

GENITAL INFLAMMATION TEST (GIFT) FOR SEXUAL AND REPRODUCTIVE HEALTH: POINT-OF-CARE SCREENING TOOL FOR SEXUALLY TRANSMITTED INFECTIONS AND BACTERIAL VAGINOSIS

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Background:

Genital inflammation caused by treatable conditions like sexually transmitted infections (STIs) and bacterial vaginosis (BV) is a key risk factor for HIV acquisition. In resource-limited settings STIs/BV are currently managed syndromically following WHO recommendations. However, most STI/BV cases are asymptomatic and therefore missed. We have validated biomarkers of vaginal inflammation (IL-1 α , IL-1 β , IP-10) caused by STIs/BV in five African cohorts. We aim to develop and implement a low-cost rapid point-of-care test (POCT), called the Genital Inflammation Test (GIFT), to measure these biomarkers and increase STI/BV case-finding.

Methods:

We developed two lateral flow immunochromatographic prototypes measuring both IL-1 α /IL-1 β in a multiplexed assay and IP-10. The devices were evaluated using recombinant cytokines and vaginal swabs collected from asymptomatic non-pregnant South African women (14-35 years) and the results were compared to ELISA. Optimal vaginal swab type and equipment-free processing methods were determined. Cytokine yields were compared following different: (1) swab processing conditions (vortex vs manual compression); (2) swab types (FloQ vs dacron); (3) elution volumes.

Results:

The prototype devices had analytical sensitivities <50pg/ml for IL-1 α and IL-1 β and <70pg/ml for IP-10. The test line intensities observed by the naked eye correlated with ELISA concentrations ($r=0.76$, $p<0.0001$; $r=0.86$, $p<0.0001$; $r=0.97$, $p<0.0001$) for IL-1 α and β and IP-10, respectively. Swab compression by hand in soft nozzle tubes preloaded with PBS buffer yielded higher cytokine concentrations compared to processing with a vortex. Cytokine concentrations yielded from FloQ swabs were greater than those from dacron swabs.

Conclusion:

GIFT results correlated significantly with ELISA results, showing the devices can detect cytokines in lateral vaginal wall swabs, with IP-10 and IL-1 β detection most accurate than IL-1 α . This POCT could significantly improve STI and BV management by increasing case-finding. The GIFT device, prospective user acceptability and cost-effectiveness are currently being evaluated in three settings in Africa.

Disclosure of Interest Statement:

Lindi Masson and Jo-Ann Passmore are on European and South African patents for a Method for Diagnosing an Inflammatory Condition in the Female Genital Tract and co-lead the development of the GIFT device.