

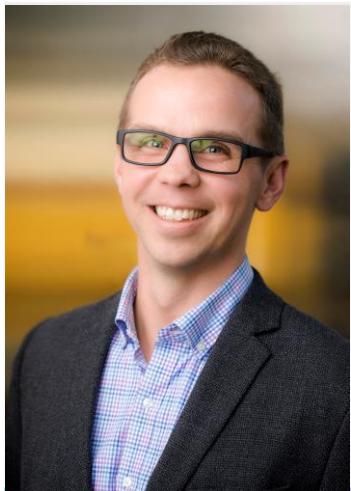


Diagnostics Defining Therapy

Colin Denver
CEO
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Executive Team



Colin Denver
CEO



Alison Todd (PhD)
CSO



Elisa Mokany (PhD)
CTO



Bhavin Raval
(CPA, FGIA, FCIS)
CFO

Board

Biotech Investments Holding
Andrew Denver
• Universal Biosensors Inc
• Cochlear

CM Capital Venture Trust
Andrew Jane
• Universal Biosensors Inc
• Osprey Medical

Northpond Ventures, LP
Michael Rubin
Platinum International
Bianca Ogden

John Klopp
• Johnson & Johnson
• DuPont medical products

Deliver innovative
clinical diagnostics to improve
patient outcomes

Company Overview



- 2009** Company spun out of J&J, VC funding established
- 2010 onwards** Novel technologies developed & licensed
- 2013 onwards**
-  Custom tests for research market (equity investment)
 -  >1.5 million reactions sold
- 2016** European headquarters (London), Release of **ResistancePlus® MG**
- 2017** USA Incorporation (1st US sale), Release of **PlexPCR® VHS**
- 2018** Resistance Guided Therapy included in International STI guidelines, Release of **ResistancePlus® GC**
- 2019** Announced Cepheid partnership. Release **ResistancePlus® MG Flexible** Release of **PlexPCR® RespiVirus**. Secured US\$15 M funding.
- 2020** Announced LabCorp partnership. Secured US\$15 M funding.

Partnerships and Global Impact



Working with LabCorp to develop and introduce new tests to improve care in women's health and infectious disease



Partnership with Cepheid delivering Mgen testing with antibiotic resistance on the GeneXpert® System



FDA breakthrough status granted for **ResistancePlus® GC** recognizing unique commercial offering for gonorrhoea and antibiotic susceptibility testing



GSK collaboration agreement providing existing and custom test development to support antibiotic clinical trials and new product development



Influencing national and international management guidelines for *M. genitalium* and gonorrhoea infections

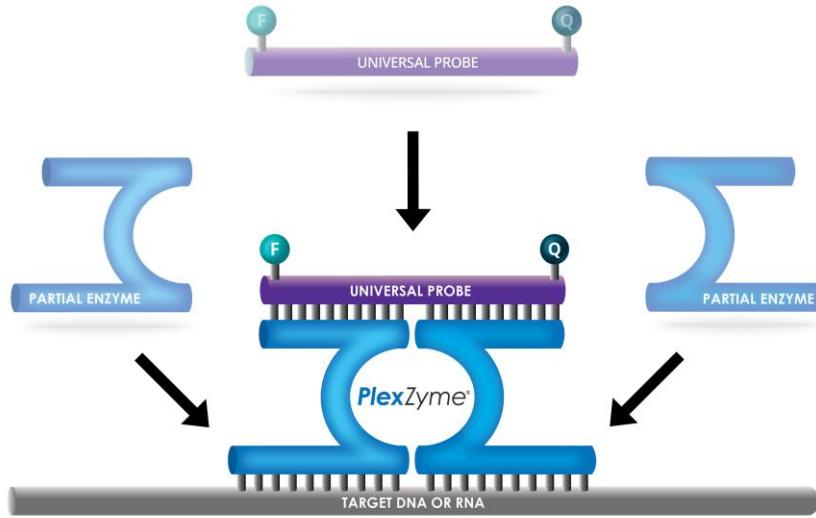


Licensing partnership with Biocartis to advance diagnosis and treatment of cancer

