

“This technology brings STI testing to target populations”:

Opportunities and challenges with chlamydia and gonorrhoea point of care testing in a peer-led community service

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Always was,
Always will be.



RAPID ▶

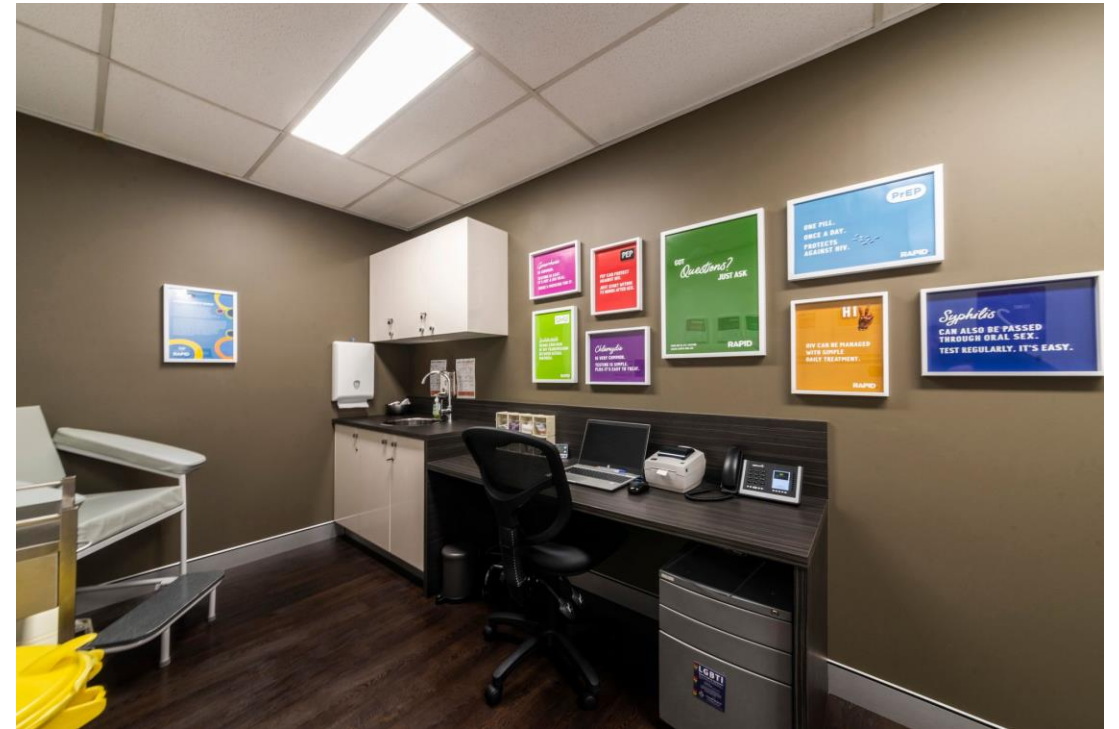
RAPID

- RAPID is a peer-led community-based sexual health clinic
- We provide asymptomatic screening for STIs:
 - Immunochromatographic testing for *Human Immunodeficiency Virus* and *Treponema pallidum*
 - Nucleic acid amplification testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*



