



*High levels of  
Mycoplasma genitalium  
antibiotic resistance  
are observed in Australia*

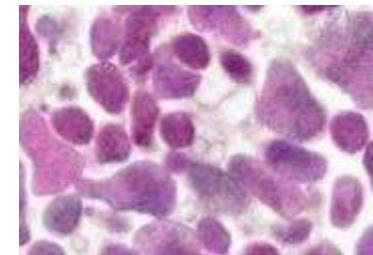
Simon Bone, PhD  
European Application Specialist  
[simonb@speedx.com.au](mailto:simonb@speedx.com.au)

# *Mycoplasma genitalium* (MG)



## *M. genitalium* as an STI

- ⌚ Men – Non-Gonococcal Urethritis (6-50%)
- ⌚ Women – Cervicitis, Pelvic Inflammatory Disease (5-20%)



## Anti-microbial resistance

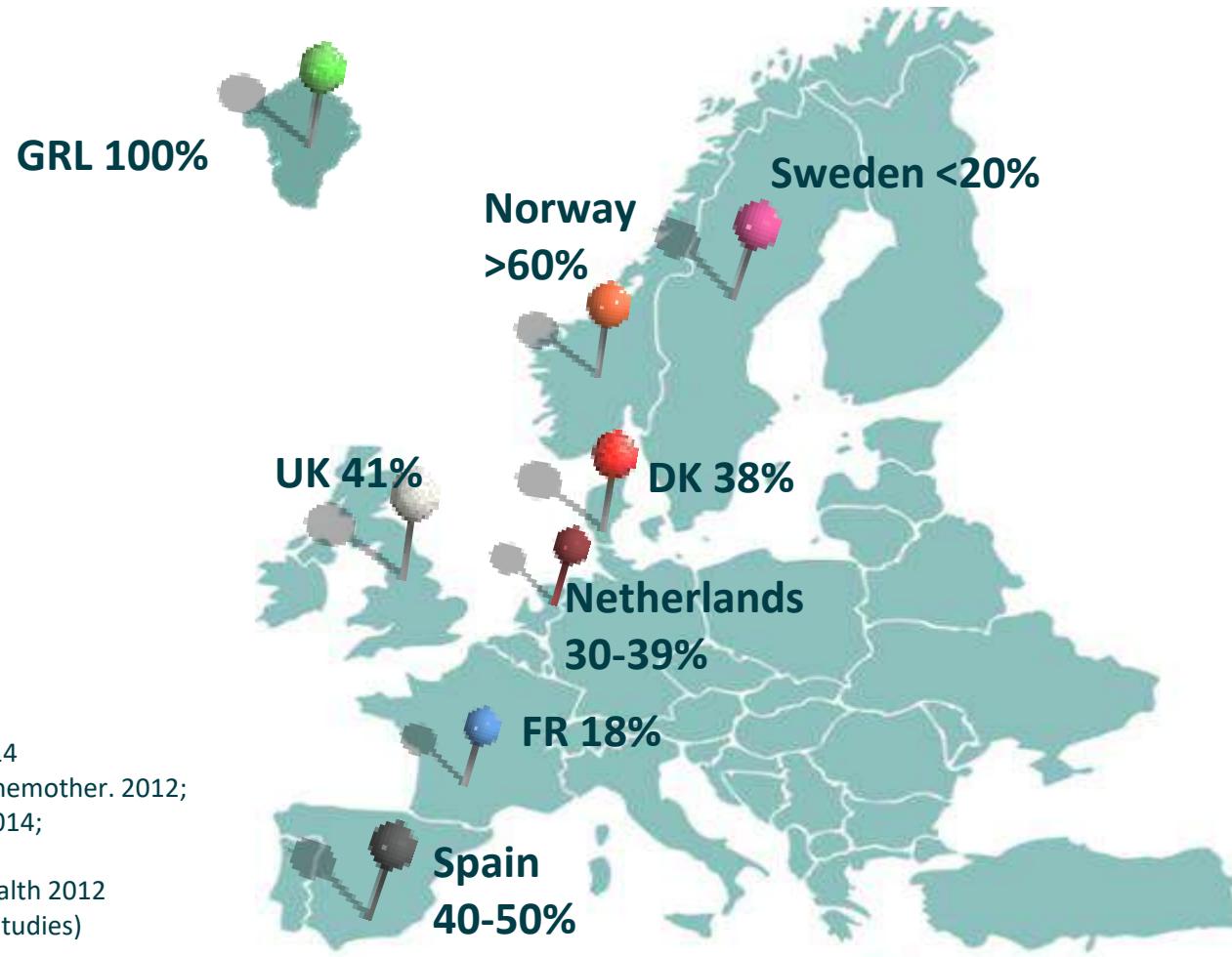
- ⌚ 1<sup>st</sup> line treatment = Azithromycin (macrolide antibiotic)
- ⌚ Macrolide resistance associated with 23S rRNA mutations
- ⌚ A2058G, A2059G, A2058T, A2058C, A2059C (E. coli numbering)