Intellectual Property

	Technology	Patent Family	Granted / Pending
SpeeDx Inventions 12 Patent families 87 Granted 45 Pending	PlexZymes	WO 2007/041774	AU, AU-D, CA, CN, EP, EP-D, HK, IL, IN, JP, KR, MX, NZ, SG, US, US-CIP, ZA; BR
		WO 2008/040095	AU, BR, CA, CN, EP, HK, IL, JP, MX, NZ, SG, US, ZA
		WO 2008/122084	AU, CA, CN, EP, HK, IN, KR, MX, NZ, SG, US, ZA
		WO 2007/065926	AU, EP, US; CN, CA
		WO 2008/122598	AU, AU-D, EP, US; CA
		WO 2013/033792	AU, CN, EP, IL, JP, KR, MX, NZ, RU, SG, US, US-CIP, ZA; BR, CA, HK, IN <u>IP protection for PlexZymes until 2032</u>
	PlexPrime	WO 2013/123552	AU, CN, EP, HK, IL, JP, KR, MX, NZ, SG, US; BR, CA, IN, JP-D, US-CIP, ZA <u>IP protection for PlexPrime until 2032</u>
	DoC	WO 2013/188912	AU, CN, EP, HK, IL, JP, NZ, SG, US, ZA; CA, IN
	EzyAmp	WO 2012/065231	AU, CA, CN, EP, HK, IL, JP, KR, NZ, MX, SG, US, ZA; BR
	M-bag	WO 2018/187829	AU, CA, CN, EP, HK, IS, IN, JP, NZ, SG, US, ZA
	VITA PCR	WO 2019/119072	AU, BR, CA, CN, EP, HK, IS, IN, JP, KR, MX, NZ, RU, SG, US, ZA
	LOCS	PCT/IB2019/056811	30 month national phase deadline is Feb 2021

Patented molecular technology for enhanced qPCR-based diagnostics



PlexZyme®

PlexPCR®

More targets per test

- **PlexPCR® VHS**
- **PlexPCR® RespiVirus**

Insert:

- Non-complementary to target
- Unique sequence can be used for each variant

5' region:

- Complementary to the target sequence

3' region:

- Containing extra mismatch to increase specificity
- 3' base matches SNP or mutation