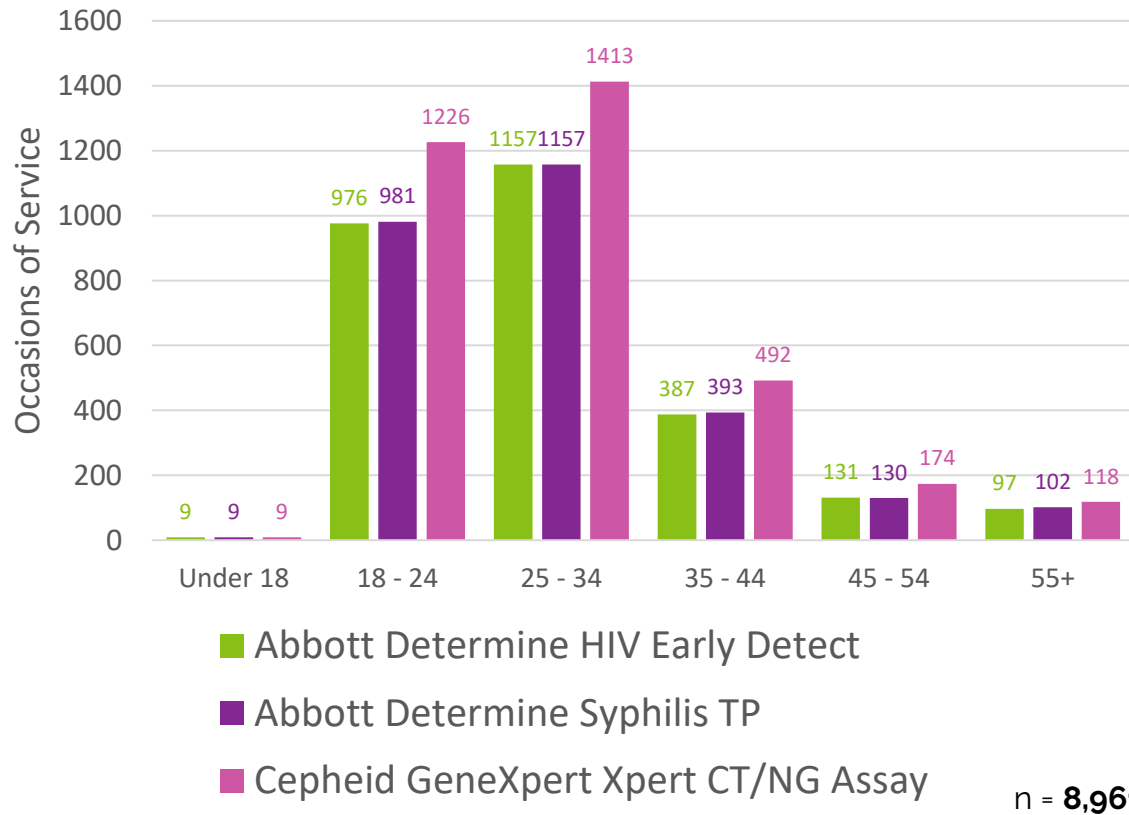
RAPID

- A public health intervention seeking to:
 - address barriers to testing uptake
 - deliver health promotion on a combination of prevention strategies for people at risk of HIV and other STIs
- Clinical oversight and governance provided by an infectious diseases physician and through several committees



