

## **RAMP Project Abstract: SOSHANGUVE, SOUTH AFRICA**

**Project Title:** Diagnosing Bacterial Vaginosis: A Comparison between the Nugent scoring system, Allplex™ Bacterial Vaginosis assay and Point-of-Care BVBlue Test, South Africa

**Project Type:** Short-term Project 8 weeks On-site

**Proposed Project Dates:** 8 weeks On-site between July 1, 2023 – August 31, 2023

**Project Site:** Setshaba Research Centre, Soshanguve, South Africa

### **Project Overview:**

Bacterial vaginosis (BV) is the commonest cause of abnormal vaginal discharge in women of reproductive age, yet the etiology remains unclear. In sub-Saharan Africa, a prevalence of 46–53% has been reported. There is no simple test to diagnose BV because no single bacterial strain is attributable to BV infection. The Nugent scoring system is the gold standard method; however, it is time consuming, costly, and needs laboratory equipment and expertise. There is no consensus on the testing modalities used to diagnose BV, particularly in low-income settings. We therefore aim to compare real-time PCR (RT-PCR) and Point-of-Care BVBlue test against the Nugent scoring system for the diagnosis of BV.

Setshaba Research Centre, based in Soshanguve, Tshwane, South Africa, conducts HIV vaccine and prevention trials under the HIV Vaccine Trials Network and HIV Prevention Trials Network. For this project, the scholar will work with a microbiologist/immunologist as the mentor, and will be supported by the community engagement and laboratory staff, other experienced researchers at our center, and a collaborating statistician at the South African Medical Research Council. The project will require two months at our center. The scholar will have the opportunity to interact with potential participants who are symptomatic for BV, obtain their consent, administer a questionnaire and manage specimens with the guidance and support of the community engagement team. She/he will learn to process the specimens and conduct three different methods to detect and quantify BV (Nugent scoring system, the rapid Point-of-Care BVBlue Test and Real-Time multiplex PCR assay). Thereafter, the scholar will analyze the data with guidance from the mentor and statistician, and will prepare an oral/poster presentation and a manuscript for publication with assistance from the other investigators.

### **Project Summary:**

This study aims to compare the Nugent scoring system, Point-of-Care BVBlue Test and Real Time-PCR for the diagnosis of BV using vaginal swabs from 18–49-year-old women presenting with symptoms of STIs/BV at various primary healthcare clinics in the Soshanguve sub-district, South Africa. The objectives of the study are:

- To determine the sensitivity, specificity and predictive values (positive and negative) for detecting BV using the Allplex™ Bacterial Vaginosis assay compared to the gold standard Nugent scoring system.
- To determine the sensitivity, specificity and predictive values (positive and negative) for detecting BV using the Point-of Care BVBlue Test compared to the gold standard Nugent scoring system.

We aim to enroll 135 participants into the study. After written informed consent has been obtained from each study participant, a questionnaire will be used to collect socio-demographic and clinical data. Three self-administered vaginal swabs will be collected from each participant. Samples will be labelled, placed in a cooler box with an icepack and transported to the Setshaba Research Centre laboratory for processing and testing. The secretions from the first vaginal swab will be used to determine the prevalence of bacterial vaginosis using the Nugent scoring system. The second vaginal swab will be used to conduct the Point-of-Care BVBlue Test where the results are read immediately. The third swab will be used for Real-Time multiplex PCR assay that simultaneously detects seven bacteria associated with BV. The following outcomes will be measured:

- Frequency and percentages of reported clinical symptoms and socio-demographics
- Prevalence of BV (Proportion of participants with suspected bacterial vaginosis confirmed by Nugent scoring system, Point-of-Care BVBlue Test and RT-PCR)
- Sensitivity, specificity and predictive values (positive and negative) for detecting BV using the Allplex™ Bacterial Vaginosis assay compared to the gold standard Nugent scoring system.
- Sensitivity, specificity and predictive values (positive and negative) for detecting BV using the Point-of-Care BVBlue Test compared to the gold standard Nugent scoring system.

*If COVID-19 restricts the scholar from working onsite, then all data collection and Nugent scoring system, Point-of-Care BVBlue Test and RT-PCR testing will be performed by site staff. The scholar will subsequently work with the statistician and other investigators to analyze and interpret the data, prepare a poster/oral presentation and write up the findings for a publication remotely.*

**Regulatory requirements for the project and plans for completing them:**

The proposal will be submitted to the University of Witwatersrand Human Research Ethics Committee in January 2023. Approval will be obtained before the project starts in May 2023 as it generally takes 3 months for approval. The scholar will be required to complete GCP training; virtual or online courses are available.

**Expected Deliverables:**

The scholar will receive training on all study and reporting procedures:

- Obtaining informed consent
- Collection of clinical and socio-demographic data
- Processing of samples and performing of Nugent scoring system, Point-of-Care BVBlue Test and real-time PCR
- Analysis of data and preparation of results
- Manuscript writing
- A poster/oral presentation at an HVTN Full Group meeting (May 2024)
- Publication in a peer-reviewed journal.

**Project Contact Person(s) (Name, Email):**

Dr Ayman Osman ([AOSman@setshaba.org.za](mailto:AOSman@setshaba.org.za)) - Mentor

Dr Athmanundh Dilraj ([ADilraj@setshaba.org.za](mailto:ADilraj@setshaba.org.za))