## Current testing methods

- ⌚ MG detection – PCR
- ⌚ Macrolide resistance detection – Sequencing, HRMA, FRET assays

***Clinically relevant rapid NAAT is required***

# MG macrolide resistance in Europe



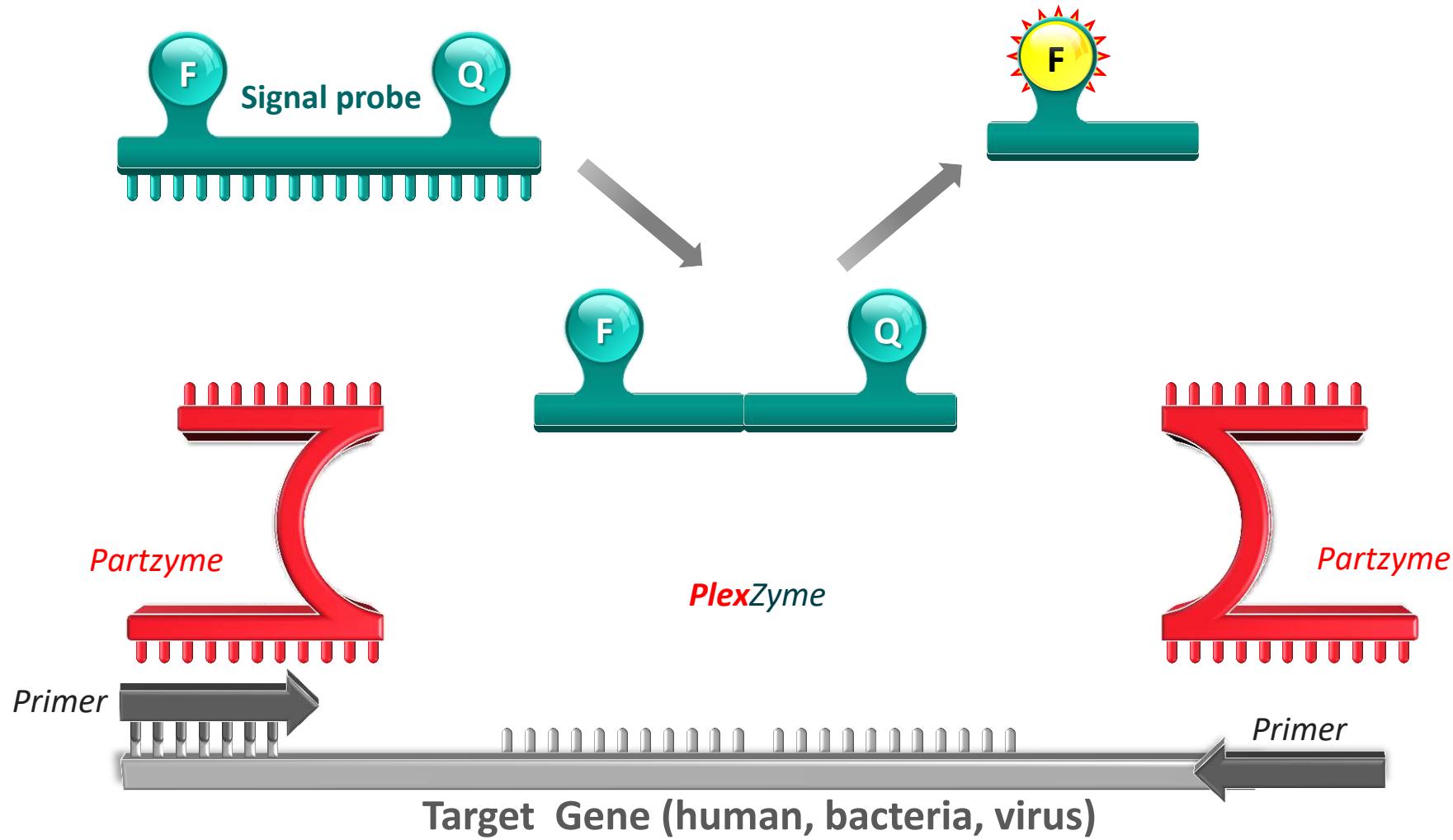
Gosse et al JCM. 2016  
Salado-Rasmussen et al CID. 2014  
Chrisment et al. J. Antimicrob. Chemother. 2012;  
Touati et. al, J. Clin. Microbiol. 2014;  
Le Roy, Emerg. Inf. Dis, 2016;  
Gesink et al Int J Circumpolar Health 2012  
(NB not all data from published studies)

