



**Australian Government**

**Department of Health**

## **MSAC Application 1627**

# **Point-of-care test for diagnosis of Neisseria gonorrhoea, Chlamydia trachomatis and Trichomonas vaginalis infection in Aboriginal and Torres Strait Islander patients presenting at health services in areas with high sexually transmitted infection burden**

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires in order to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

The application form will be disseminated to professional bodies / organisations and consumer organisations that have will be identified in Part 5, and any additional groups that the Department deem should be consulted with. The application form, with relevant material can be redacted if requested by the Applicant.

Should you require any further assistance, departmental staff are available through the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

# PART 1 – APPLICANT DETAILS

## 1. Applicant details (primary and alternative contacts) The Kirby Institute

Corporation / partnership details (where relevant):

Corporation name: The Kirby Institute

ABN: 57 195 873 179

Business trading name:

**Primary contact name: REDACTED**

Primary contact numbers **REDACTED**

Business: **REDACTED**

Mobile:

Email: **REDACTED**

**Alternative contact name: REDACTED**

Alternative contact numbers

Business: **REDACTED**

Mobile:

Email: **REDACTED**

## 2. (a) Are you a consultant acting on behalf of an Applicant?

Yes

No

**(b) If yes, what is the Applicant(s) name that you are acting on behalf of?**

Insert relevant Applicant(s) name here.

## 3. (a) Are you a lobbyist acting on behalf of an Applicant?

Yes

No

**(b) If yes, are you listed on the Register of Lobbyists?**

Yes

No

## PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

### 4. Application title

Rapid on-demand point-of-care test for the diagnosis of *Neisseria gonorrhoea* (NG), *Chlamydia trachomatis* (CT) and *Trichomonas vaginalis* (TV) infection in Aboriginal and Torres Strait Islander patients presenting at health services in areas with high sexually transmitted infection (STI) burden.

### 5. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

Chlamydia (CT), gonorrhoea (NG) and trichomonas (TV) are sexually transmitted bacterial infections, often asymptomatic,<sup>1,2</sup> mostly affecting young people aged 15-29 years.<sup>3</sup> In remote/very remote communities these infections are a significant public health issue with notification rates of CT 5 times higher, NG 30 times higher, and rates of TV 5 times higher, compared to non-Indigenous Australians.<sup>4,5</sup> Easily cured with antibiotics<sup>6</sup>, untreated infection can cause pelvic inflammatory disease resulting in chronic abdominal pain, as well as increasing the risk of tubal infertility and ectopic pregnancy.<sup>7,8</sup> Untreated infection in pregnant women can lead to premature delivery with additional risks for infected newborn babies.<sup>9,10</sup> In men, consequences of untreated infections are urethritis, epididymitis, and arthritis, and NG can cause disseminated gonococcal infection which may be life-threatening.<sup>11,12</sup> Additionally these infections can increase the risk of acquiring and transmitting HIV infection.<sup>13,14</sup>

### 6. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

Provision of a rapid on-demand nucleic acid amplification test (NAAT) for use at point-of-care (POC) in clinics servicing remote communities enables laboratory equivalent, on-the-spot diagnosis for CT, NG and/or TV infection within 90 minutes, facilitating antibiotic treatment for patients and initiation of contact tracing. Current CT/NG guidelines for Aboriginal and Torres Strait Islander peoples aged 15-34 years in remote communities recommends opportunistic screening and treatment of symptomatic patients. Guidelines for TV vary nationally with opportunistic screening recommended for men and women in the Northern Territory, for women only in Queensland and if clinically indicated based on symptoms or history in Western Australia. The test device is approved by the Australian Therapeutic Goods Administration. The POC test replaces laboratory-based testing, utilises routine samples (urine, vaginal, cervical/urethral swabs), and is acceptable to patients and feasible for clinical staff, including Aboriginal Health Workers/Practitioners and Nurses Practitioners, to use as part of a primary healthcare program.

