



## GENITAL INFLAMMATION TEST (GIFT)

*A low-cost, point-of-care test to identify genital inflammation associated with sexually-transmitted infections in symptomatic and asymptomatic individuals*

### BACKGROUND

Untreated sexually transmitted infections (STIs) and bacterial vaginosis (BV) are associated with adverse reproductive outcomes, and local inflammation caused by these is associated with increased risk of HIV acquisition (2.4-fold increase) and may reduce the efficacy of topical antiretroviral prophylaxis. Genital inflammation and untreated STIs and BV also cause adverse reproductive outcomes including pelvic inflammatory disease, infertility, preterm delivery and maternal and neonatal sepsis. In resource-limited settings, these conditions are only treated if women present with clinical symptoms, however, a large number of these women are frequently asymptomatic, or do not recognize their symptoms, and are therefore not treated. For those who do present with symptoms, laboratory-based tests are used to diagnose STIs and BV, but these are expensive, require experienced laboratory staff and equipment, and do not offer immediate results. Often, patients do not return for treatment and the possibility of transmission of the STIs or acquisition of HIV may occur during that time. There is thus an urgent need for inexpensive, true point-of-care (POC) diagnostic tools to significantly increase case finding and treatment of STIs and BV, particularly in resource-limited settings.

### TECHNOLOGY DESCRIPTION

The Genital InFLammation Test (GIFT) is an inflammatory biomarker POC triage test for the identification of genital inflammation in both symptomatic and asymptomatic individuals. The test detects three key biomarkers of inflammation in the female genital tract caused by a wide range of STIs, BV and pathogenic bacteria, making this an ideal single, inexpensive, rapid POC screening tool to identify the large pool of women who have STIs, BV or inflammatory bacterial infections, and who are at increased risk of HIV infection and reproductive complications. It is envisaged that the device will be used as a routine part of HIV prevention and reproductive healthcare programmes and that, either all women who have a positive GIFT test would be triaged for further specific STI testing, or women who have a positive GIFT test would be treated or referred based on other risk factors in line with syndromic management.

### VALUE PROPOSITION

The Genital InFLammation Test (GIFT) is an inexpensive, user-friendly, rapid, equipment-free point of care screening device which would allow women to be tested for genital inflammation at any healthcare facility and treated appropriately, in order to increase case finding, reduce the overall STI and BV burden, reduce the risk of HIV acquisition and improve reproductive health.

### CURRENT STATUS

The biomarkers have been validated and their performance tested in cohorts of women from different geographical areas in South Africa. The performance of the biomarkers was compared to the current standard of care and shown to be better than syndromic management in predicting the presence of an STI or BV. The biomarkers have been incorporated into a prototype point of care device showing adequate positive/negative visual differences. The device is being optimized and validated using clinical samples prior to testing in patients in local clinics. A cost analysis, budget impact analysis, cost effectiveness analysis and modelling study are being conducted to estimate the cost implications of using the device for screening and the impact of this on the prevalence and incidence of STIs and BV in South Africa.

### INTELLECTUAL PROPERTY STATUS & PUBLICATIONS

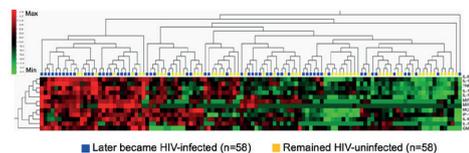
National phase patent applications based on PCT/IB2014/065740 are pending (granted in South Africa).

Masson L, Arnold KB, Little F, Mlisana K, Lewis DA, Mkhize N, Gamielien H, Ngcapu S, Johnson L, Lauffenburger DA, Karim QA. Inflammatory cytokine biomarkers to identify women with asymptomatic sexually transmitted infections and bacterial vaginosis who are at high risk of HIV infection. *Sex Transm Infect.* 2016 May 1;92(3):186-93.

Masson, Lindi, Shaun Barnabas, Jennifer Deese, Katie Lennard, Smritee Dabee, Hoyam Gamielien, Shameem Z. Jaumdally, et al. "Inflammatory cytokine biomarkers of asymptomatic sexually transmitted infections and vaginal dysbiosis: A multicentre validation study." *Sexually Transmitted Infections* (2018). Jul 17:sextrans-2017.

### OPPORTUNITIES

The technology developers are seeking commercialization partners for the technology.



FOR MORE INFORMATION PLEASE CONTACT:

info.ship@mrc.ac.za  
+27 (0)21 938 0991