***Guidelines in Europe now include resistance testing***



**PlexPCR™**  
***ResistancePlus™***  
Technology

# PlexPCR™



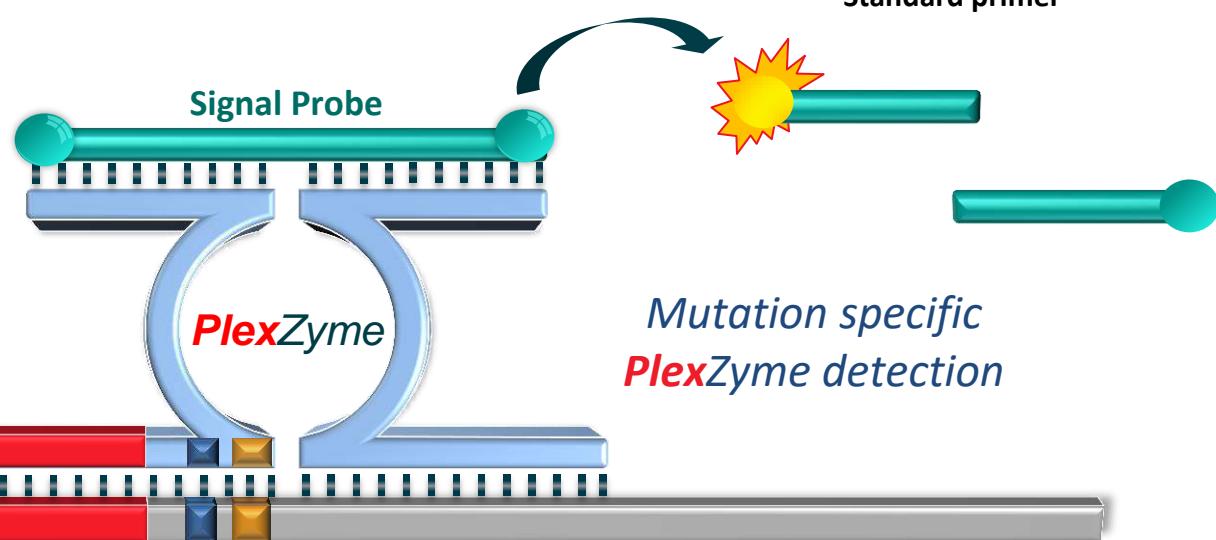
**Highly Specific, Extremely Sensitive**