### 7. (a) Is this a request for MBS funding?

- Yes  
 No

### (b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

- Amendment to existing MBS item(s)  
 New MBS item(s)

### (c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

N/A

### (d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

N/A

**(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?**

- i.  A new item which also seeks to allow access to the MBS for a specific health practitioner group
- ii.  A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
- iii.  A new item for a specific single consultation item
- iv.  A new item for a global consultation item(s)

**(f) Is the proposed service seeking public funding other than the MBS?**

- Yes
- No

**(g) If yes, please advise:**

N/A

**8. What is the type of service:**

- Therapeutic medical service
- Investigative medical service
- Single consultation medical service
- Global consultation medical service
- Allied health service
- Co-dependent technology
- Hybrid health technology

**9. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):**

- i.  To be used as a screening tool in asymptomatic populations
- ii.  Assists in establishing a diagnosis in symptomatic patients
- iii.  Provides information about prognosis
- iv.  Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
- v.  Monitors a patient over time to assess treatment response and guide subsequent treatment decisions
- vi.  Is for genetic testing for heritable mutations in clinically affected individuals and, when also appropriate, in family members of those individuals who test positive for one or more relevant mutations (and thus for which the Clinical Utility Card proforma might apply)

**10. Does your service rely on another medical product to achieve or to enhance its intended effect?**

- Pharmaceutical / Biological
- Prosthesis or device
- No

Current recommended treatment regimens for confirmed CT,NG and TV infection are a single dose of antibiotics as described in the Australian STI Management Guidelines for use in Primary care. <sup>6</sup> Recommendations for the prescribed dose may vary according to the situation (uncomplicated or complicated) and site of infection (genital, pharyngeal or ano-rectal) infection.

**Table 1: Recommended\* treatment regimens for Chlamydia and Gonorrhoea**

Scenario	Recommended regimen	Alternate regimen
<b>Chlamydia</b>		
Uncomplicated genital or pharyngeal infection	Doxycycline 100mg PO, BD 7 days OR Azithromycin 1g PO, stat	
Ano-rectal infection	Doxycycline 100mg PO, BD 7 days if asymptomatic, but 21 days if symptomatic	Azithromycin 1g PO, stat, and repeat in 1 week
Pregnant women	Azithromycin 1g PO, stat	
Rectal coinfection	For rectal coinfection with gonorrhoea, treatment should be given for both infections i.e.: Ceftriaxone 500mg IMI, stat in 2mL 1% lignocaine PLUS Doxycycline 100mg PO, BD 7 days if asymptomatic, but 21 days if symptomatic	Rectal coinfection
<b>Gonorrhoea</b>		
Uncomplicated ano-genital, ano-rectal or pharyngeal infection if in remote area	Amoxicillin 3g PO, stat PLUS Probenecid 1g PO, stat PLUS Azithromycin 1g PO, stat (when chlamydia not excluded).	If the infection is likely to have been acquired beyond local or other remote locations, use alternative treatment
Adult gonococcal conjunctivitis	Ceftriaxone 500mg IMI, stat in 2mL 1% lignocaine PLUS Azithromycin 1g PO, stat	
Rectal coinfection	For rectal coinfection with chlamydia, treatment should be given for gonorrhoea AND chlamydia i.e.: Ceftriaxone 500mg IMI, stat in 2mL 1% lignocaine PLUS Doxycycline 100mg PO, BD 7 days if asymptomatic, but 21 days if symptomatic (see ano-rectal syndromes)	Rectal coinfection
Pregnant women	Ceftriaxone 500mg IMI, stat in 2mL 1% lignocaine PLUS Azithromycin 1g PO, stat	
Alternative treatment Uncomplicated ano-genital, ano-rectal or pharyngeal infection	Ceftriaxone 500mg IMI, stat in 2mL 1% lignocaine PLUS Azithromycin 1g PO, stat	Alternative treatments are not recommended because of high levels of resistance, except for some remote Australian locations and severe allergic reactions. Seek advice
<b>Trichomonas</b>		
Uncomplicated infection	Metronidazole 2g PO with food, stat. OR Tinidazole 2g PO stat.	Metronidazole 400mg PO with food, BD for 5 days.

