



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

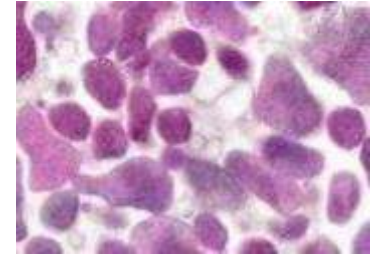
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Mycoplasma genitalium (MG)



M. genitalium as an STI

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



Anti-microbial resistance

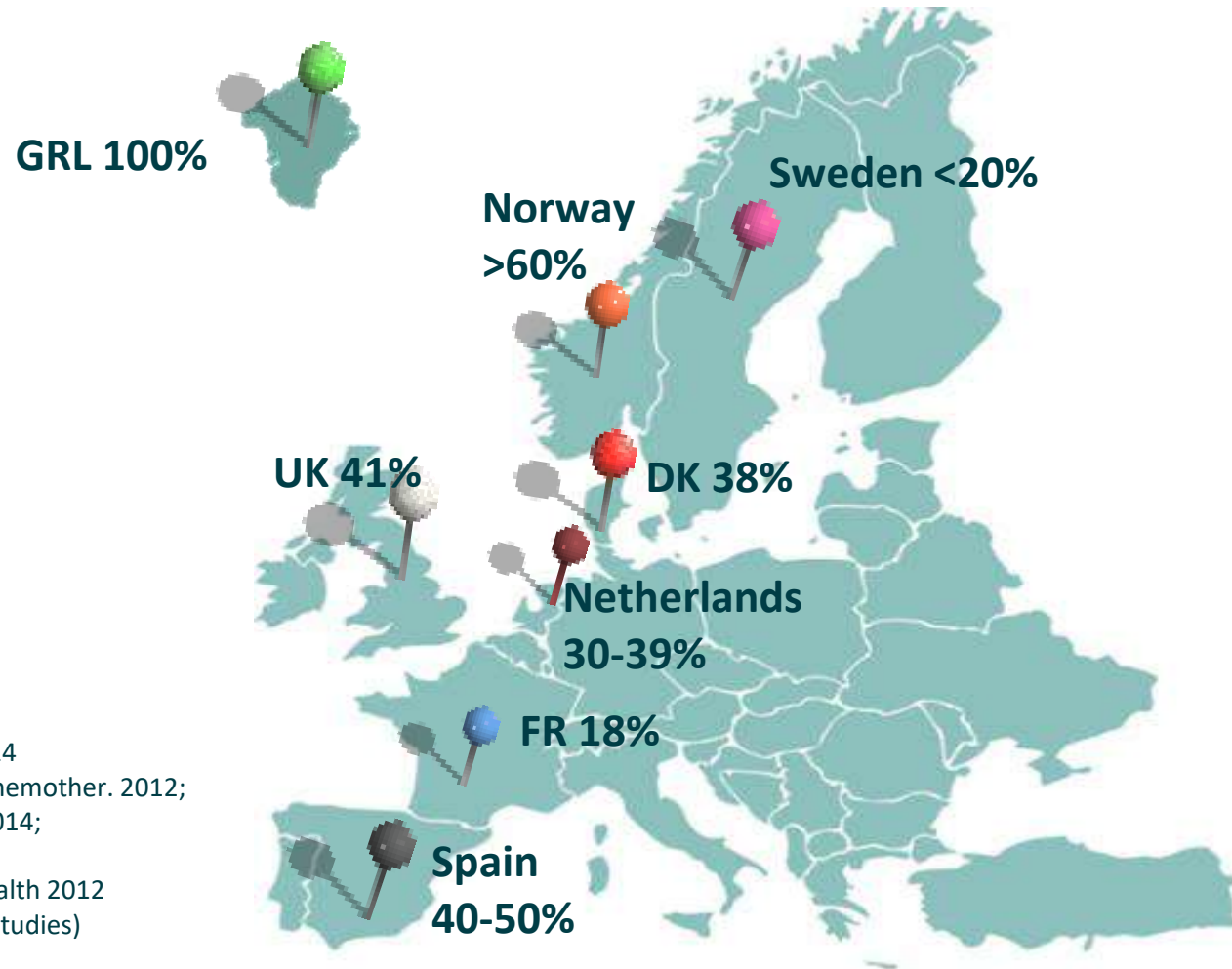
- 🌀 1st line treatment = Azithromycin (macrolide antibiotic)
- 🌀 Macrolide resistance associated with 23S rRNA mutations
- 🌀 A2058G, A2059G, A2058T, A2058C, A2059C (E. coli numbering)