# ResistancePlus™

*Mutation Specific*  
**PlexPrimer**

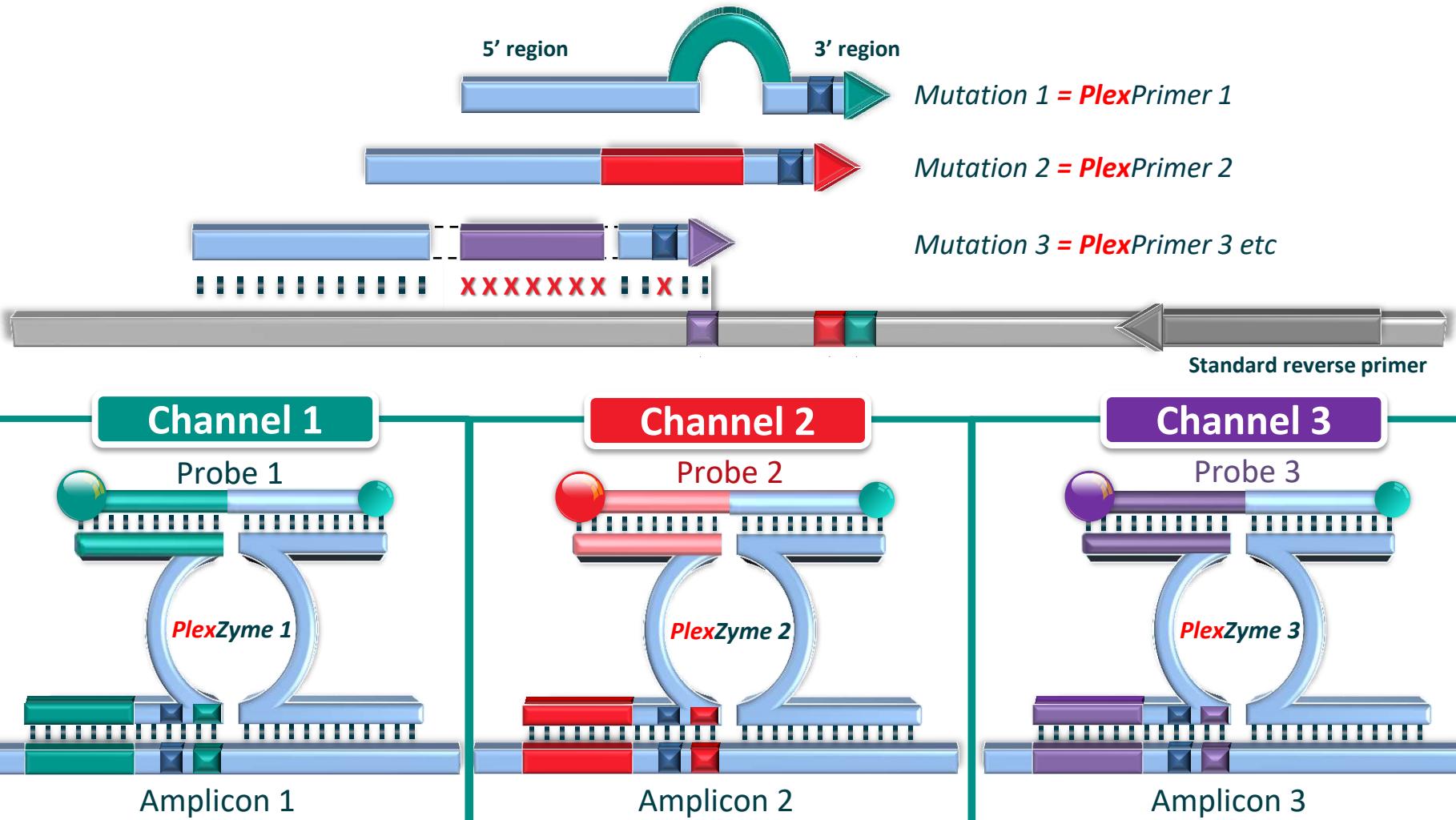


- ✓ increases SPECIFICITY
- ✓ differs for each mutant



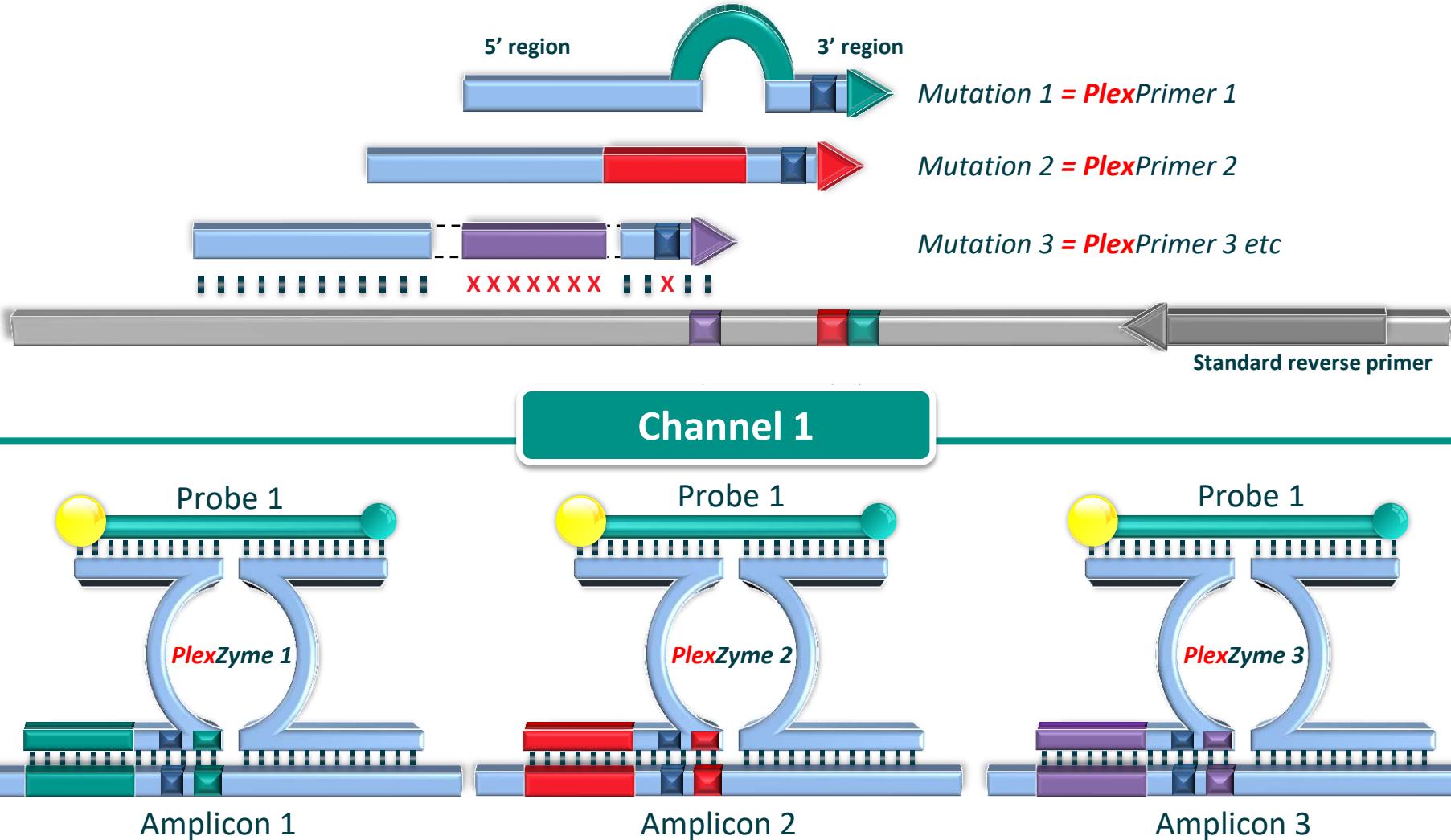
**Mutation specific amplification AND mutation specific detection**

# ResistancePlus™



**Highly sensitive multiplex assay for clustered mutations**

# ResistancePlus™



**Highly sensitive multiplex assay for clustered mutations**

# ResistancePlus™ MG



Go beyond detection

- 5 most common 23S rRNA mutations related to macrolide resistance
- Rapid qPCR results (<1.5 hours)  
Allows actionable clinical information
- Multiple Specimen Types  
Swabs (Urogenital & Rectal), Urine (Male, Female)

Channel	7 Targets/1 test
1	<b>Pathogen:</b> <i>M. genitalium</i> (MgPa)
2	<b>5 Resistance Markers:</b> 23S rRNA mutations (A2058T, A2058C, A2058G, A2059C, A2059G)
3	<b>Internal Control</b>

# Prospective Clinical Study

Melbourne, Australia



1089 samples received Nov 2015-Dec 2015

Melbourne Sexual Health Centre

Catriona Bradshaw

Symptomatic male & female

- ❶ NGU,
- ❶ Cervicitis
- ❶ Proctitis
- ❶ PID
- ❶ Sexual contacts

Royal Womens Hospital

Sepehr Tabrizi

Non-symptomatic female

- ❶ Contraceptive advice
- ❶ Insertion of intra-uterine contraceptive device
- ❶ Termination of pregnancy

	Urine/ urethral swab	Anal swab	Cervical/ vaginal swab	Sample numbers
Male	354	34	n/a	388
Female	203	2	496	701
Total	557	36	496	1089

# Results of Prospective Study



## MG prevalence 6.0%

- Male 10.8%
- Female 3.3%

		In house qPCR (16S rRNA)		
		+	-	Total
SpeedDx	+	64	0	64
	-	1	1024	1025
	Total	65	1024	1089