\*Australian STI Management Guidelines for use in primary care<sup>6</sup>

**11. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?**

- Yes  
 No

**(b) If yes, please list the relevant PBS item code(s):**

**Table 2 Medications for treatment of chlamydia, gonorrhoea and trichomonas currently listed under the PBS**

Code	Medicinal product name (Name, form, strength and pack size)	Indication
<b>Oral</b>		
2709N	Doxycycline 100 mg tablet, 7	CT
2702F	Doxycycline 100 mg tablet, 7	PID
2714W	Doxycycline 100 mg tablet, 7	Urethritis
9105F	Doxycycline 100 mg tablet, 7	CT
9107H	Doxycycline 100 mg tablet, 7	PID
9108J	Doxycycline 100 mg tablet, 7	Urethritis
8200N	Azithromycin 500mg tablet, 2	Urethritis Cervicitis due to CT
1889K	Amoxicillin 500 mg capsule, 20	NG
1940D	Probenecid 500 mg tablet, 100	NG
1621H	Metronidazole 400 mg tablet, 21	TV
1465D	Tinidazole 500mg tablet, 4	TV
<b>Injectables</b>		
9058R	ceftriaxone 500 mg injection, 1 vial 2mL 1% lignocaine	NG
10209H	lidocaine (lignocaine) hydrochloride monohydrate 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules	

**(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?**

- Yes (please provide PBAC submission item number below)  
 No

**(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?**

N/A

**12. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?**

- Yes  
 No

**(b) If yes, please provide the following information (where relevant):**

N/A

**(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?**

- Yes  
 No

**(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?**

- Yes  
 No

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

N/A

**13. Please identify any single and / or multi-use consumables delivered as part of the service?**

**Table 2 Description of consumable items for POCT using CT/NG Rapid assay based on a swab or urine specimen obtained from the patient.**

Frequency of use	Description of consumables
<b>Single use</b>	
<b>GeneXpert® CT/NG and TV Rapid PCR test items</b>	
Patient CT/NG test kits (Box of 10)	Xpert® CT/NG assay cartridge Sterile disposable transfer pipette
Patient TV test kits (Box of 10)	Xpert® TV assay cartridge Sterile disposable transfer pipette
EQA panel (4 swabs) - six monthly checks specific to 1. CT/NG and 2. TV	EQA samples Sterile disposable transfer pipette Xpert Ct/NG assay cartridge
QC samples - monthly checks specific to 1. CT/NG and 2. TV	QC samples Sterile disposable transfer pipette Xpert Ct/NG assay cartridge
<b>Other items</b>	
	Disposable gloves
	Sterilizing solution (for cleaning work area)
	Paper wipes (for cleaning work area)
	Small water absorbing cloth (for work surface)
	Test tube rack multi use
	Hazardous waste bag
	Biohazard bin multi use

Abbreviations EQA: External quality assurance, QC: Quality control

## PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

14. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

Type of therapeutic good: IVD

Manufacturer's name: Cepheid AB

Sponsor's name: Cepheid Holdings Pty Ltd

- (b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

Class III

15. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

No

- (b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

Yes (if yes, please provide details below)

No

1. ARTG ID 207540 Cepheid GeneXpert (CT/NG) and 2. ARTG ID 290014 Cepheid GeneXpert (TV)

<b>Product type</b>	1. IVD
<b>Effective date</b>	28/3/2013
<b>GMDM</b>	CT774 Multiple-bacteria IVDs
<b>Intended purpose</b>	The CT/NG Assay assay is a qualitative in vitro real-time nucleic acid amplification test (NAAT) for the automated and rapid on-demand detection and differentiation of genomic DNA from <i>Chlamydia trachomatis</i> (CT) / <i>Neisseria gonorrhoeae</i> (NG) at the point-of-care to aid in the diagnosis of chlamydial and/or gonorrhoeal urogenital infection.
<b>Specific conditions</b>	No Specific Conditions included on Record
<b>Product type</b>	2. IVD
<b>Effective data</b>	9/06/2017
<b>GMDM</b>	CT822 Trichomonas IVDs
<b>Intended purpose</b>	The Cepheid Xpert TV assay, performed on the GeneXpert Instrument Systems, is a qualitative in vitro diagnostic test for the detection of <i>Trichomonas vaginalis</i> (TV) genomic DNA. The test utilizes automated real-time polymerase chain reaction (PCR) to detect <i>Trichomonas vaginalis</i> genomic DNA. The Xpert TV assay uses female and male urine specimens, endocervical swab specimens, or patient-collected vaginal swab specimens (collected in a clinical setting). The Xpert TV assay is intended to aid in the diagnosis of trichomoniasis in symptomatic or asymptomatic individuals.
<b>Specific conditions</b>	No Specific Conditions included on Record

16. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

N/A

17. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

N/A



## PART 4 – SUMMARY OF EVIDENCE-

18. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

No	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
<b>ANALYTICAL and CLINICAL VALIDITY</b>					
1.	Study of diagnostic accuracy	Performance of the GeneXpert CT/NG assay compared to that of the Aptima AC2 assay for detection of rectal Chlamydia trachomatis and Neisseria gonorrhoeae by use of residual Aptima Samples	The Cepheid GeneXpert CT/NG assay was compared with the GenProbe Aptima Combo2 assay, using 409 rectal swabs. Using Aptima as the gold standard, the sensitivity, specificity, positive and negative predictive values of GeneXpert for detection of C.trachomatis and N.gonorrhoeae were 86%, 99.2%, 92.5%, 98.4% and 91.1%, 100%, 100%, 98.6%, respectively. The assay showed excellent specificity.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/22993183">https://www.ncbi.nlm.nih.gov/pubmed/22993183</a>	December 2012 <sup>15</sup>
2.	Study of diagnostic accuracy	Comparison of the Abbott m2000 RealTime CT assay and the Cepheid GeneXpert CT/NG assay to the Roche AmpliCor CT assay for detection of Chlamydia trachomatis in ocular samples from Tanzania	The GeneXpert CT/NG assay (GeneXpert) and the Abbott m2000 RealTime CT (m2000) assay were compared to AmpliCor for detecting ocular Chlamydia trachomatis. The m2000 assay sensitivity was 100% (95% CI, 90% to 100%), and specificity was 98.46% (95% CI, 95.2% to 99.2%); GeneXpert 100% (95% CI, 90% to 100%), and 100% (95% CI, 98.1% to 100%) respectively. The m2000 and GeneXpert assays appear to perform as well as the AmpliCor assay	<a href="https://www.ncbi.nlm.nih.gov/pubmed/23486714">https://www.ncbi.nlm.nih.gov/pubmed/23486714</a>	May 2013 <sup>16</sup>

No	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
3.	Study of diagnostic accuracy	Analytical evaluation of GeneXpert CT/NG, the first genetic point-of-care assay for simultaneous detection of <i>Neisseria gonorrhoeae</i> and <i>Chlamydia trachomatis</i> .	GeneXpert CT/NG was evaluated with 372 characterized bacterial strains. Sensitivity of 10 genome copies/reaction was obtained for both agents. Four <i>Neisseria mucosa</i> and two <i>Neisseria subflava</i> isolates were positive for one of two gonococcal targets; however, the assay flagged all as negative. The assay was analytically highly sensitive and specific.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/23554203">https://www.ncbi.nlm.nih.gov/pubmed/23554203</a>	June 2013 <sup>17</sup>
4.	Study of diagnostic accuracy	Performance of the Cepheid CT/NG Xpert Rapid PCR Test for Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> .	Evaluation of Xpert CT/NG assay against PIS determined by Gen-Probe Hologic APTIMA Combo 2 and ProbeTec ET CT/NG. n= 1,722 females, 1,387 males. CT sensitivity: endocervical 97.4%; vaginal 98.7%; urine-female: 97.6%, male: 97.5%. Specificity ≥ 99.4%. NG sensitivity: endocervical and vaginal specimens 100%; urine-female: 95.6%, male: 98.0%. Specificity ≥ 99.8%.	<a href="http://www.ncbi.nlm.nih.gov/pubmed/23467600">http://www.ncbi.nlm.nih.gov/pubmed/23467600</a>	June 2013 <sup>18</sup>
5.	Study of diagnostic accuracy	A field evaluation of a new molecular-based point-of-care test for chlamydia and gonorrhoea in remote Aboriginal health services in Australia.	Evaluation of performance and ease-of-use of GeneXpert CT/NG against two single-organism ICTs in field setting. GeneXpert sensitivity/specificity was 100% and 99.5% for CT, and 100% sensitivity and specificity for NG (n=198). Diaquick CT sensitivity/specificity was 27.3% and 66.7% (n=104); Gonorrhoea Card sensitivity/specificity was 66.7% and 76.9% (n=29).	<a href="https://www.ncbi.nlm.nih.gov/pubmed/25426655">https://www.ncbi.nlm.nih.gov/pubmed/25426655</a>	March 2015 <sup>19</sup>