PlexPrime®

ResistancePlus®

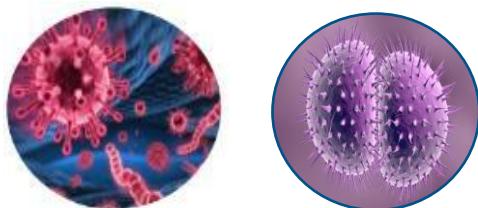
Distinguish resistance markers

- **ResistancePlus® MG**
- **ResistancePlus® GC**

Improving Standard of Care

Diagnosis

Detect the pathogen



Stewardship

Select the right drug



Resistant

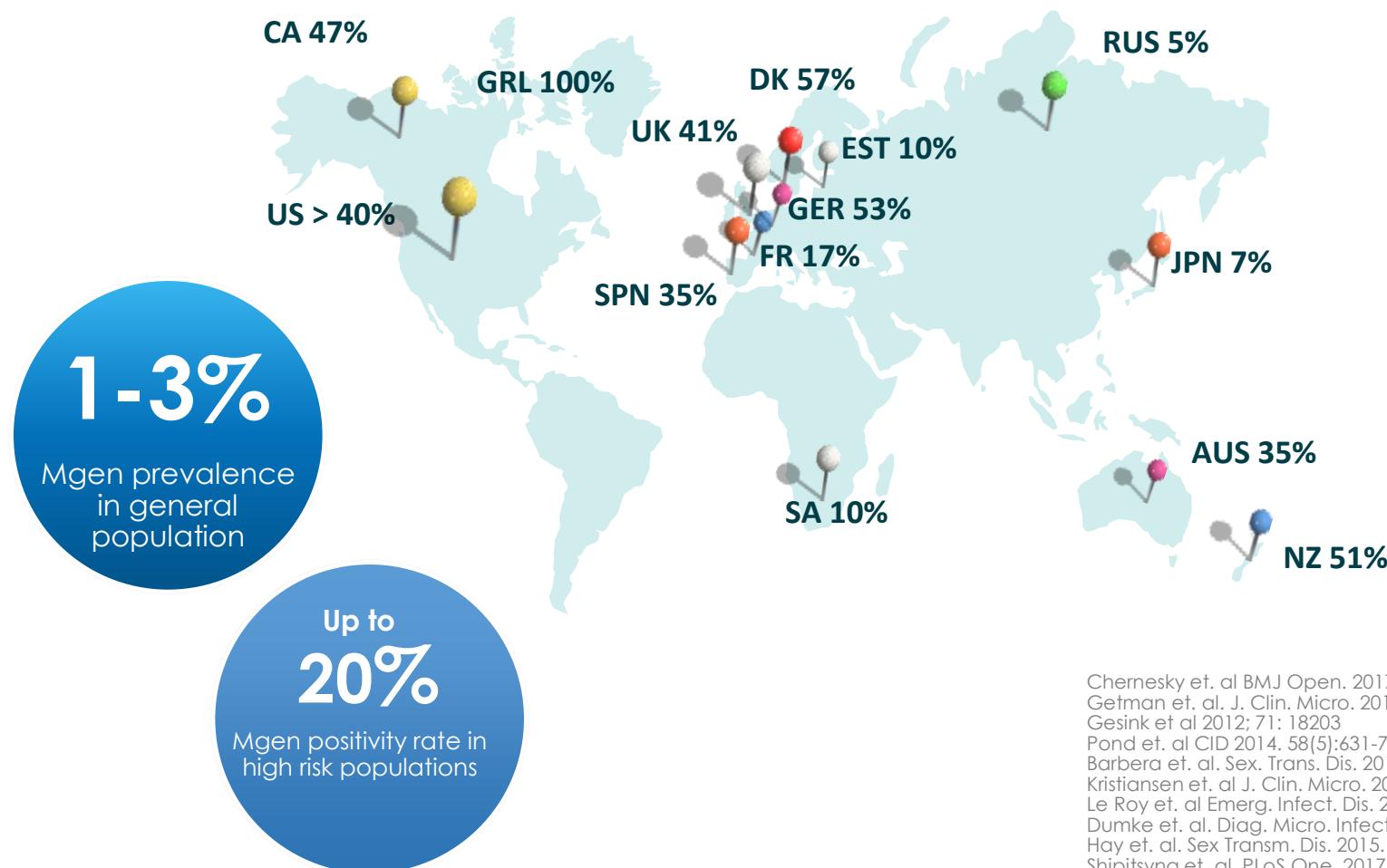


Sensitive

Resistance Guided Therapy

Diagnostic tests that provide detection of bacteria
and guidance on effective antibiotic treatment

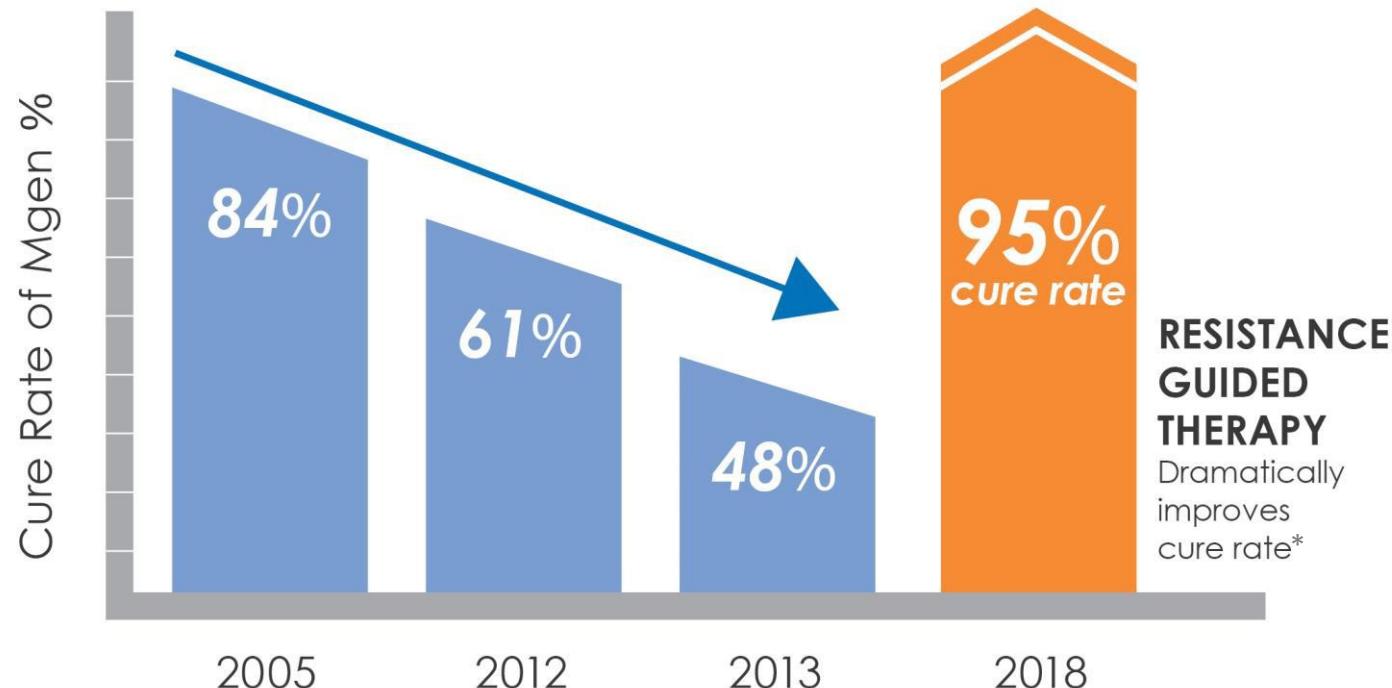
M. genitalium Azithromycin Resistance Rates