	%	95% CI
Sensitivity	98.5	91.7 to 99.9
Specificity	100.0	99.6 to 100.0
PPV	100.0	94.4 to 100.0
NPV	99.9	99.5 to 100.0

## MG 23S rRNA mutant prevalence 63.1%

- Male 81.0% (34/42)
- Female 30.4% (7/23)
- (Male rectal 100%)

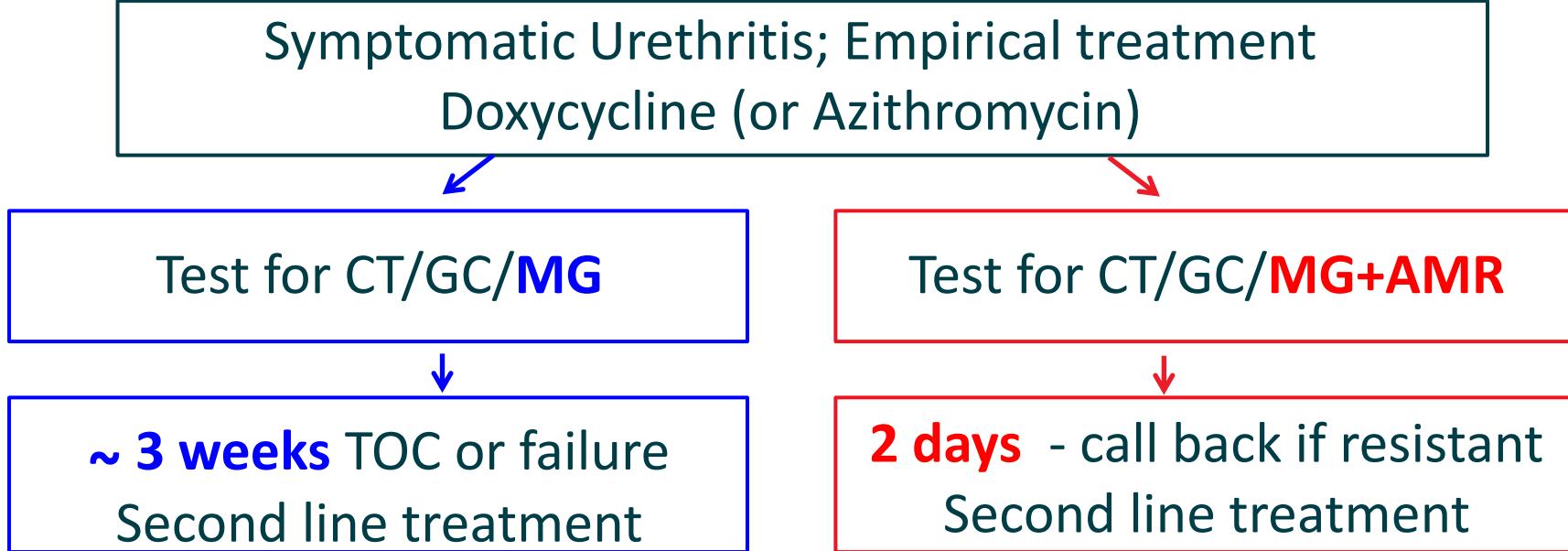
		Sanger Sequencing		
		Mutant	Wild type	Total
SpeedDx	Mutant	38	1	39
	Wild type	0	25	25
	Total	38	26	64*

	%	95% CI
Sensitivity	100.0	90.8 to 100.0
Specificity	96.2	80.4 to 99.9
PPV	97.4	86.5 to 99.9
NPV	100.0	86.3 to 100.0

\* Only includes MG positive samples by both methods

**High Clinical Sensitivity and Specificity**

# *Improved patient care with ResistancePlus™ MG*



- Patient has MG+AMR ~ 6 weeks
- Community spread of AMR MG
- Removes MG+AMR from community within days
- IUSTI management guidelines

*Improved patient outcome & reduced spread AMR*

# Collaborators

- ❶ Sepehr Tabrizi
- ❶ Catriona Bradshaw
- ❶ Christopher Fairley
- ❶ Suzanne Garland
- ❶ Jenny Su



the women's  
the royal women's hospital



**MSHC**  
MELBOURNE SEXUAL HEALTH CENTRE  
Part of **AlfredHealth**



# Thank you!

*For further queries:*

Simon Bone, PhD  
European Application Specialist  
[simonb@speedx.com.au](mailto:simonb@speedx.com.au)

**Visit SpeeDx at booth #40**