No	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
6.	Study of diagnostic accuracy	Value of repeat testing using Cepheid GeneXpert CT/NG for indeterminate PCR results when diagnosing Chlamydia trachomatis and Neisseria gonorrhoeae.	This 6-month audit of COBAS 4800 CT/NG assay use found 77/9472 (0.81%) results to be indeterminate for CT and/or NG. After introduction of the Cepheid assay, indeterminate results fell significantly to 9 (0.10%), reducing reliance on repeat sampling, improving turnaround time, laboratory workflow and patient experience.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/24810211">https://www.ncbi.nlm.nih.gov/pubmed/24810211</a>	May 2014 <sup>20</sup>
7.	Study of diagnostic accuracy	The performance of non-NAAT point-of-care (POC) tests and rapid NAAT tests for chlamydia and gonorrhoea infections. An assessment of currently available assays.	Sensitivity/specificity data for 11 POC/1 rapid NAAT were applied to 100 patients consecutively diagnosed with CT and 100 consecutively diagnosed with NG. POC tests would need to be used with NAAT, increasing early treatment rates expense and false-positives. Used alone, rapid NAAT would reduce average time-to-treat with small reduction in sensitivity/specificity.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/25935930">https://www.ncbi.nlm.nih.gov/pubmed/25935930</a>	December 2015 <sup>21</sup>
8.	Study of diagnostic accuracy	Validation of the GeneXpert® CT/NG Assay for use with Male Pharyngeal and Rectal Swabs.	A total of 570 swabs were collected from 144 patients. GeneXpert® detected 13/15 CT positive rectal swabs with APTIMA® assay (relative sensitivity (RS)=88.2%), 1/2 CT positive pharyngeal swabs (RS=50%), and 7/9 NG positive pharyngeal swabs (RS =77.8%). While not as sensitive as the APTIMA® assay, GeneXpert® is still viable option for STI screening.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/27536736">https://www.ncbi.nlm.nih.gov/pubmed/27536736</a>	March 2016 <sup>22</sup>

No	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
9.	Study of diagnostic accuracy	Rapid and point-of-care tests for the diagnosis of <i>Trichomonas vaginalis</i> in women and men.	Performance comparison for detection of TV between OSOM lateral flow, AmpliVue, Solana, and GeneXpert compared with wet preparation/culture. Sensitivity of all tests was higher compared with wet preparation/culture. Sensitivity using the GeneXpert was 96.4% (self-collected vaginal swabs), 98.9% (endocervical specimens) and 98.4% (urine) and for men 97.2% (urine). The specificity for all assays was excellent.	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5723541/?report=classic">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5723541/?report=classic</a>	December 2017 <sup>23</sup>
10.	Study of diagnostic accuracy	Clinical evaluation of the Cepheid Xpert TV Assay for detection of <i>Trichomonas vaginalis</i> with prospectively collected specimens from men and women	1,867 women and 4,791 men were included in the analysis. The diagnostic sensitivities and specificities of the Xpert TV assay, compared to patient infected status; for female specimens (urine samples, self-collected vaginal swabs, and endocervical swabs) ranged from 99.5-100% and 99.4- 99.9%, respectively and for male urine samples 97.2% and 99.9%, respectively.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/29167292">https://www.ncbi.nlm.nih.gov/pubmed/29167292</a>	January 2018 <sup>24</sup>
11.	Study of diagnostic accuracy	Molecular test for chlamydia and gonorrhoea used at point of care in remote primary healthcare settings: a diagnostic test evaluation	This is the first evaluation of performance of GeneXpert used routinely at point-of-care by clinicians in remote health services in Australia compared to reference laboratory NAATs. Clinicians conducted 2486 tests: CT concordance was 99.4% (95% CI 99.1 to 99.7); NG concordance was 99.9% (95% CI 99.7 to 100.0).	<a href="https://www.ncbi.nlm.nih.gov/pubmed/29748180">https://www.ncbi.nlm.nih.gov/pubmed/29748180</a>	May 2018 <sup>25</sup>

