The evaluation of ResistancePlus GC (beta) assay for the detection of gonorrhoea ciprofloxacin resistance and susceptibility

L. Y. Tan[1], S. M. Ebeyan[1], M. Windsor[1], A. Bordin[2], L. Mhango[2], S. M. Erskine[1], E. Trembizki[2], E. Mokany[1], D. Whiley[2,3] on behalf of the GRAND2 study investigators

1 SpeeDx Pty Ltd; 2 University of Queensland Centre for Clinical Research, The University of Queensland; 3 Pathology Queensland Central Laboratory, Brisbane

Intro

- Antimicrobial - resistant *Neisseria gonorrhoeae* (GC) is a serious public health concern, new management strategies are urgently needed.
- The development of molecular diagnostic tests that can detect *N. gonorrhoeae* as well as resistance/susceptibility markers enable the targeted use of antibiotics.
- We evaluated the ***Resistance****Plus* GC® (beta) assay* (SpeeDx) detecting GC, gyrA S91F and S91 WT markers associated with ciprofloxacin resistance/susceptibility.

Methods

- Results for GC isolates (n=822) were compared to iPLEX-MLST and iPLEX-AMR typing, and antimicrobial susceptibility phenotypes.
- Results for GC positive clinical specimens (n=262 pos) were compared to cobas® 4800 CT/NG and in-house real-time PCR (opa & porA) for GC detection, and gyrA real-time PCR for gyrA detection.
- GC negative clinical specimens (n=290) were compared to cobas® 4800 CT/NG.
- Specificity was also evaluated for non-gonococcal commensal species (n=110).

Results

- 100% sensitivity for GC detection in clinical isolates.
- Sensitivity/specificity for gyrA S91F/WT detection in GC clinical isolates
  - 100%/100% compared to genotype
  - >99%/>97% compared to phenotype
- GC positive clinical specimens
  - >96% sensitivity for GC detection
  - 100% sensitivity/specificity *gyr*A S91F/WT detection
- 100% specificity for GC negative clinical specimens and non-gonococcal isolates.

Conclusion

- The ***Resistance****Plus* GC (beta) assay is suitable for the detection of *N. gonorrhoeae* and gyrA markers associated with resistance/ susceptibility to ciprofloxacin directly from clinical samples.
- This assay could be implemented for the individualised treatment of gonorrhoea infections as well as to enhance current antimicrobial resistance surveillance methods.

The first commercial diagnostic test for gonorrhea to enable ciprofloxacin treatment*

Results for *N. gonorrhoeae* positive clinical specimens

In-house gyrA qPCR result	*ResistancePlus* GC (beta) result	Specimen Type					
		Cervical swab	Genital swab	Penile swab	Pharyngeal swab	Urethral swab	Vaginal swab
gyrA mutant	GC detected, gyrA mutant detected	15		7	12	8	3
gyrA wild-type	GC detected, gyrA mutant not detected	33	4	16	39	32	25
	GC detected, gyrA mutant indeterminate	5		1		1	6
	IC invalid			1			
NC^	GC detected, gyrA mutant not detected	2		1	10	2	2
	GC not detected. IC valid	2		1	1	1	3
	GC detected, gyrA mutant detected	1			8	1	
	GC detected, gyrA mutant indeterminate	5			11		2
	IC invalid						1

Non-gonococcal isolates tested showed no cross-reactivity

Neisseria and *Moraxella* isolates	No. tested
Moraxella catarrhalis	7
Moraxella osloensis	2
Neisseria elongata	1
Neisseria flavescens	1
Neisseria lactamica	16
Neisseria mucosa	1
Neisseria polysaccharea	4
Neisseria sicca	4
Neisseria subflava	14
Neisseria weaveri	1
N. meningitidis	55
Total	**110**

* Not for sale in the USA

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