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NOT FOR IN VITRO DIAGNOSTICS

NOT FDA APPROVED

Amur Vaginal Microbiota Panel A

Bandit Biosystems — Multiplex qPCR Primer/Probe & Controls Kit for Vaginal Microbiota Detection

Bandit BIOSYSTEMS

Description

The **Amur Vaginal Microbiota Panel A** is a multiplex qPCR primer/probe and controls kit used to detect nucleic acid from specific pathogens and microbiota associated with vaginal health. The panel can be used in multiplex qPCR tests to detect nucleic acid from the organisms associated with Sexually transmitted infections, Bacterial Vaginosis (BV) and yeast infections.

Key Product Features

- Detects nucleic acid from 37 pathogen and microbiota targets plus human RNaseP internal control
- Optimized for 96-well and 384-well formats at 15 µL reactions
- 10 multiplexed 15X Primer/Probe Mixes included
- 4 Positive Controls included

Important Notices

- May not detect emerging novel mutated strains
- Amplification Master mix kit must be purchased separately (PN: 500024)
- Use of alternate master mixes is not supported by Bandit Biosystems

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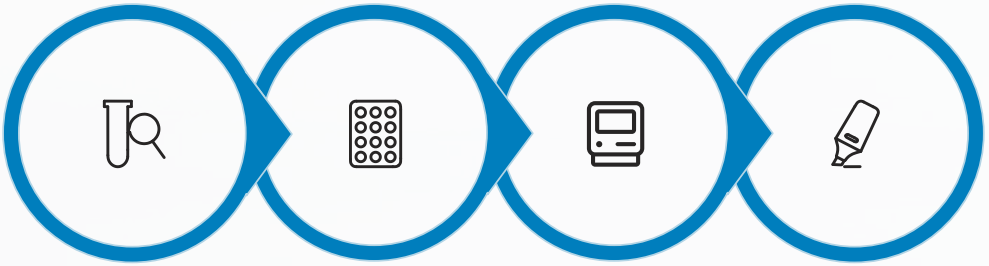
Target Pathogens & Microbiota

The panel simultaneously detects the following 37 pathogens, antibiotic resistance genes and microbiota targets, plus human RNaseP (hRPP) as an internal sample integrity control in a single multiplex qPCR workflow:

Target	Target
(Herpes simplex virus) HSV 2	*Lactobacillus crispatus*
(Herpes Simplex virus) HSV 1	*Lactobacillus jensenii*
Treponema pallidum	*Lactobacillus iners*
Gardnerella vaginalis	*Lactobacillus gasseri*
Neisseria gonorrhoeae	*Megasphaera* 1
Chlamydia trachomatis	*Megasphaera* 2
Trichomonas vaginalis	*Mobiluncus curtisii*
Haemophilus ducreyi	*Mobiluncus mulieris*
Mycoplasma genitalium	*Candida krusei*
Ureaplasma urealyticum	*Candida tropicalis*
Atopobium vaginae	*Candida glabrata*
Group B Strep (S*treptococcus agalactiae*)	*Candida parapsilosis*
Escherichia coli	*Candida albicans*
Enterococcus faecalis	*Candida lusitaniae*
Prevotella bivia	*Candida auris*
Staphylococcus aureus	VanA (Antibiotic resistance gene)
Bacteroides fragilis	MecA (Antibiotic resistance gene)
Mycoplasma hominis	VanB (Antibiotic resistance gene)
BVAB2	Human RNaseP (hRPP) — Internal Control

Test Principle

The Amur Vaginal Microbiota Panel A leverages **TaqMan-based multiplex qPCR chemistry** to simultaneously detect multiple vaginal microbiota and pathogen targets in a single reaction.



Sample Extraction | qPCR Plate Setup | qPCR Amplification | Fluorescence Analysis

During amplification, the 5' nuclease activity of Taq polymerase degrades the probe, separating the reporter dye from the quencher and generating a fluorescent signal that increases with each cycle. The human RNaseP (hRPP) gene is used as an internal sample integrity control.