SAFETY & TOLERABILITY/ACCEPTABILITY					
1.	Observational study	"I Do Feel Like a Scientist at Times": A Qualitative Study of the Acceptability of Molecular Point-Of-Care Testing for Chlamydia and Gonorrhoea to Primary Care Professionals in a Remote High STI Burden Setting.	The GeneXpert platform (CT/NG assay) was evaluated within a RCT in 12 remote Australian health services. Interview participants (n=16) generally found the test easy to use, and that it improved management of STIs - resulting in more timely and targeted treatment, earlier commencement of partner notification, and reduced follow up.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/26713441">https://www.ncbi.nlm.nih.gov/pubmed/26713441</a>	December 2015 <sup>26</sup>
2.	Observational study	Review of use of a new rapid real-time PCR, the Cepheid GeneXpert(R) (Xpert) CT/NG assay, for Chlamydia trachomatis and Neisseria gonorrhoeae: results for patients while in a clinical setting	Commentary on GeneXpert® platform and CT/NG assay noting: US FDA-clearance December 2012 for use with female endocervical and vaginal swabs and female/male urine specimens; near-perfect sensitivity and specificity in urogenital specimens; ease of use- requiring no hands-on manipulation from specimen loading until results are available in approximately 90 minutes.	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4061495/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4061495/</a>	March 2014 <sup>27</sup>
3.	Observational study	Point-of-Care Testing for Chlamydia and Gonorrhoea: Implications for Clinical Practice	The introduction of POC testing to improve STI service delivery requires careful consideration of both its advantages and limitations. Perceived advantages were around provision of counselling around prompt receipt of results and treatment, however review of STI testing. If implemented review of clinical management guidelines may be required.	<a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4067364/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4067364/</a>	June 2014 <sup>28</sup>
	Observational study	Public health implications of molecular point-of-care testing for chlamydia and gonorrhoea in remote primary care services in Australia: a qualitative study	There is a high level of support from clinicians and public health practitioners for wider access to CT/NG POC tests citing potential benefits, including earlier, more accurate treatment decisions and reductions in ongoing transmission. However, the data also highlight the need for systems to ensure maintenance of disease surveillance.	<a href="https://bmjopen.bmj.com/content/5/4/e006922">https://bmjopen.bmj.com/content/5/4/e006922</a>	April 2015 <sup>29</sup>

SAFETY & TOLERABILITY/ACCEPTABILITY					
4.	Observational study	A novel point-of-care testing strategy for sexually transmitted infections among pregnant women in high-burden settings: results of a feasibility study in Papua New Guinea.	Women attending their first ANC visit were invited to be tested for CT/NG and TV (GeneXpert) and (BVBlue). Participants received same-day test results and antibiotic treatment as indicated. Point-of-care STI testing and treatment using a combination of novel, newly-available assays was feasible during routine ANC in this setting.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/27268218">https://www.ncbi.nlm.nih.gov/pubmed/27268218</a>	June 2016 <sup>30</sup>
CLINICAL EFFECTIVENESS IN REMOTE AND VERY REMOTE COMMUNITIES IN AUSTRALIA					
1.	Cross over cluster randomised controlled trial	Molecular point-of-care testing for chlamydia and gonorrhoea among Indigenous people attending remote primary health services: a cross-over cluster randomised controlled trial	RCT of POC testing with GeneXpert CT/NG (intervention) vs laboratory NAAT (control) at 12 remote/very remote health services. Among 16-29 year olds, 249(78%) cases in intervention arm were treated within 3 days, compared to 122(30%) in control arm (RR=2.5,95%CI:1.8–3.3;p<0.001); median time-to-treatment was 0 and 9 days respectively.	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4231474/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4231474/</a>	October 2018 <sup>31</sup>

\* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

\*\*Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.

\*\*\* If the publication is a follow-up to an initial publication, please advise.

**19. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.**

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
2.	Cost effectiveness analysis	Cost effectiveness analysis of using a point of care "Rapid Test" for detection of <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> compared with standard care in very remote communities in Australia.	A decision-analytic model was built to compare the costs and benefits of utilising a point of care rapid assay NAAT (nucleic acid amplification test) for detection of <i>C. trachomatis</i> and <i>N. gonorrhoeae</i> compared to standard care for individuals in very remote regions of Australia over a 10-year period, from a health system perspective. Benefits were measured in quality-adjusted life years gained. Sensitivity analyses were undertaken for all model parameters.		May 2020

\* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

\*\*Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.

\*\*\*Date of when results will be made available (to the best of your knowledge).

## PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

### **20. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

The proposed medical service would primarily be delivered by General Practitioners, Nurse Practitioners and Aboriginal Health Workers/Practitioners.

- National Rural Health Alliance (NRHA)  
The NRHA represents 35 national organisations working to improve the health and wellbeing of people in rural and remote Australia. Members include consumer groups (such as the Country Women’s Association of Australia), the Aboriginal and Torres Strait Islander health sector (NACCHO and the Australian Indigenous Doctor's Association), health professional organisations (representing doctors, nurses and midwives, allied health professionals, dentists, pharmacists, optometrists, paramedics, health students, chiropractors and health service managers) and service providers (such as the Royal Flying Doctor Service).