Client demographics

RAPID: Test Type by Age, Jul - Dec 2022



RAPID: Gender & Sexual Partners, Jul - Dec 2022



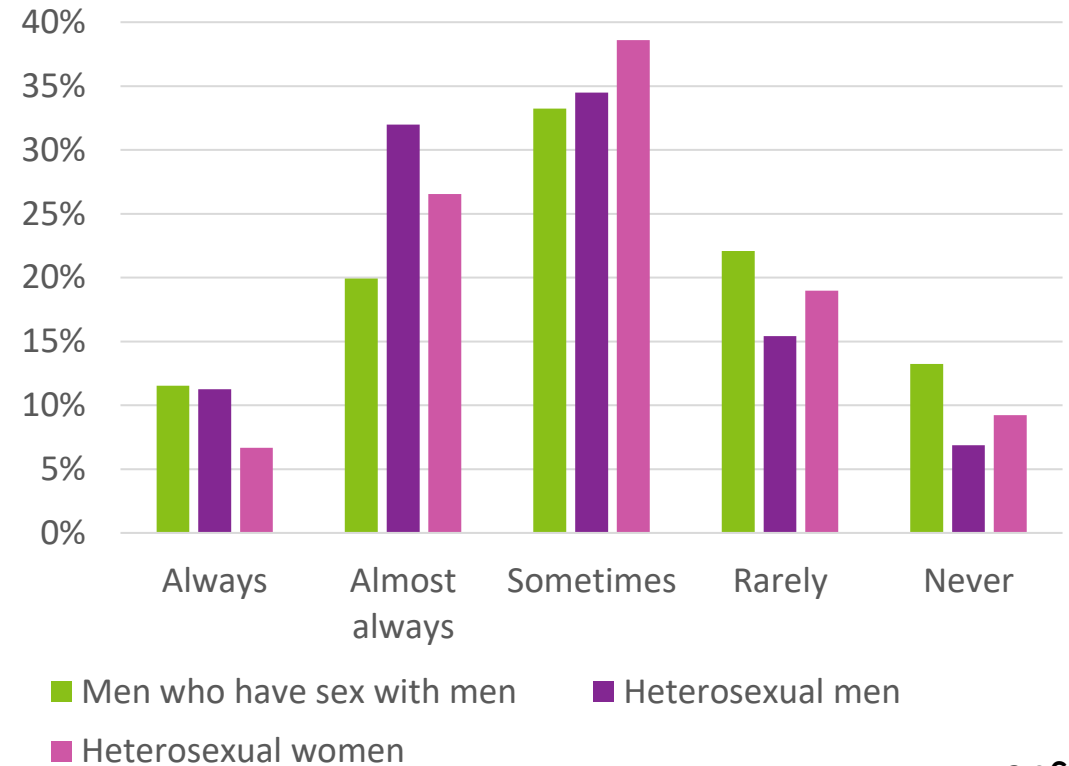
Behavioural risk factors

RAPID: Number of Sexual Partners, Sep 2022 - Feb 2023



n = 2,931

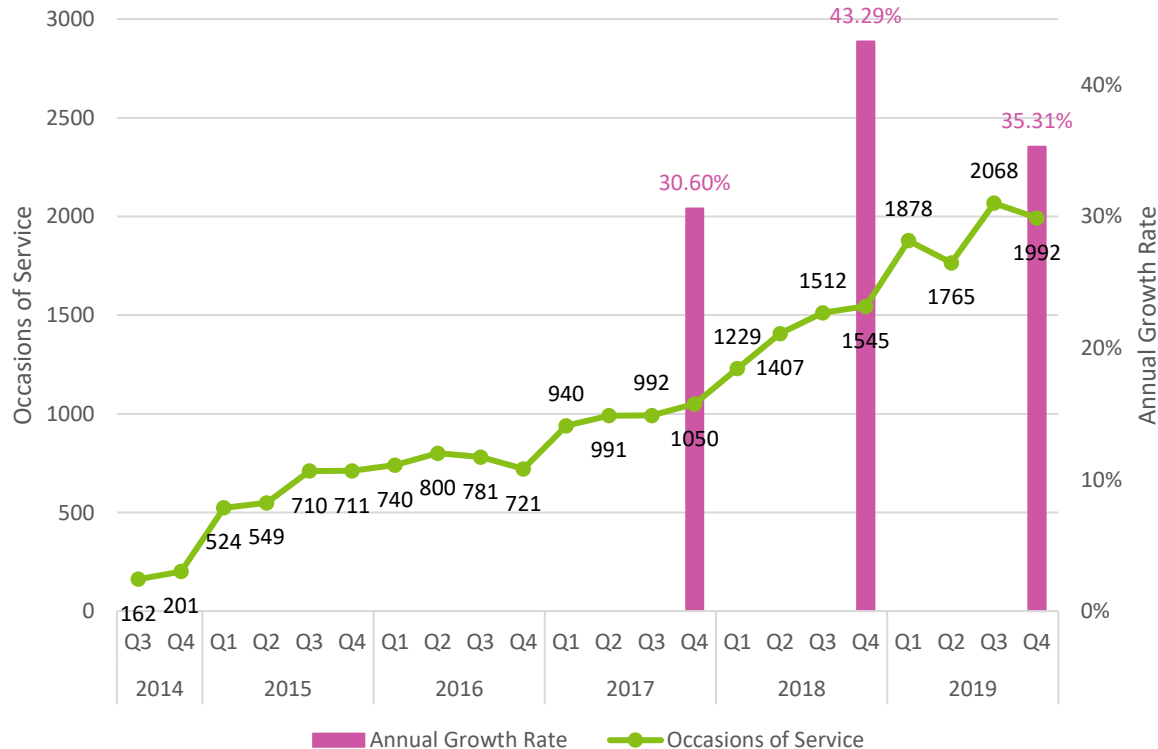
RAPID: Condom Usage, Sep 2022 - Feb 2023



n = 2,969

Growth associated with increased testing provision

RAPID: Quarterly Occasions of Service, 2017 -2019



2014

- Service established - HIV POCT

2015

- Introduction of syphilis POCT

2017

- Introduction of CT/NG POCT

Case for model expansion: analytical validity

	Chlamydia ¹				Gonorrhoea ¹			
	Sensitivity (%)	Specificity (%)	PPV ^ (%)	NPV ^ (%)	Sensitivity (%)	Specificity (%)	PPV # (%)	NPV # (%)
Urine (male)	98.5	99.8	98.1	99.8	98.3	99.9	98.2	99.9
Urine (female)	98.1	99.8	98.1	99.8	94.4	>99.9	98.2	99.7
Pharyngeal swab	95.9	99.7	97.1	99.6	94.7	98.8	81.8	99.7
Rectal swab	86.0	99.4	93.7	98.5	91.2	99.6	92.9	99.5