Step 1

Sample Extraction — isolate DNA using a validated extraction method

Step 2a

Master Mix Setup — combine 2X Master Mix, nuclease-free water, and 15X Primer/Probe Mix as described in Master Mix setup table

Step 2b

Add 4 µL extracted sample, positive control, or NTC to each well containing 11 µL master mix

Steps 3–4

Run qPCR and analyze fluorescence data per channel

Required Instrumentation

Equipment	Specification
qPCR Instrument	Any instrument capable of detection in FAM, HEX, Cy5, and ROX fluorescence channels or similar wavelengths

Reagents, Kit Contents & Storage

The Amur Vaginal Microbiota Panel A kit includes the primer/probe mixes and positive controls required for multiplex qPCR. Amplification master mix must be purchased separately. The following kit configuration is available:

Kit 500001 — 48 Reactions

Plexes 1–10 (Part Numbers 400003–400012) + Positive Controls 450003, 450004, 450005, 450006

Component Details

Part Number	Description	Volume	Storage
400003–400012	15X Individual Primer/Probe Mixes — (10) Multiplexes	(10) × 48 µL	−20°C
450003 450004 450005 450006	WH Positive Controls — 4 individual control tubes with specific controls in each tube	(4) × 100 µL	−20°C

Recommended But Not Included

Part Number	Description	Volume	Storage
500024	SeqOnce qPCR Multiplex Amplification Kit 3600	(6) × 0.6 mL Master Mix (400084) + (2) × 1 mL Water	−20°C

Store all kit components at −20°C upon arrival. Only one master mix kit (PN: 500024) is required. Use of alternate master mixes is not supported by Bandit Biosystems.

Quality Control

Quality Control Requirements

Include a **Negative Control (Water/NTC)** and **Positive Control** in every assay run

Human RNaseP (RNaseP) Extraction Control is included in select Primer /Probe Mix as an internal DNA control extracted together with the sample DNA, controlling for extraction procedure and detecting potential PCR inhibition.

Controls are provided at approximately **~10,000 copies/ µL**; dilutions may be made in Tris-EDTA (TE) pH 8.0 or provided dilution buffer

Controls are **not intended to be extracted** — add directly to amplification reaction

Controls Provided

Control	Part Number	Targets Included
Infectious Disease Control 3	450003	*Candida krusei*, *Candida tropicalis*, *Candida glabrata*, Human RNaseP control, *Candida parapsilosis*, *Candida albicans*, *Candida lusitaniae*, *Candida auris*
Infectious Disease Control 4	450004	HSV1, *Treponema pallidum*, *Chlamydia trachomatis*, *Trichomonas vaginalis*, *Mycoplasma genitalium*, *Ureaplasma urealyticum*
Infectious Disease Control 5	450005	HSV 2, Human RNaseP control, *Neisseria gonorrhoeae*, *Haemophilus ducreyi*, *Atopobium vaginae*, *Gardnerella vaginalis*
Infectious Disease Control 6	450006	Group B Strep, *Lactobacillus iners*, *Escherichia coli*, *Lactobacillus gasseri*, *Enterococcus faecalis*, Megasphaera 1, *Prevotella bivia*, Megasphaera 2, *Staphylococcus aureus*, *Mobiluncus curtisii*, *Bacteroides fragilis*, *Mobiluncus mulieris*, *Mycoplasma hominis*, VanA, BVAB2, MecA, *Lactobacillus crispatus*, VanB, *Lactobacillus jensenii*, Human RNaseP control

PRIMER/PROBE MULTIPLEX CONFIGURATION

The panel is organized into **10 multiplexes (Plexes 1–10)**, each detecting 4 targets across FAM, HEX, Cy5, and ROX fluorescence channels. Select all four dyes for each labeled well.

Plex 1 — Target	**Channel**
HSV 2	FAM
HSV1	HEX
Treponema pallidum	Cy5
Gardnerella vaginalis	ROX
Plex 2 — Target	**Channel**
Neisseria gonorrhoeae	FAM
Chlamydia trachomatis	HEX
Trichomonas vaginalis	Cy5
RNaseP	ROX
Plex 3 — Target	**Channel**
Haemophilus ducreyi	FAM
Mycoplasma genitalium	HEX
Ureaplasma urealyticum	Cy5
Atopobium vaginae	ROX
Plex 4 — Target	**Channel**
Group B Strep	FAM
Escherichia coli	HEX
Enterococcus faecalis	Cy5
Prevotella bivia	ROX
Plex 5 — Target	**Channel**
Staphylococcus aureus	FAM
Bacteroides fragilis	HEX
Mycoplasma hominis	Cy5
BVAB2	ROX