The main professional bodies/organisations representing GPs are:

- Royal Australian College of General Practitioners (RACGP)  
The RACGP is the professional body for general practitioners (GPs) in Australia and is responsible for maintaining standards and developing guidelines for quality clinical practice, and supporting and facilitating education and training.
- Australian Indigenous Doctors’ Association (AIDA)  
AIDA is a professional association supporting Aboriginal and Torres Strait Islander doctors and medical students as well as providing perspectives aimed at improving the health and life outcomes of Aboriginal and/or Torres Strait Islander peoples.
- Rural Doctors’ Association of Australia (RDAA)  
RDA is a professional body representing the interests of rural and remote doctors and the communities they live and work in.
- The Australian College of Rural and Remote Medicine (ACRRM)  
ACRRM is a professional body promoting the interests of rural and remote doctors and provides a specialised continual development program to doctors working in rural and remote areas.

The main professional bodies/organisations representing nurses and Aboriginal Health Workers and Practitioners:

- National Aboriginal and Torres Strait Islander Health Worker Association (NATSIHWA):  
NATSIHWA is the peak body for Aboriginal and/or Torres Strait Islander Health Workers and Aboriginal and/or Torres Strait Islander Health Practitioners in Australia. The organisation facilitates and promotes professional development and the use of effective models of care for Aboriginal and/or Torres Strait Islanders.
- Australian Nursing and Midwifery Foundation (ANMF)  
ANMF is the main representative organisation representing nurses and midwives in all sectors within Australia.
- Australian Primary Health Care Nurses Association (APNA)  
APNA is the peak representative body for nurses working in primary health care.

### **21. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

The Royal College of Pathologists of Australasia



**22. List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

Consumer organisations relevant to the proposed medical services include but are not limited to:

- Aboriginal Health Council of Western Australia (AHCWA)
- Kimberley Aboriginal Medical Services Council (KAMSC)
- Aboriginal Health Council of South Australia (AHCSA)
- Aboriginal Medical Services Alliance Northern Territory (AMSANT)
- Apunipima- Cape York Health Council
- Nganampa Health Council
- Ngaanyatjarra Health Service
- Katherine West Health Board Aboriginal Corporation

**23. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

None that we are aware of

**24. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

Name of expert 1: **REDACTED**

Telephone number(s): **REDACTED**

Email address: **REDACTED**

Justification of expertise: **REDACTED**

Name of expert 2: **REDACTED**

Telephone number(s): **REDACTED**

Email address: **REDACTED**

Justification of expertise: **REDACTED**

*Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.*

## PART 6 – POPULATION (AND PRIOR TESTS), INDICATION, COMPARATOR, OUTCOME (PICO)

### **PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION**

#### **25. Define the medical condition, including providing information on the natural history of the condition and a high-level summary of associated burden of disease in terms of both morbidity and mortality:**

Both *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) are gram negative bacteria and *Trichomonas vaginalis* (TV) is a single-celled protozoan parasite which can be transmitted by oral, vaginal or anal sex. In women CT causes urethritis and salpingitis manifesting as dysuria, abnormal vaginal discharge or post coital bleeding. Infection can also effect the upper genital tract causing irregular uterine bleeding and abdominal or pelvic discomfort.<sup>32</sup> In men, CT can cause dysuria, epididymitis and proctitis.<sup>32</sup> There are different sero-variants or strains of CT which can cause trachoma, a cause of blindness and lymphogranuloma venereum, a sexually transmitted infection which effects the lymphatic system which this application does not apply to. TV causes urethral discharge and dysuria in men, and vaginal discharge, dysuria, and abdominal pain in women.<sup>33</sup> In men, untreated and persistent TV infection is a cause of urethritis and is associated with prostatitis, epididymitis and decreased sperm cell motility,<sup>34</sup> and in women cervical dysplasia and infertility.<sup>35 36</sup> NG causes gonorrhoea which can manifest as abnormal vaginal discharge, bleeding and dysuria in women, and may result in urethral discharge and dysuria in men.<sup>37 38</sup> If untreated, gonorrhoea may result in septic arthritis and disseminated gonococceamia,<sup>11 12</sup> and in neonates, gonococcal ophthalmia neonatorum. In remote areas, co-infection of CT and NG is common, and TV infection is also associated with both infections, however more often detected with NG.<sup>39</sup>