GeneXpert® X VI System processing unit
– 16 module instrument



Xpert® CT/NG – RT PCR

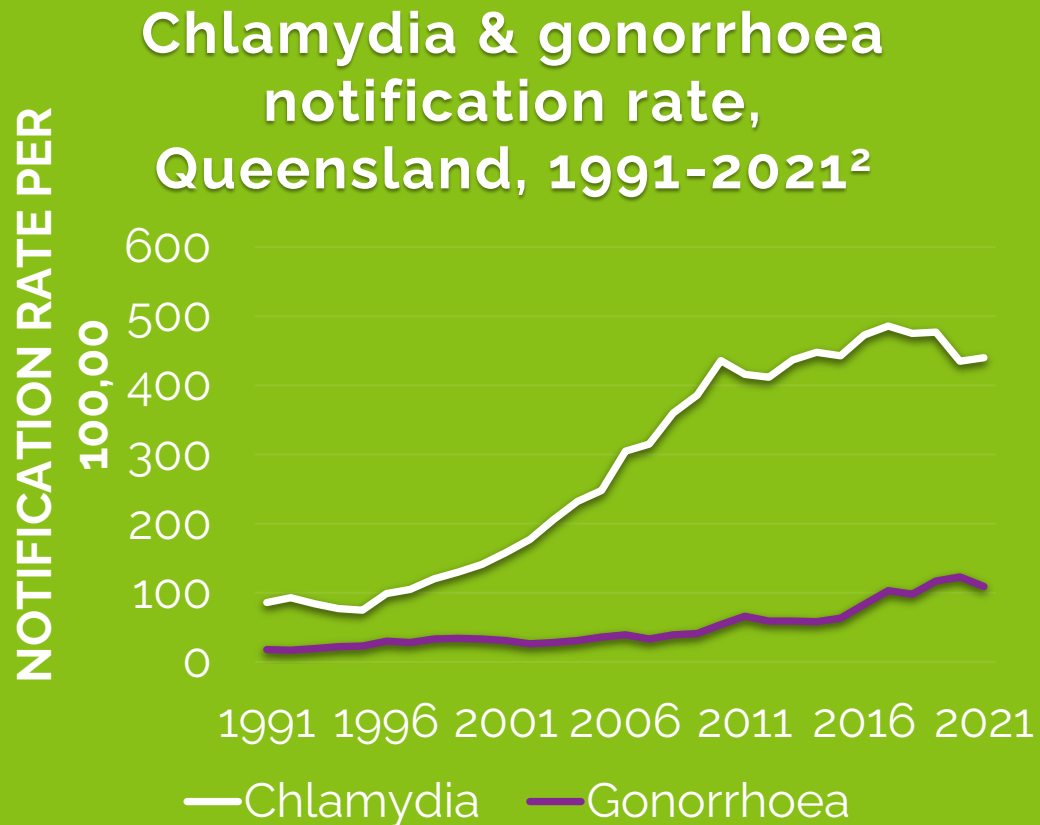
^ CT prevalence 9.5%
NG prevalence 5.4%



1. Cepheid. Data Sheet - XPERT CT/NG. Cepheid; 2018 [cited 2018 09/01/2018]



Case for model expansion: clinical validity



- HIV seroconversion up to **x5 greater** in presence of other STI ³
- Chlamydia detected in **1 in 20** young people screened ⁴
- Gonorrhoea **reduced susceptibility** to first-line antibiotic treatment ⁴
- **3-monthly CT & NG testing** for asymptomatic MSM⁵

Case for model expansion: clinical utility

- Engagement from high risk populations⁶
 - **64.7%** of MSM did not meet testing guidelines
 - **2x greater** CT & NG coinfection in clients tested at SOPV venues
- Acceptable to clients⁶
 - **99.3%** accepted CT & NG testing at 1st visit
 - **98.4%** satisfied with service

- Effective model⁶
 - **27.3%** infections would not have been detected
 - **98.4%** informed of result < 24hrs and linked into care

“This sort of technology really enables us to bring STI testing to target populations”

