Risk) 16-well

Art. Nr. 23202

High Risk			Low Risk
HPV16	HPV39	HPV58	HPV6
HPV18	HPV45	HPV59	HPV11
HPV31	HPV51	HPV66	HPV42
HPV33	HPV52	HPV68	HPV43
HPV35	HPV56	HPV82	HPV44

Research Use Only/Not for *in-vitro* diagnostic use

Lesions and Ulcers 12-well (RUO)

Art. Nr. 87191

Herpes viruses
HSV-1 (Human herpesvirus 1)
HSV-2 (Human herpesvirus 2)
VZV (Human herpesvirus 3)
Other viruses
Adenovirus group B, C, E
Enterovirus
Mpox virus
Bacteria
Chlamydia trachomatis LGV
Treponema pallidum
Haemophilus ducreyi

RIDA®GENE Portfolio

RIDA®GENE

The R-Biopharm RIDA®GENE kits are based on real-time PCR technology, which enables direct and qualitative detection of sexually transmitted infections, gastrointestinal infections, hospital-acquired infections (HAI) and respiratory tract infections.

The RIDA®GENE PCR assays are characterized by their flexible use.

Matching their existing workflow, the assays can be used with different extraction and detection systems.

As almost all RIDA®GENE products are processed in the same way, the tests can be combined as required.

RIDA®GENE STI Mycoplasma Panel

100 Tests

Art. Nr. PG4945

Mycoplasma hominis
Mycoplasma genitalum
Ureaplasma urealyticum
Ureaplasma parvum

Your advantages

Sample material:
- Genital swabs, urine

Panel compositions:
- Detection of common mycoplasmas/ureaplasmas
- Combined processing with other RIDA®GENE products possible

Research Use Only/Not for *in-vitro* diagnostic use

RIDA®GENE Mpox Virus (RUO)

100 Tests

Art. Nr. PG4915RUO

Mpox viruses (MPXV) DNA

Your advantages

Sample material:
- Swabs

Panel compositions:
- Combined processing with other RIDA®GENE products possible
- Detection of clade I and clade II

Vivalytic Portfolio

Vivalytic

Vivalytic is an all-in-one universal platform for molecular diagnostics, developed by Bosch Healthcare Solutions GmbH. It offers exceptional benefits for healthcare professionals in laboratories, clinics and physicians offices. The ability to run different analysis methods in a fully automated manner within short timeframes almost anywhere desired sets it apart from traditional diagnostic platforms with manual workflows.

A comprehensive assay menu, covering a huge number of clinically relevant parameters, complements the fully automated approach of previously manual analysis steps. The Vivalytic STI Panel uses a sophisticated panel approach for simultaneous detection of 10 common sexually transmitted pathogens. It enables healthcare professionals to start the appropriate treatment immediately as well as enhancing the containment of STIs.

Vivalytic STI 15 Cartridges

Art. Nr. V2010

Bacterial and parasitic infections
Neisseria gonorrhoeae (NG)
Mycoplasma genitalium (MG)
Ureaplasma urealyticum (UU)
Chlamydia trachomatis (CT)
Trichomonas vaginalis (TV)
Haemophilus ducreyi (HD)
Mycoplasma hominis (MH)
Treponema pallidum (TP)

Viral infections
Herpes simplex Virus 1 (HSV 1)
Herpes simplex Virus 2 (HSV 2)

Vivalytic MG, MH, UP/UU 15 Cartridges

Art. Nr. V1016

Bacterial infections
Mycoplasma genitalium
Mycoplasma hominis
Ureaplasma parvum/urealyticum

Research Use Only/Not for *in-vitro* diagnostic use

Vivalytic MPXV (RUO) 15 Cartridges

Art. Nr. V1018RUO

MPXV virus and Orthopoxvirus species

Your advantages

Sample material:
- various swabs, urine

Panel compositions:
- Simultaneous detection of 10 common sexually transmitted pathogens.
- The MPXV assay detects clade 1 and clade 2 as well as Orthopoxvirus species

Reliable quality controls

With the help of External Quality Controls it is possible to find and correct errors in the preanalytical, analytical, and post-analytical phases of an assay workflow to ensure the delivery of accurate results. The External Quality Controls resemble patient specimens and are prepared and processed according to the diagnostic manufacturer's instructions for handling patient specimens. When used regularly, a laboratory should be able to detect deviations in the assay workflow early on.

Microbix's Quality Assessment Products (QAPs™) portfolio currently offers quality controls under the brands PROCEEDx™, ONBOARDx™ and REDx™, which can be used together with tests for molecular and immunological diagnosis of bacterial, viral and parasite associated diseases in the areas of respiratory infections, gastrointestinal infections, sexually transmitted infections, genital ulcer disease infections, and human papillomavirus infections.

RED™ controls

IVD Quality control

Can be used for ongoing external quality control, benchmarking laboratory testing performance, operator training & competency, and end-to end workflow evaluation.

PROCEED™

Verification/Validation RUO

Used for assay verification/ validation, training and R&D purposes.

ONBOARD™ kit

Verification/Validation RUO

For assay verification/ validation, instrument qualification and operator training. Consists of various PROCEEDx™ samples.

Your advantages

- In clinically relevant matrix
- Produced from native pathogens when possible
- Very similar to patient samples
- Not infectious
- Cross-assay and cross-instrument compatible
- Applicable in conjunction with nucleic acid based and immunodiagnostic assays
- Positive and negative controls available
- stable for up tot wo years
- Point-of-Care-Testing compatibility

Detailed information about our Quality Assessment Products (QAPs™) portfolio from Microbix can be found here:

https://r-b.io/microbix-en