Chernsky et. al BMJ Open. 2017;7(7) :e016300
 Getman et. al. J. Clin. Micro. 2016 Sep;54(9):2278-83
 Gesink et al 2012; 71: 18203
 Pond et. al CID 2014. 58(5):631-7.
 Barbera et. al. Sex. Trans. Dis. 2017. 44(8):457-462.
 Kristiansen et. al J. Clin. Micro. 2016. 54(6):1593-1597
 Le Roy et. al Emerg. Infect. Dis. 2016. 22(9):1677-9.
 Dumke et. al. Diag. Micro. Infect. Dis. 2015. 86(2):221-3.
 Hay et. al. Sex Transm. Dis. 2015. 42(3):140-2.
 Shipitsyna et. al. PLoS One. 2017. 12(4):e0175763.
 Kikuchi et. al. J. Antimicro. Chemother. 2014. 69(9):2376-82.
 Bissessor et al Clin. Infect. Dis. 2015;60(8):1228-36

ResistancePlus® MG

Enables Resistance Guided Therapy



Outcomes of Resistance-guided Sequential Treatment of *Mycoplasma genitalium* Infections: A Prospective Evaluation

Tim R. H. Read,^{1,2} Christopher K. Fairley,^{1,2} Gerald L. Murray,^{3,4,5,6} Jorgen S. Jensen,⁷ Jennifer Danielewski,^{3,4} Karen Worthington,² Michelle Doyle,² Elisa Mokany,⁸ Litty Tan,⁸ Eric P. F. Chow,^{1,2} Suzanne M. Garland,^{3,4,6,9} and Catriona S. Bradshaw^{1,2}

STI Management Guidelines

Mycoplasma genitalium

A/Prof. S. Tabrizi
Approached SpeedDx
to design IVD for
Mgen + resistance



2014

Resistance testing
recommended if
available



2017

Recommends Resistance
Guided Therapy (based
on Australia)