– Peer tester

Improving affordability through specimen pooling

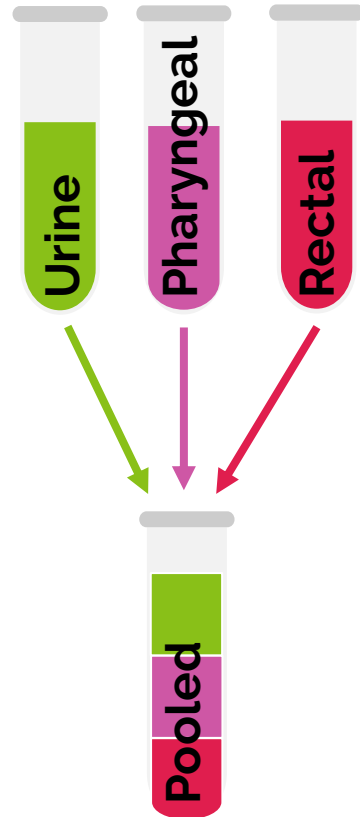
Individual specimens

X 3



Pooled specimens

X 1



Original RAPID protocol – 7 ml urine volume⁷

CSIRO PUBLISHING

Sexual Health, 2020, 17, 15–21
<https://doi.org/10.1071/SH19028>

Reduced sensitivity from pooled urine, pharyngeal and rectal specimens when using a molecular assay for the detection of chlamydia and gonorrhoea near the point of care

Steven G. Badman^{A,H,*}, Sara F. E. Bell^{B,*}, Judith A. Dean^B, Jime Lemoire^C, Luke Coffey^C, Joseph Debattista^D, Andrew M. Redmond^{C,E}, Owain D. Williams^B, Charles F. Gilks^{B,†} and David M. Whiley^{F,G,†}

Sensitivity
CT 90.0%
NG 89.7%

Revised RAPID protocol – 1 ml urine volume⁸

Research letter

Improved sensitivity from pooled urine, pharyngeal and rectal specimens when using a molecular assay for the detection of chlamydia and gonorrhoea near point of care

Judith Ann Dean¹, Sara Fiona Elizabeth Bell¹, Luke Coffey², Joseph Debattista³, Steven Badman⁴, Andrew M Redmond^{2, 5}, David M Whiley^{6, 7}, Jime Lemoire², Owain David Williams¹, Chris Howard², Charles F Gilks¹

Sensitivity
CT 98.0%
NG 93.2%

7. Badman SG et al. *Sex Health* 2020;17(1):7. 8. Dean JA et al. *Sexually Transmitted Infections* 2021;97(6):471-2.

Operationalising mPOCT

- RAPID's use of the GeneXpert system is considered "off-label"
 - Proceeds in the setting of research under the TGA's Clinical Trial Notification Scheme (CTN scheme)
- This approach is unsustainable in terms of funding and future certainty
- A National Association of Testing Authorities accreditation process was investigated
 - Deemed unsuitable due to capital outlay and complexity
- Alternate medical testing model subverts success of community-led approach

Other Challenges

- **Surveillance**

- No direct notification of notifiable conditions

- **Lack of alternative CT/NG POCT**

- Not Australian approved
- Limited anatomical sites
- Paper based test - poor performance

- **Additional resourcing requirements**

- Training
- Data management
- Providing result and referrals

- **Cost**

- Community-based organisation funding models
- Technology, cartridges
- Additional staff

- **Performance criteria**

- Extended test development time >30 minutes⁹
- No antimicrobial susceptibility POCT for NG

Summary

- Community-based CT/NG POC testing:
 - improves access for high-risk populations
 - acceptable to clients and staff
 - implementation limited by regulatory requirements and cost
- Stakeholder collaboration required to support integration into STI management pathways



GeneXpert Advisory Committee

- **The University of Queensland (UQ)**
 - A/Prof Judith Dean (POCHE)
 - Prof Charles Gilks (UQ SPH)
 - Sara Bell (UQCCR)
 - A/Prof David Whiley (UQCCR)
- **Cepheid**
 - Dr Steven Badman
- **The University of New South Wales (UNSW)**
 - Prof Rebecca Guy (Kirby Institute)
- **Queensland Positive People (QPP)**
 - Melissa Warner
 - Luke Coffey
 - Cassio Oliveira
- **Metro North Health**
 - Dr Joseph Debattista
 - A/Prof Andrew Redmond
 - Dr Eugene Priscott

Disclosure of Interests

- QPP is funded by the Queensland Government
- Cepheid provided GeneXpert-XVI instrument and Xpert CT/NG assay cartridges
- Metro North Health provided funding via their Seed and Link programs
- Support provided through the Queensland Professorial Chair in Blood-Borne Virus and Sexually Transmissible Infections
- Dr Steven Badman is a RAPID GeneXpert research committee member, a former employee of The Kirby Institute for Infection and Immunity in Society at UNSW, and is currently employed by Cepheid.



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- 8. Dean JA, Bell SFE, Coffey L, Debattista J, Badman S, Redmond AM, et al. Improved sensitivity from pooled urine, pharyngeal and rectal specimens when using a molecular assay for the detection of chlamydia and gonorrhoea near point of care. *Sexually Transmitted Infections* 2021;97(6):471-2.
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