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



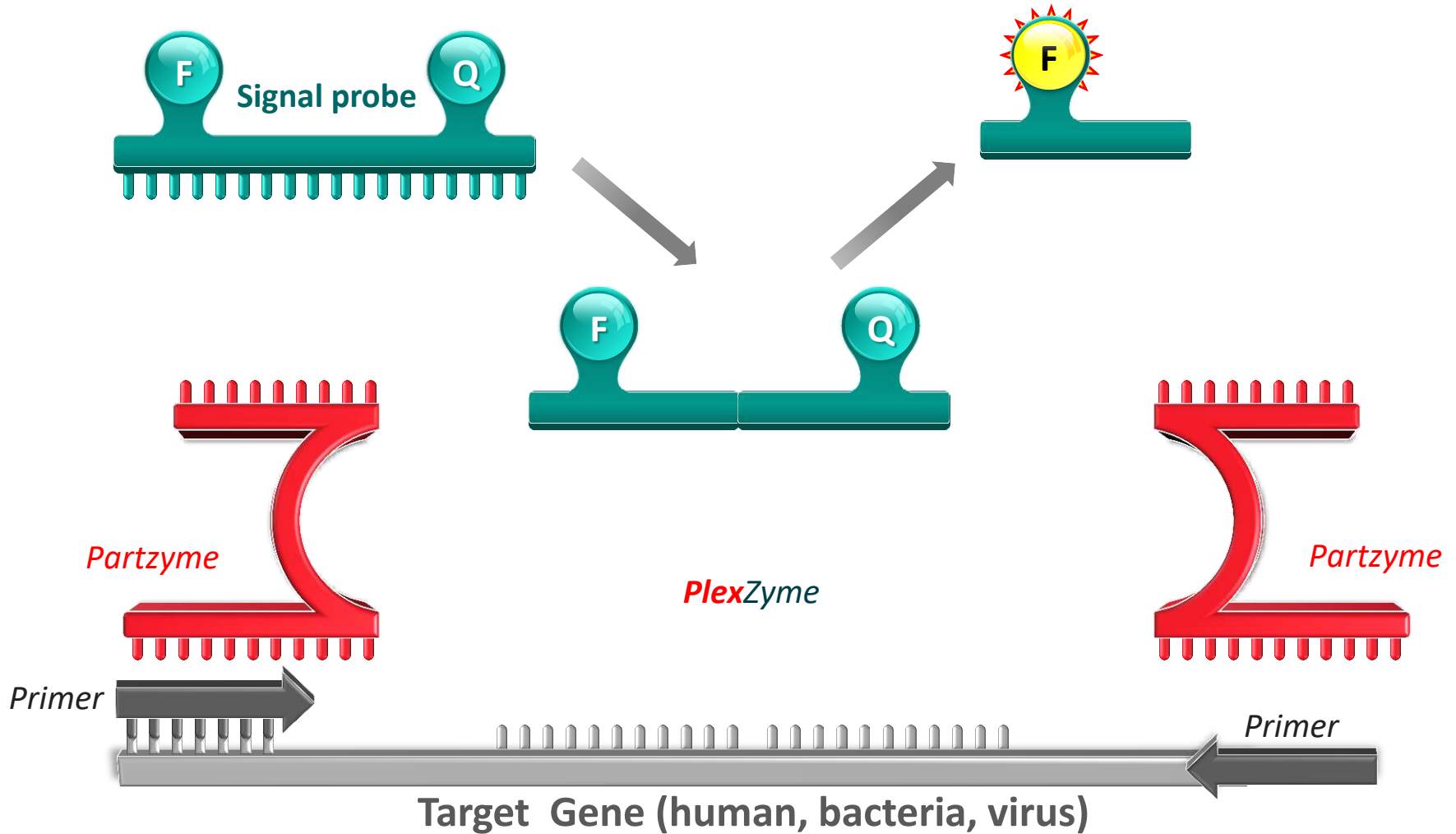
***Plex*PCR™**

***ResistancePlus*™**

Technology

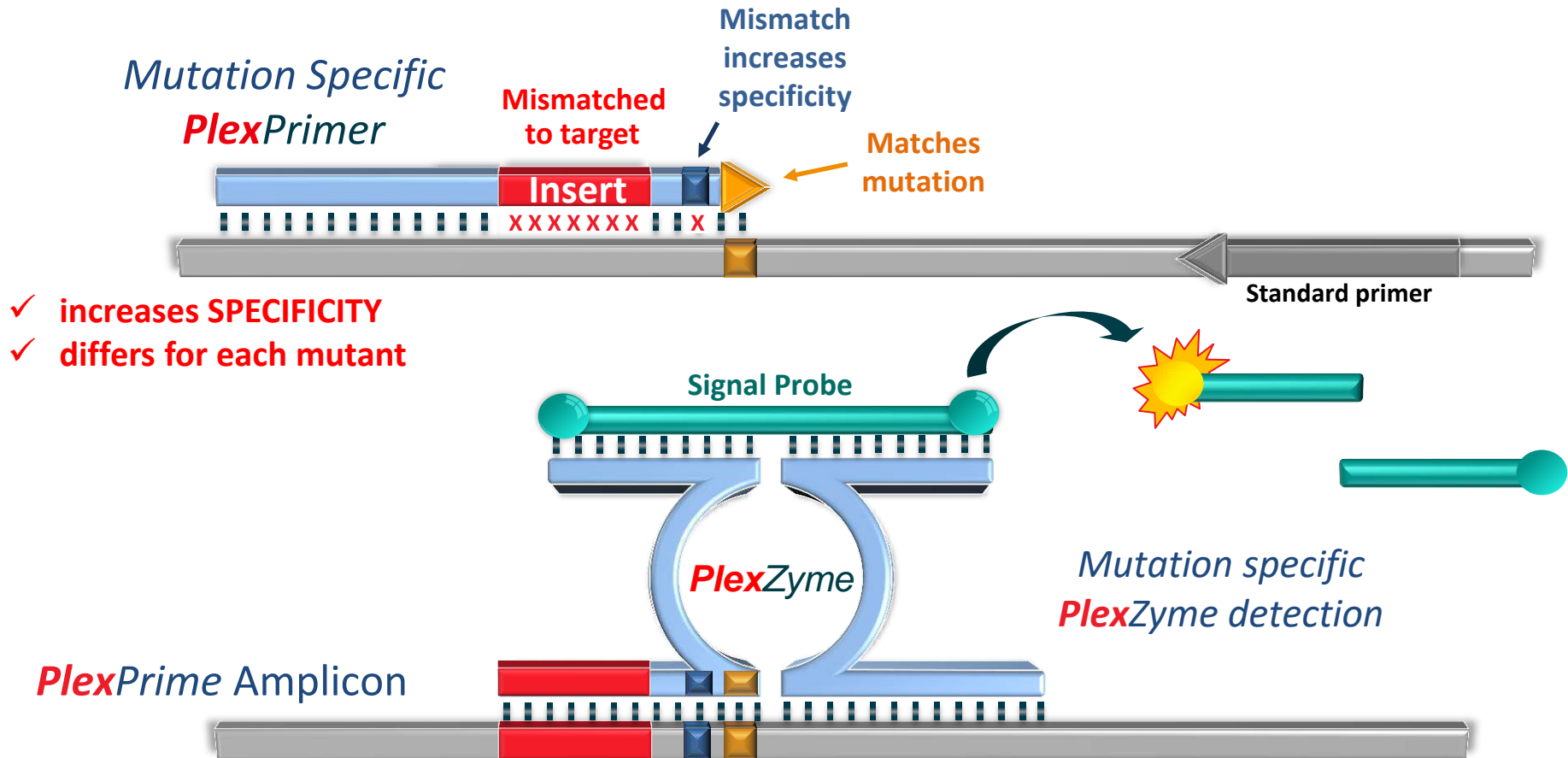


PlexPCR™



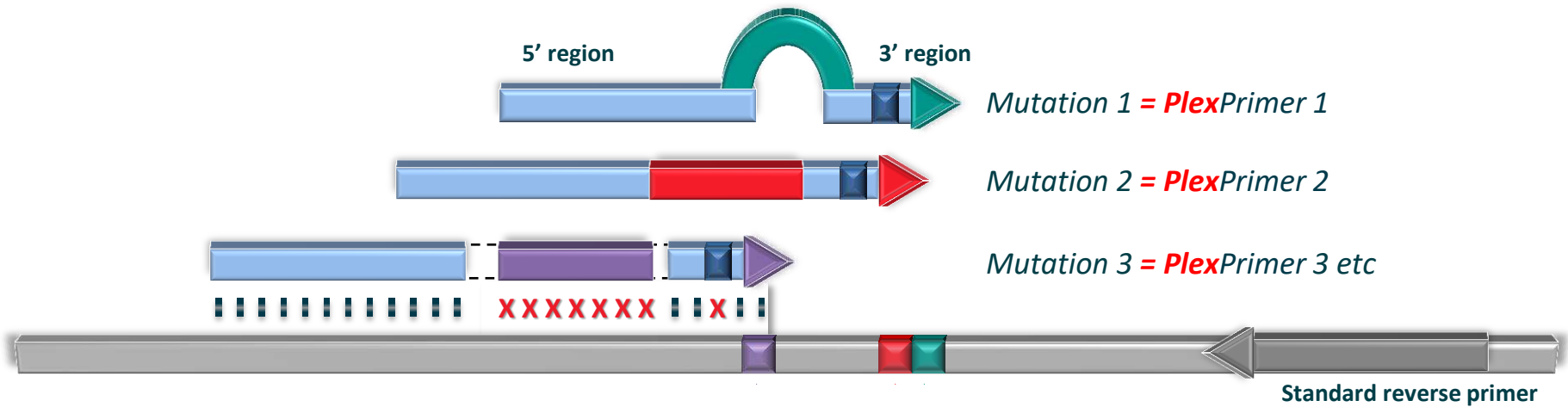
Highly Specific, Extremely Sensitive

ResistancePlus™



Mutation specific amplification AND mutation specific detection

ResistancePlus™



Channel 1

Probe 1

PlexZyme 1

Amplicon 1

Channel 2

Probe 2

PlexZyme 2

Amplicon 2

Channel 3

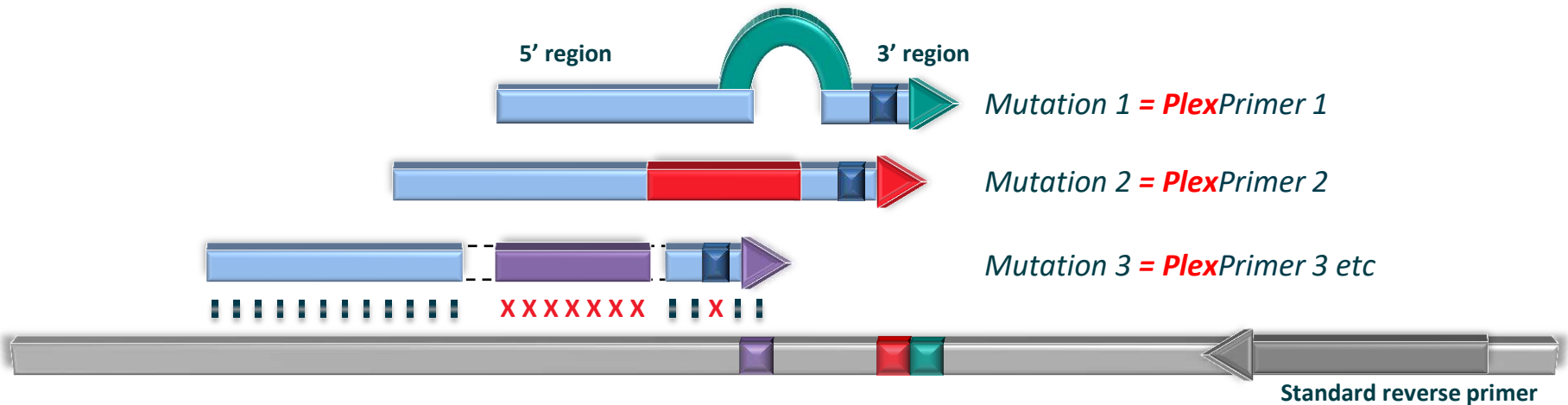
