

+BVPro®

A RAPID, POINT-OF-CARE TEST FOR THE
DIAGNOSIS OF BACTERIAL VAGINOSIS

FOR PROFESSIONAL USE



WHAT IS BVPRO?

BVPro is a simple, 15-minute, point-of-care diagnostic for professional use with patients presenting with symptoms of vaginosis. It detects sialidase enzyme activity from a vaginal swab sample which is a well-established clinical marker of bacterial vaginosis, (Briselden, 1992). The CE marked diagnostic has been designed in the familiar lateral flow format (typical of pregnancy tests) so that the visual result is easy to interpret.

WHY IS DETECTION OF BACTERIAL VAGINOSIS (BV) IMPORTANT?

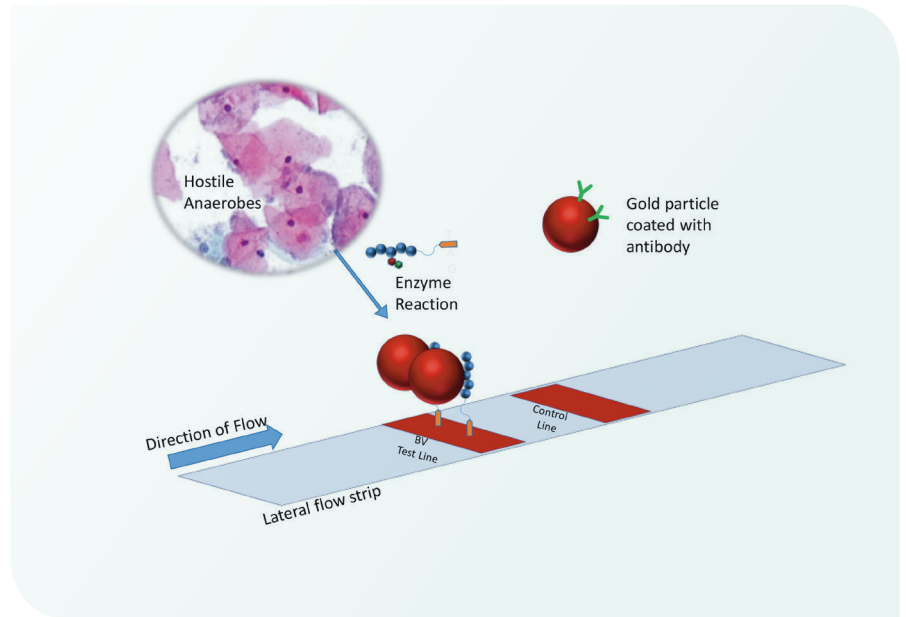
BV is associated with serious medical complications such as post-operative infections, a greater susceptibility of contracting sexually transmitted

infections (STIs) such as genital herpes and HIV, and also a higher risk of preterm birth in pregnant women. (Sherrard & et al.) Women suffering

recurrent BV infection can have poor self-esteem and frustration at not feeling “in control” of their vaginal health. (Bilardi & et al. 2013)

HOW DOES BVPRO WORK?

Bacterial sialidase is a “glycosidase” enzyme which degrades sugars; specifically, sialic acid, and is reported to weaken the natural mucosal barriers in the vagina allowing anaerobic bacteria to colonise and out-compete healthy lactobacilli. BVPro uses patented technology to detect sialidase activity using lateral flow by supplying the enzyme with an artificial substrate (Patent No. 2008290311, 2008). When the substrate is modified by sialidase it is captured at the test line by antibodies and their binding partners on gold particles giving the distinctive red colour positive result. If the enzyme is not present, the substrate remains unchanged and is not detected by the antibodies on the gold particles leaving a blank line. A positive test indicates the presence of bacterial vaginosis.



HOW TO USE BVPRO

For the medical practitioner, it is a simple 1-2-3 procedure:

1

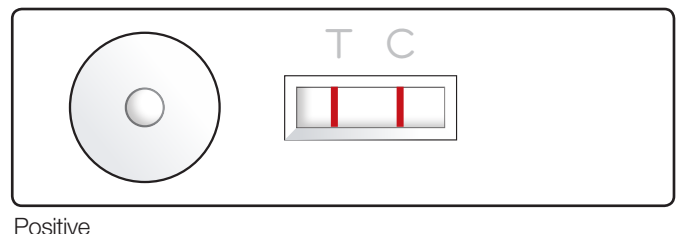
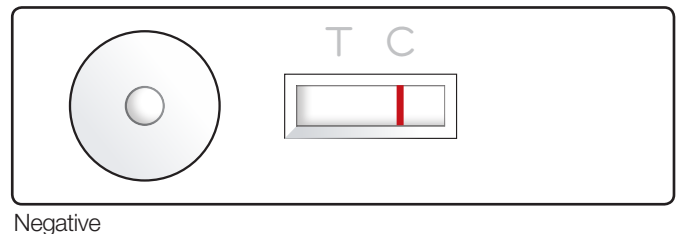
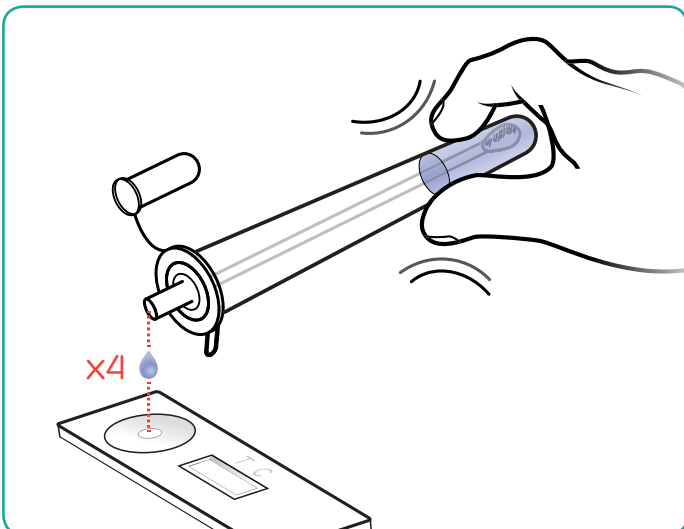
Add buffer solution to the extraction tube.