Plex 6 — Target	**Channel**
Lactobacillus crispatus	FAM
Lactobacillus jensenii	HEX
Lactobacillus iners	Cy5
Lactobacillus gasseri	ROX
Plex 7 — Target	**Channel**
Megasphaera 1	FAM
Megasphaera 2	HEX
Mobiluncus curtisii	Cy5
Mobiluncus mulieris	ROX
Plex 8 — Target	**Channel**
Candida krusei	FAM
Candida tropicalis	HEX
Candida glabrata	Cy5
RNaseP	ROX
Plex 9 — Target	**Channel**
Candida parapsilosis	FAM
Candida albicans	HEX
Candida lusitaniae	Cy5
Candida auris	ROX
Plex 10 — Target	**Channel**
VanA	FAM
MecA	HEX
VanB	Cy5
RNaseP	ROX

HEX may be replaced by VIC or JOE. ROX may be replaced by Texas Red. Cy5 may be replaced by Quasar 670 if not available on your instrument. Select all four dyes for each labeled well.

Recommended Protocol

Follow these setup instructions carefully to ensure optimal assay performance. All steps should be performed in a clean room or designated setup area. Reaction volumes have been optimized at **15 µL** and may be run in either 96 or 384-well instruments.

01

Extract DNA

Extract DNA from sample per a separate validated protocol as determined by the individual user.

02

Thaw Reagents

Completely thaw Master Mix, nuclease-free water, and all 10 primer/probe mixes on ice (~30 min) or at room temperature (~5 min). Vortex briefly at max speed, then spin down.

03

Prepare Master Mix

In a clean area, combine per reaction: **7.5 µL** 2X Master Mix (PN: 400084) + **2.5 µL** nuclease-free water + **1 µL** 15X Primer/Probe Mix. Each of the 10 plexes must be prepared separately. Vortex briefly to mix.

04

Dispense & Add Sample

Distribute **11 µL** of master mix to all designated wells. Add **4 µL** of extracted sample DNA, positive control, or NTC to appropriate wells.

05

Seal & Centrifuge

Seal the plate and centrifuge for 30 seconds at 3,000 RPM (or highest available speed) to collect mixed samples.

06

Run qPCR

Place the sealed plate into the qPCR instrument and run per the thermal cycling conditions below. Collect fluorescence during the 59°C annealing/extension phase.

Reaction Setup & Thermal Cycling Conditions

Master Mix Reaction Setup (15 µL Total Volume)

Component	Volume / Reaction	Final Concentration
2X Master Mix (PN: 400084)	7.5 µL	1X
Nuclease-Free Water	2.5 µL	N/A
15X Primer/Probe Mix	1 µL	1X
Extracted Sample / Control / NTC	4 µL	N/A

Vortex thoroughly before use.

Prepare each of the 10 plex master mixes separately — do not combine.

Thermal Cycling Conditions

Cycling Step	Stage	No. of Cycles	Temperature	Holding Time
Enzyme Activation	1	1	95°C	2 minutes
Amplification — Denaturation	2	40	95°C	3 seconds
Amplification — Annealing/Extension *	2	40	59°C	30 seconds

*Collect fluorescence during the annealing/extension phase (59°C) on FAM, HEX, Cy5, and ROX channels (or equivalent).

Interpretation of Results

Appropriate cut-off values for positivity and analysis must be independently established. The guidelines below are for general use and should not be used as the sole method of interpretation.

Ct Value Interpretation

Ct Value	Result	Interpretation
Ct < 40	+	Nucleic Acid Detected
Ct > 40	–	Nucleic Acid Not Detected

Causes of False-Negative Results

- Improper sample collection
- Degradation of genetic material during shipping/storage
- Specimen collection after pathogen genetic material can no longer be found in the specimen matrix
- Unvalidated media or assay reagents
- Presence of qPCR inhibitors
- Mutation in pathogen genomes
- Improper vortexing and centrifuging when preparing qPCR reactions
- Expired reagents

Causes of False-Positive Results

- Cross contamination during specimen handling or preparation
- Cross contamination between samples
- Specimen mix-up
- DNA contamination during product handling
- Improper sealing of the PCR plate

Support & Contact

For technical support, ordering inquiries, or to request Safety Data Sheets (SDS), please reach out to the Bandit Biosystems team:

Phone

855-792-1225

Email

info@bandit.bio

SDS Requests

Safety Data Sheets available on request via phone or email

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