VAGINOSIS
Differential diagnosis

Molecular solutions to
meet your laboratory needs

VAGINAL PANEL REALTIME PCR KIT

One-step, real-time amplification to detect nucleic acids from *Gardnerella vaginalis* (GV), *Lactobacillus* spp. (LB), *Atopobium vaginae* (AV), *Trichomonas vaginalis* (TV), *Candida glabrata* (CG), *Candida* spp. (CSPP), *Candida albicans* (CA), and *Candida krusei* (CK) in human vaginal swabs.

- Multiplex PCR of **10 targets in two reaction tubes** per sample.
- Simultaneous analysis of **8 pathogens** using specific targets: GV, LB, AV, TV, CG, CSPP, CA and CK.
- **Automatic interpretation of results**. Relative quantification of bacterial vaginosis (LB, GV and AV)
- Suitable for **qPCR cyclers associated with VIRCOM interpretation software**.
- **Endogenous human *RNAse P* control** for monitoring the carry-over of amplification inhibitors, sample integrity and the correct amplification set-up.
- Fast and reliable **results in less than 2 hours**.
- **Lyophilized** master mix and positive control to ensure stability and reduce transportation costs.
- **New pre-dispensed format** of 96 x 0.1 ml tear-off plate with 12 break-a-part 8-tube strips (LPD) for greater user convenience.

Ref. RTPCR005-LPD

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Differential diagnosis of vaginosis

APPLICATIONS

Human vaginal swab samples.

CONTENT

Master mix A and B, Reconstitution solution, Positive and Negative control. Each mix includes internal control primers/probes for human specimen validation that allows detecting improper sample collection or degradation.

Kit formats:

Ref. RTPCR005-LPD contains caps and 96 x 0.1ml Tear Off 8-Tube Strip Mat with pre-dispensed lyophilized master mix.

COMPATIBILITY

Extraction systems: BioMérieux (NucliSENS® easyMag®), Roche (MagNA Pure System), TANBead (Maelstrom 4800 and 9600), Thermo Fisher Scientific (KingFisher Flex) and Bruker (GenoXtract 12), among others.

RealTime PCR thermocyclers: Bio Rad (CFX96 Touch™).

TARGETS

	Mix	Target	Channel
G. vaginalis	A	***16s* gene**	FAM
Lactobacillus spp.	A	***rplK* gene**	HEX/VIC
A.vaginae	A	***16s* gene**	Texas Red/ROX
T. vaginalis	A	***TRIDNATARP* gene**	Cy5
C. glabrata	B	***ITS* gene**	FAM
Candida spp.*	B	***ITS* gene**	HEX/VIC
C. albicans	B	***ITS* gene**	Texas Red/ROX
C. krusei	B	***ITS* gene**	Cy5
Internal Control	A, B	**Human *RNase P* gene**	Quasar 705 (Cy5.5)

** Candida tropicalis/Candida parapsilosis/Candida dubliniensis*

INTERPRETATION OF RESULTS

The interpretation of results requires the use of VIRCOM MOLECULAR COMMUNICATIONS SOFTWARE that performs an automatic calculation using the relative presence of three markers (LB, GV and AV) to detect bacterial vaginosis and classify the vaginal flora (G1-G4).

Normal Flora

There is no significant alteration based on the relative presence of *Lactobacillus* spp. and *G. vaginalis/A. vaginae* markers:

- **Grade 1**: Only *Lactobacillus* spp. is present.
- **Grade 2**: Flora dominated by *Lactobacillus* spp. but with presence of *G. vaginalis/A. vaginae*.

Bacterial Vaginosis

Significant alteration between the presence of *Lactobacillus* spp. and *G. vaginalis/A. vaginae*:

- **Grade 3**: Flora associated with bacterial vaginosis dominated by *G. vaginalis/A. vaginae*, yet with presence of *Lactobacillus* spp.
- **Grade 4**: Flora associated with bacterial vaginosis or abnormal flora. *Lactobacillus* spp. is scarce or absent in the sample. *G. vaginalis/A. vaginae* might predominate. Alteration of the normal flora may also be caused by other microorganisms not included in this kit.

Likewise the kit qualitatively detects the presence of *Trichomonas vaginalis* and different species of *Candida* spp, including *C. glabrata* and *C. krusei,* which are relevant for their resistance to azoles.

PERFORMANCE

	Sensitivity	Specificity	No. of samples
Bacterial Vaginosis	96%	92%	100
Trichomonas vaginalis	96%	100%	100
Candida glabrata	96%	100%	100
Candida spp.	97%	100%	113
Candida albicans	94%	100%	100
Candida krusei	96%	100%	100

The classification of the samples as bacterial vaginosis or normal flora was made by comparing Gram staining and the Nugent score. The detection of *T. vaginalis* or *Candida* DNA was carried out by comparing with other commercial RTPCR kits.

INFORMATION AND RELATED PRODUCTS

Description	Reference	Content
VAGINAL PANEL REALTIME PCR KIT	RTPCR005-LPD	48 tests
CT/NG/TV/MG REALTIME PCR KIT	RTPCR006/-LPD	96 tests
AMPLIRUN TOTAL CT/NG/TV/MGE CONTROL (SWAB)	MBTC024-R	10 vials

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