

Diagnosis of Bacterial Vaginosis (BV)

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Technology description

Background

Bacterial vaginosis (BV) is the most common vaginal condition, affecting an estimated 30% of women at any given time. While many women remain asymptomatic, when signs and symptoms do arise they include an elevated vaginal pH > 4.5, discharge, and malodour due to amines. BV is also associated with a number of co-morbidities, including increased transmission and acquisition of HIV and other sexually transmitted infections, and increased risk of preterm labour. In most instances, diagnosis is dependent upon microscopy of vaginal fluid to identify BV-like bacteria alone (Nugent Scoring), or in combination with clinical signs (Amsel Criteria). Diagnostic accuracy using these methods are poor due to: the diverse morphology of “healthy” and “unhealthy” bacteria; the fact that up to 57% of women with BV are asymptomatic; and the variability in microscopy interpretation due to subjective human error. Misdiagnosis creates stress for the patient, delays appropriate intervention and places a financial burden on the health care system. In addition, this process is time consuming for the clinician or laboratory performing the diagnosis.

Technology Overview

The inventors have demonstrated that the vaginal metabolome is strongly correlated with bacterial diversity in both pregnant and non-pregnant Rwandan women. Using an untargeted metabolomics approach, the inventors have also identified a number of metabolites as novel biomarkers of BV independent of pregnancy status, in particular GHB and 2-hydroxyisovalerate (2HV). Given the highly conserved nature of the vaginal microbiota across different populations and ethnicities, it is expected that these biomarkers to be globally applicable for the diagnosis of BV (validated in a blinded replication cohort from Tanzania with 91% accuracy for clinical BV).

Keywords

Bacterial vaginosis, Diagnosis, BV biomarker, *Gardnerella vaginalis*, *Dialister*, *Prevotella*, *Atopobium*, 2-hydroxyisovalerate, 2-HV, γ -hydroxybutyrate, GHB, metabolic profiling

Advantages

- enables development of a rapid BV screening test based on stable and specific biomarkers
- improves BV diagnostic accuracy and speed
- reduces costs through improved patient management

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