Probe 3

PlexZyme 3

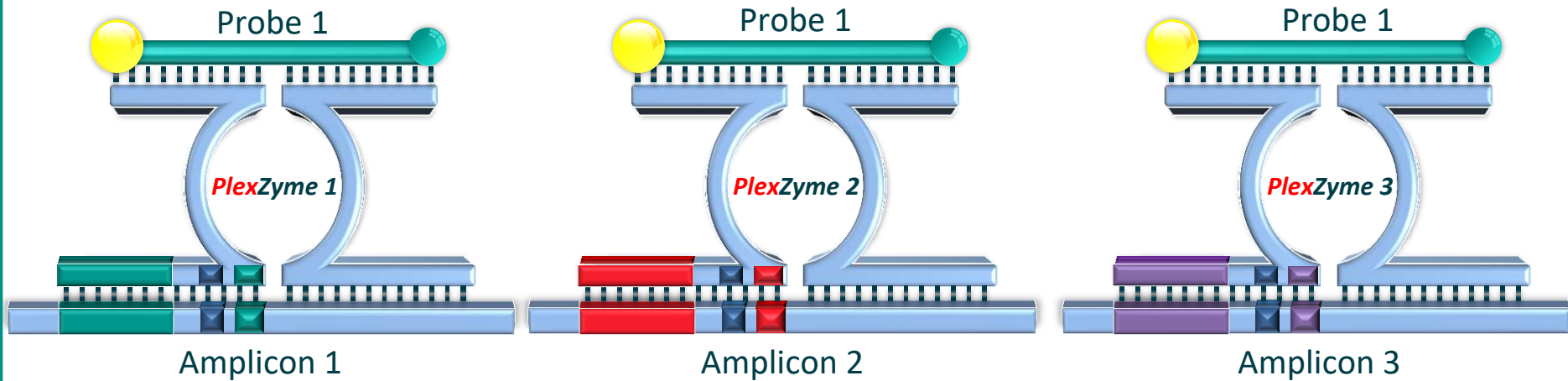
Amplicon 3

Highly sensitive multiplex assay for clustered mutations

ResistancePlus™



Channel 1



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

Prospective Clinical Study

Melbourne, Australia



1089 samples received Nov 2015-Dec 2015

Melbourne Sexual Health Centre
Catriona Bradshaw

Symptomatic male & female

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

Royal Womens Hospital
Sepehr Tabrizi

Non-symptomatic female

- 🌀 Contraceptive advice
- 🌀 Insertion of intra-uterine contraceptive device
- 🌀 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)				%	95% CI
		+	-	Total			
SpeedX	+	64	0	64	Sensitivity	98.5	91.7 to 99.9
	-	1	1024	1025	Specificity	100.0	99.6 to 100.0
	Total	65	1024	1089	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				%	95% CI
		Mutant	Wild type	Total			
SpeedX	Mutant	38	1	39	Sensitivity	100.0	90.8 to 100.0
	Wild type	0	25	25	Specificity	96.2	80.4 to 99.9
	Total	38	26	64*	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



Symptomatic Urethritis; Empirical treatment
Doxycycline (or Azithromycin)

Test for CT/GC/**MG**

~ **3 weeks** TOC or failure
Second line treatment

Test for CT/GC/**MG+AMR**

2 days - call back if resistant
Second line treatment

- 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

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



the women's
the royal women's hospital



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

Thank you!

For further queries:

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