Nov 2018

CDC STD
Guidelines update
meeting



June 2019

ResistancePlus® MG
FDA Submission



Q2 2020

2016



Australia & UK/EU

ResistancePlus® MG
launched

Mar 2018



Australia

Treat based on resistance
result
Resistance Guided Therapy

Apr 2019



France

Recommends
Resistance Guided
Therapy

Oct 2019

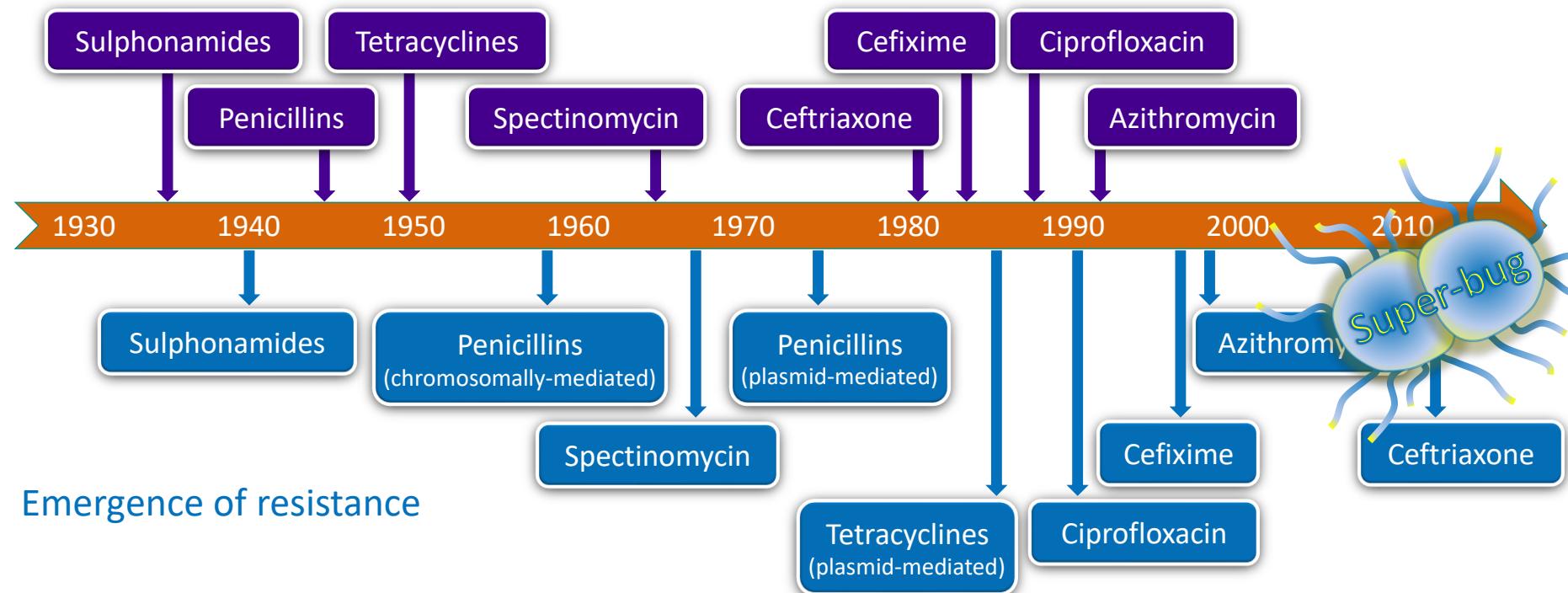


UK & EU

ResistancePlus MG
Flexible for GeneXpert*

Neisseria gonorrhoeae (GC)

Antibiotics used for treatment



1st line treatment = Ceftriaxone is the last available

Ciprofloxacin treatment for GC

British Association for Sexual Health and HIV
national guideline for the management of
infection with *Neisseria gonorrhoeae* (2019)



First line empirical treatment is now monotherapy with ceftriaxone 1g intramuscularly

If antimicrobial susceptibility test results from all sites of infection are available prior to treatment and the isolate is sensitive to ciprofloxacin, then this should be used for treatment in preference to ceftriaxone

