EVALUATION OF A GYRA REAL-TIME PCR TEST FOR GUIDING CIPROFLOXACIN THERAPY OF GONORRHOEA

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Introduction:

Antimicrobial-resistant *Neisseira gonorrhoeae* is a serious public health issue, and new management strategies are urgently needed, including antibiotic stewardship, improved diagnostics, and better utilization of existing drugs. The development of molecular diagnostic tests that can detect *N. gonorrhoeae* as well as resistance/susceptibility markers enable the targeted use of drugs and the conservation of last-line treatments. The ResistancePlus® GC assay (SpeeDx) is a multiplex real-time qPCR assay, which combines detection of *N. gonorrhoeae* and gyrase A markers associated with ciprofloxacin resistance/susceptibility.

Methods:

Analytical performance studies have been conducted to determine the sensitivity and specificity of the ResistancePlus GC (beta) (SpeeDx) assay using characterised strains and commercially available material for *N. gonorrhoeae* and commensal species.
The clinical performance of the ResistancePlus GC (beta) test was also evaluated on sample banks of clinical specimens as well as *N. gonorrhoeae* clinical isolates collected from Australia. Performance was compared to cobas 4800/NG (Roche) and in-house qPCR for *N. gonorrhoeae* detection, and gyrA genotype (in-house gyrA qPCR or sequencing), as well as phenotype (antimicrobial susceptibility testing) for isolates.

Results:

Analytical sensitivity of the assay was determined to be 15 geq/reaction for detection of *N. gonorrhoeae* S91 wild-type and S91F mutant strains. Specificity against a range of commensal species and *Neisseria spp*, including *Neisseria meningitis* was 100%.
Preliminary results indicate excellent performance for clinical specimens, with 96.9% sensitivity (123/127) and 99.7% specificity (288/289) for *N. gonorrhoeae* detection, and 100% sensitivity (20/20) and 98.6% specificity (70/71) for determining gyrA status. Testing on 70 *N. gonorrhoeae* clinical isolates showed high concordance to gyrA genotype and antimicrobial susceptibility testing.

Conclusion:

In a clinical setting where ciprofloxacin resistance is low, establishing susceptibility status using the ResistancePlus GC assay before treatment decisions are made will allow ciprofloxacin to be utilized for the vast majority of patients.