



## A NOVEL POLYMER FOR DIAGNOSIS OF BACTERIAL VAGINOSIS AND TRICHOMONIASIS INFECTIONS.

Pardo-Yissar V (IL) [1]

**Background:** Traditional methods for diagnosis of bacterial vaginosis (BV) and Trichomonas Vaginalis (TV) are subjective and some requires expert personnel. As a result, the diagnosis is often inaccurate and the treatment is frequently inappropriate. The association between BV/TV and serious health effect, including PID, cervicitis, postoperative infection, preterm delivery, and HIV infection are well documented.

An accurate diagnosis will reduce those complications.

**The new method:** A novel polymer indicator has been developed to improve these diagnoses. It comprises a mixture of polymer, plasticiser, wetting agent, ion-balance reagent and an indicator; applied on a substrate. The indicator changes from yellow to blue at pH>5.1 and in presence of vaginal watery discharge with low buffer capacity at pH 4.3-5.1. The polymer is used as a swab impregnated within an indicator for ob/gyn office (BV Test PRO).

**Performance:** A pivotal study compared the results of VS-SENSE PRO to “Gold-Standard Methods”. The BV Test PRO Sensitivity, Specificity, PPV, and NPV are 91.8%, 92.9%, 91.8%, and 92.9%, respectively.

**Conclusion:** The BV Test PRO gives extra sensitivity in diagnosing of abnormal vaginal discharge, and is beneficial for physicians and patients in fast and easy diagnosis of vaginal infection. The BV Test PRO with its high Sensitivity & Specificity assist the gynaecologist in diagnosis of BV/TV. This is a rapid (10 seconds) office test, clear to read the results and interpret, save the need to send discharge specimen for lab test, and enables prescribing treatment during the first visit.

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