## EVALUATION OF A SPECIMEN POOLING METHOD FOR MOLECULAR POINT-OF-CARE DETECTION OF CHLAMYDIA AND GONORRHOEA

## Authors:

Badman SG<sup>1</sup>, <u>Bell SFE<sup>2</sup></u>, Dean JA<sup>2</sup>, Lemoire J<sup>3</sup>, Debattista J<sup>4</sup>, Redmond AM<sup>3 5</sup>, Williams OD<sup>2</sup>, Gilks CF<sup>2</sup>, Whiley DM<sup>2</sup>

<sup>1</sup> Kirby Institute, University of New South Wales, <sup>2</sup> The University of Queensland, <sup>3</sup>Queensland Positive People, <sup>4</sup> Metro North Public Health Unit, <sup>5</sup> Metro North Hospital and Health Service

#### Introduction:

The aim of the study was to evaluate the performance of pooled self-collected urogenital, pharyngeal and anorectal specimens compared to individual samples for the detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) at the point-of-care (POC).

#### Methods:

Clients aged 16 years and over attending urban, peer-led community testing services were offered CT/NG molecular POC testing using GeneXpert (Cepheid, Sunnyvale, CA). With consent, participants provided three self-collected specimens (urine, pharyngeal and rectal swabs) for testing. If any specimen provided a positive result, all three specimens were pooled and retested. Results of the pooled test were compared against individual test results to determine agreement between the two methods

#### **Results:**

In total 387 participants provided three individual anatomical specimens with 75 (19.4%) participants having infection detected in at least one individual specimen. For the detection of CT, the positive percent agreement (PPA), negative percent agreement (NPA) and overall rate of agreement (ORA) of pooled testing compared to individual testing was 91.8% (95% CI 79.5-97.4), 100% (95% CI 89.9-100) and 94.7% respectively (Cohens kappa ( $\kappa$ )=0.886 (0.778-0.994). For NG, the PPA, NPA and ORA was 92.1% (95% CI 77.5-97.9), 100% (95% CI 88.3-100) and 97.3% respectively ( $\kappa$ =0.920 (0.832-1)). Agreement varied by anatomical site and organism type, with pharyngeal samples with low microbial loads less likely to be detected on pooling. Additional experimentation suggested false negative results could be minimised by adjusting sample volumes in the pool.

#### **Conclusion:**

This study confirmed people accessing community based services for POC testing have a high prevalence of undiagnosed CT (13.7%) and NG (10.3%). Based on the these results further research is warranted to determine if the agreement of the pooling method can be improved and a clinically acceptable level of detection reached. If achieved, significant costs would be saved when screening at risk populations at the POC.

# **Disclosure of Interest Statement:**

The *Peer delivery of point of care testing for STI within a community setting* project was funded by a LINK Innovation Fund, Metro North Hospital and Health Service

and an HIV Foundation Queensland grant. Cepheid provided the GeneXpert instrument hire and some cartridges free of charge. The remainder were paid for by the projects.

No conflicts of interest declared.