

# A DIAGNOSTIC EVALUATION OF A MOLECULAR ASSAY USED FOR TESTING AND TREATING ANORECTAL CHLAMYDIA AND GONORRHOEA INFECTIONS AT THE POINT-OF-CARE IN PAPUA NEW GUINEA

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**Background:** Papua New Guinea (PNG) has among the highest prevalences of sexually transmissible infections (STIs) globally with no services able to accurately test for anorectal *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) infections. Here, and for the first time, we evaluate the diagnostic performance of a molecular CT/NG assay used at the point-of-care (POC) with the aim of enhancing anorectal STI screening and same day treatment.

**Methods:** Across two study sites, 2135 men who have sex with men (MSM), transgender women (TGW) and female sex workers (FSW) taking part in PNG's first large-scale biobehavioural study were enrolled and asked to provide a self-collected anorectal swab for POC GeneXpert CT/NG testing. Same day treatment was offered if positive. With consent, additional biological samples for other STI and blood borne virus's were also collected and tested at the POC. A total of 396 randomly selected anorectal CT/NG samples were transported to Australia for comparison against the widely used Cobas 4800 CT/NG laboratory test (Roche Molecular Diagnostics, Pleasanton, CA).

**Results:** A total of 326 samples provided valid results by Cobas whereas 70 samples provided invalid results suggesting inhibition. The positive, negative and overall percentage agreements of GeneXpert CT/NG for the detection of CT were 96.7% (CI: 92.3, 98.9%), 95.5% (CI: 91.3, 98.0%) and 96.0% (93.3, 97.8%), and for NG were 93.0% (CI: 86.1, 97.1%), 100.0%, (CI:98.3%, 100.0%) and 97.8% (CI: 95.6%, 99.1%), respectively.

**Conclusions:** The overall rate of agreement between the GeneXpert and Cobas CT/NG assays was high for both CT and NG detection. Results from this study data suggest the GeneXpert CT/NG assay is suitable for testing self-collected anorectal specimens at the POC and same day treatment was feasible within key populations who are more at risk of pathogenic transmission and acquisition.

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