2

Take a vaginal swab sample from the patient and snap off into extraction tube. Incubate at room temperature for 5 minutes.

3

Apply four drops of sample extract to the lateral flow device. Read the result after 10 minutes.



PRODUCT SPECIFICATIONS

Product code: MBVP15 - 5 tests per kit
MBVP125 - 25 tests per kit

Sample: Vaginal fluid collected using the supplied sterile swab (approx. 0.1 ml)

Sensitivity: 1.56 U/ml sialidase

Assay range: 2-50 U/ml Sialidase using reference material P0720; New England Biolabs Inc, MA, US

Clinical Performance: A study of 40 clinical samples, with 11 BV positives and 29 negatives (by Hay/Ison reference assay) gave a sensitivity of 81.8% and a specificity of 96.5%

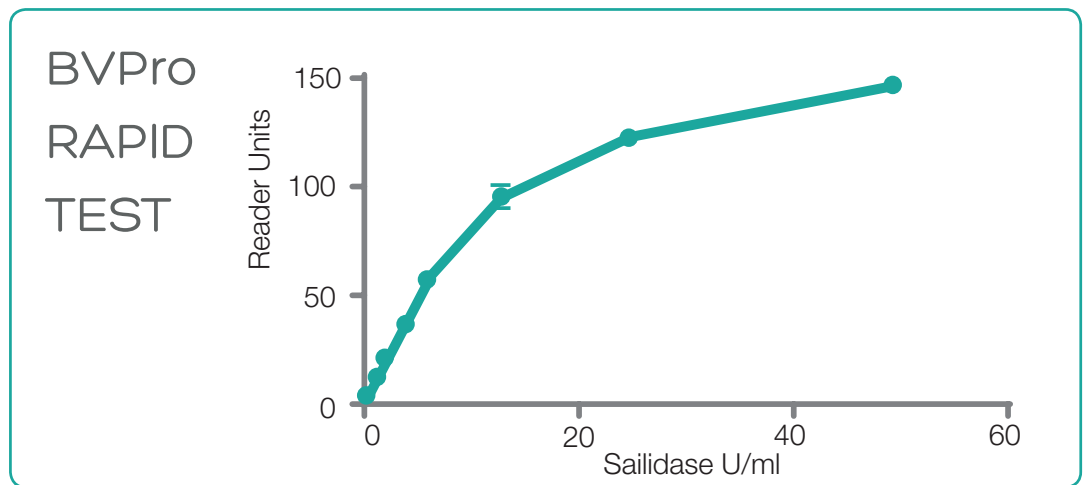
Storage: 2° - 30° C

Shelf life: Minimum 12 months

Market authorization: CE Marked for professional use.

Typical analytical performance:

A representative standard curve using BVPro devices to measure activity of sialidase enzyme reference material at 0.8 - 50 Units/mL, measured quantitatively using an optional reader. Test line intensities >10 (arbitrary reader units) are visible by eye under normal room lighting.



BVPRO VERSUS ALTERNATIVE METHODS

- BVPro provides a simple, rapid, alternative to time-consuming “wet mount” microscopic analysis for Clue cells or Gram stain scoring, e.g. Nugent Score (Nugent & *et al.* 1991).
- Clinical results from pH and/or ‘whiff test’ alone can be misleading given the conflicting evidence as to what constitutes a normal healthy pH. (Hay, 2010) (Ravel *et al.* 2011).
- BVPro provides an unambiguous result in a familiar assay format as compared to test-tube based, colour change tests for sialidase.

PRODUCT POSITIONING

BVPro can provide rapid confirmation of bacterial vaginosis allowing appropriate treatment to be given without delay. Use settings include:

- GP surgeries or other primary care settings
- GUM clinics
- Obs & Gynae clinics

COMMERCIAL AND CLINICAL OPPORTUNITY

Mologic is actively seeking marketing and distribution partnerships in EU and ROW (subject to gaining the relevant regulatory approval for each territory) either by country, regionally or globally. Should you be interested in adopting this product into your existing portfolio

or entering in to the womens health diagnostics space, please contact Mologic on **+44 (0)1234 780020** or **barbara.fallowfield@mologic.co.uk**

It is intended that continued clinical evaluation and early phase market

entry will be supported by Mologic manufacture under ISO13485.

These products can be prepared under the BVPro livery, distributor livery, or white label as required subject to local market requirements.

REFERENCES

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