ResistancePlus® GC

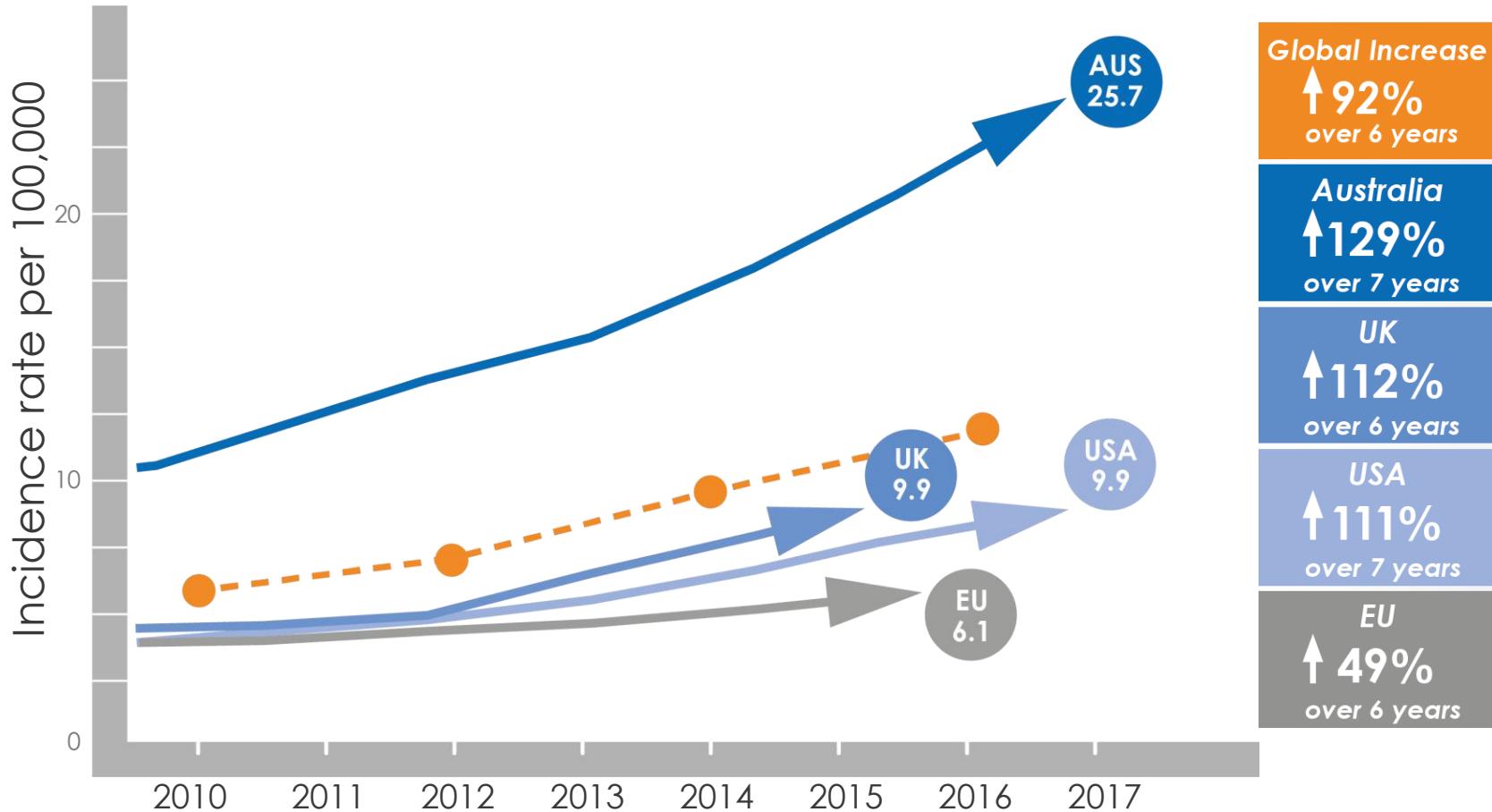
Service Evolution

- ▶ Increase in asymptomatic postal STI testing services
- ▶ CT positives can be treated at pharmacy
- ▶ GC positive – Cipro susceptible – could be treated at pharmacy
- ▶ Remote workers, zero-hour contracts – limited time off work
- ▶ Conservative patient populations – discretion
- ▶ **ResistancePlus® GC** will provide rapid AMR status of the infection which can enable a personalised treatment specific to the individual patient.

