Lenco
DIAGNOSTIC LABORATORY

BD MAX™ VAGINAL PANEL
Test #6770

Background:

Up to 75% of women experience at least one case of Vaginitis (VVC), Bacterial Vaginosis (BV) or Trichomonas (TV) in their lifetime.[1] 40 to 45% have two to three. Despite this, up to 40% with vaginitis will leave the initial medical visit undiagnosed.[2]

This potentially leads to: continued symptoms, repeat visits, inappropriate treatment, poor antimicrobial stewardship, all with higher associated healthcare costs.[3] Complications can include preterm or low birth-weight babies, late-term miscarriage, increased risk of sexually transmitted infections such as HIV and pelvic inflammatory disease.[5]

First generation tests were subjective "wet" tests (Amsel Test, Nugent Criteria) and often provided suboptimal diagnostics. Second generation tests such as the BD Affirm™ were a step forward, however offered sensitivity and specificity in the 80's and utilized lateral flow, manually read test cards. This legacy test did not discern drug resistant yeast and had a simplified BV algorithm employing only one sentinel marker (Gardnerella vaginalis). **BD MAX™ Vaginal Panel** is the first FDA-authorized microbiome-based assay that detects the 3 most common infectious causes of vaginitis in addition to 2 drug resistant yeast strains, all with the efficiency of 1 swab. It provides consistent, accurate results that surpass traditional 1st and 2nd generation methods for vaginitis detection.[4]

What is the test?

This assay provides 5 results for your symptomatic patients.

- **Candida**
  - Candida Group (C. albicans, C. dubliniensis, C. parapsilosis and C. tropicalis)
  - Candida glbrata
  - Candida krusei
- **Bacterial Vaginosis**
  - Lactobacillus species (L. crispatus and L. jensenii)
  - Gardnerella vaginalis
  - Atopobium vaginae
  - Megasphaera -1
  - BVAB-2
- **Trichomoniasis**
  - Trichomonas vaginalis

Why the BD MAX™ Vaginal Panel?

Best performance starts with the sample collection and transport. The patient or clinician collected swab is placed in the first FDA approved microbiome sample transport. Not only is the specimen viable for 14 days but also the relative species of yeast/fungus and bacteria are preserved in the relative amounts as collected. This is VITAL for VVC and BV characterization as patient symptoms are caused by an imbalance of normal vaginal flora.

Who Can Be Tested?

Symptomatic females with Vaginitis/Vaginosis: odor, discharge, discomfort.

Clinician Collection and Transfer Procedure:

1. Gently slide the swab no more than 2 inches (5cm) into the vagina.
   If the swab does not slide easily, gently rotate the swab as you push.
   If it is still difficult, do not attempt to continue. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
2. Rotate the swab for 10 to 15 seconds.
3. Withdraw the swab without touching the skin outside the vagina.
4. Fully insert the swab into the tube so that the tip is at the bottom.
5. Carefully break the shaft at the score mark. Be careful to avoid splashing.
6. Tightly re-cap the tube.
7. Label the tube with patient information (ie. Last Name, First Name, Date of Birth), date and time collected. Be careful not to obscure the bar codes on the tube.

Specimen Requirements:

BD Max Universal Vaginal Endocervical (UVE) swab kit and transport tube.

Transport/Stability:

Refrigerated specimens are stable for 14 days.

References:

1. Hainer BL et al. Vaginitis: diagnosis and treatment. Am Fam Pys. 2011; 83:807-815
2. Carr PL et al. "Shotgun" versus sequential testing. Cost –effectiveness of diagnostic strategies for vaginitis. JGIM. 2005;793-799
3. Powell K. Vaginal thrush: quality of life and treatments. Br J Nurs. 2010; 19:1107-1111.
4. BD MAX MVP™ Package Insert /Clinical Trial Data http://moleculardiagnostics.bd.com/womens-health-stds-vaginitis/
5. Kent HL. Epidemiology of vaginitis. Am J Obstet Gynecol. 1991; 165:1168-1176

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