Resistant gonorrhoea A public health issue



Syphilis Rates Rising Globally¹⁻³



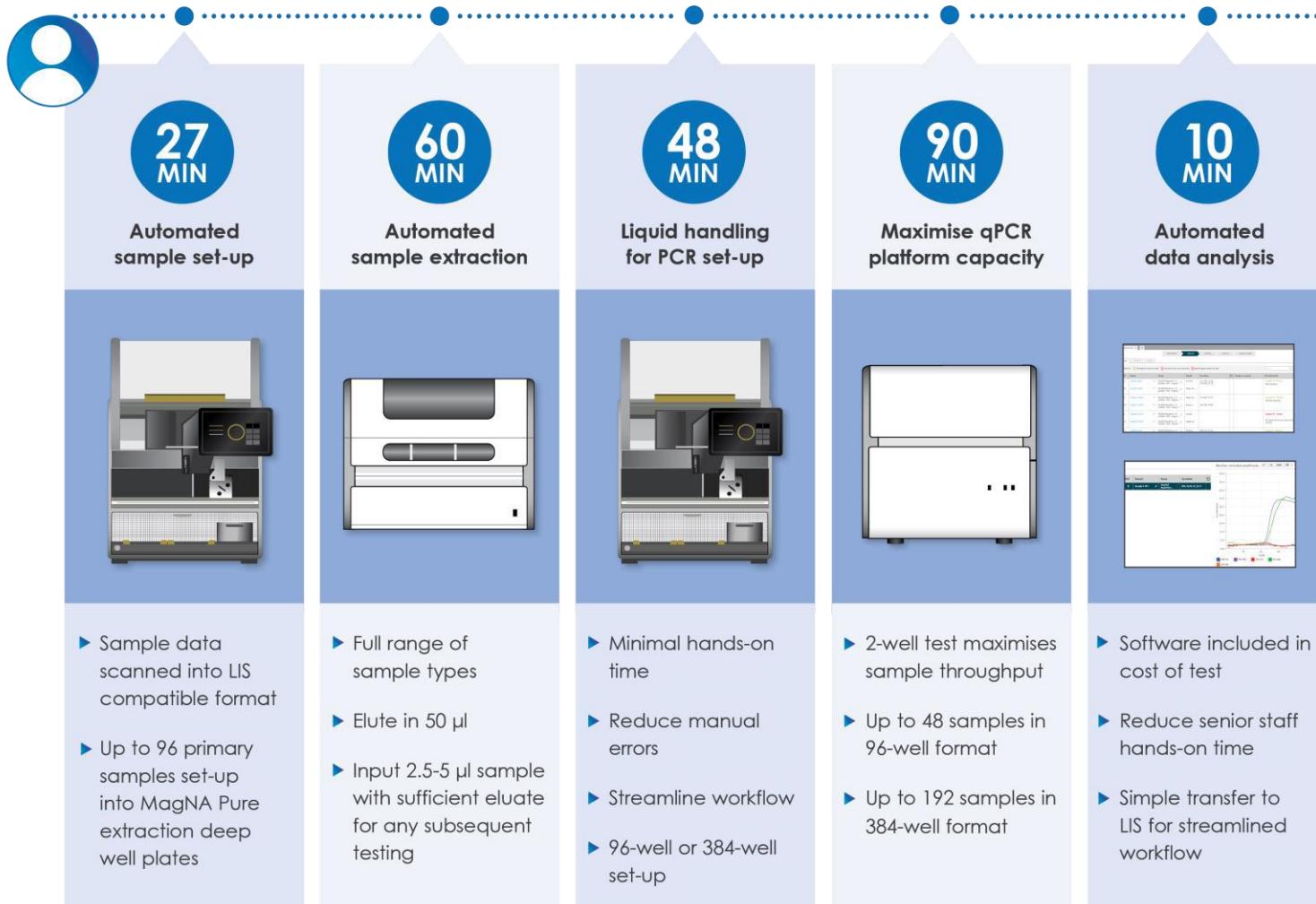
1. Australian Institute of Health and Welfare 2018. Australia's health 2018. Australia's health series no. 16.

2. ECDC surveillance atlas of infectious diseases, syphilis 2015

3. CDC Sexually Transmitted Disease Surveillance 2017

PlexPCR® RespiVirus

Automated workflow



Registered Products & Pipeline

TGA/
CE-IVD
tests

Available Now

2020*

2021*

Sexually Transmitted Infections

- **ResistancePlus® MG**
- **ResistancePlus® MG Flexible**
- **ResistancePlus® GC**
- **PlexPCR® VHS**
- **PlexPCR® HSV-1,HSV-2, VZV**

- **ResistancePlus® MG (FDA)**
- **ResistancePlus® MG (z480)**
- **ResistancePlus® GC (z480)**

- **ResistancePlus® GC (FDA)**
- **ResistancePlus® GC Flexible**

Respiratory Infections

- **PlexPCR® RespiVirus**

- **PlexPCR® SARS-CoV-2**

- **ResistancePlus® MABS/MAC**
- **PlexPCR® RespiBacteria**

Built for Success

- ▶ Strong track record of delivering market altering innovations with strong KOL endorsements
- ▶ High Growth
- ▶ Technology Platform is:
 - ▶ Flexible
 - ▶ Versatile
 - ▶ Scalable
- ▶ Strong Partnerships with Global Dx/Rx
- ▶ Robust IP position with growing royalty streams
- ▶ Product pipeline with clear regulatory pathways



Thank you!

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