CT, NG and TV infection have been found to increase the risk of progression to pelvic inflammatory disease (PID), which can cause chronic abdominal pain, with the risk of progression increasing with repeat infections.<sup>36 40</sup> The substantial morbidity associated with PID was noted in a NSW data linkage study, which found substantially higher hospitalisations for PID compared to a similar cohort who did not have a report of CT or NG infection.<sup>41</sup> It is well established that PID increases the risk of tubal infertility and ectopic pregnancy.<sup>7 8 42-44</sup> CT,NG and TV infection have been found to increase the risk of premature delivery and perinatal mortality.<sup>10 45-49</sup> Infection can also be passed from an mother with genital infection, to her baby, during a vaginal delivery, increasing the risk of poor neonatal outcomes including infant conjunctivitis and pneumonia.<sup>50</sup> Although the complications of these infections are not routinely monitored in Australia, clinical reports from remote communities indicate that PID and infertility occur at rates far higher among Indigenous women than in other parts of Australia.<sup>51-53</sup>

CT, NG and TV infections are easily curable with available antibiotics,<sup>6</sup> however, infection is often asymptomatic, particularly in women.<sup>1 2 54</sup> In the case of TV this is estimated at 70-85% of people.<sup>54</sup> One study in far north Queensland found that 92% of CT infections and 96% of NG infections were without symptoms.<sup>55</sup> This is consistent with international data,<sup>2</sup> and illustrates difficulties with management strategies reliant on presentation to clinics of symptomatic patients. Long duration of infection not only increases the risk of exposing partners to infection, but also increases the risk of complications such as PID. A recent review of sexual health clinic data in Australia estimated the population attributable fraction of PID associated with a current chlamydia infection to be 14.1% among females 16-49.<sup>56</sup> Infection can resolve spontaneously, and estimates that between 11%-44% of untreated CT infections will resolve spontaneously within 12 months,<sup>50</sup> however infection has been found to persist in some women up to four years,<sup>56</sup> however persisting infections may be subclinical, most infections generally develop clinical signs requiring treatment.<sup>57</sup> STIs including CT,NG and TV are associated with an increased risk of susceptibility for women to HIV due to an already existent inflammatory response in the genital tract and there is conversely an increased potential for transmission of HIV due to increased shedding of HIV from the genital tract.<sup>13 14 58</sup> It is also well established that inter-current STIs enhance the risk of mother to child transmission of HIV.<sup>14 59</sup>

There are significant disparities in sexual health in Australia, particularly evident in younger Aboriginal and Torres Strait Islander people compared to the non-Indigenous population. Aboriginal and Torres Strait

Islander people are disproportionately impacted by STIs compared to non-indigenous Australians. While CT and NG infections are more common in young people, TV is more common in older women and has been described as relatively rare in urban areas of Australia, however the prevalence has been reported at 17.6%<sup>60</sup>, and for pregnant women at 25.2%<sup>61</sup> in Aboriginal and Torres Strait Islander communities. Notifications rates for CT infection are also much higher in Aboriginal and Torres Strait Islander peoples compared to non-Indigenous peoples, up to three times greater for females (1535.9 vs 482.7 per 100 000 respectively) and twice as high for males (862.9 vs 359.1 per 100 000 respectively).<sup>4</sup> CT notifications rates for persons 15-19 years are four times higher (5522.7 vs 1316.3 per 100 000 respectively) and for 20-29 years, three times higher (3681.8 vs 1632.3 per 100 000 respectively) higher for indigenous compared to non-indigenous peoples. In remote and very remote regions, notifications of CT infection are 5 times higher (1661.5 vs 354.4 per 100,000) compared to non-Indigenous Australians.<sup>4</sup> Similarly for NG, notification rates in Aboriginal and Torres Strait Islander peoples compared to the non-Indigenous population. For those aged between 15-19 years, this group comprised 32% of NG notifications among Aboriginal and Torres Strait Islander compared to 7% of the non-Indigenous population. In Aboriginal and Torres Strait Islander communities the male to female ratio is 0.9:1 indicating heterosexual transmission, compared to a 3:1 ratio in the non-Indigenous population which suggests higher of frequencies of sexually transmitted infection between men. In remote and very remote regions, notification of NG infections are 30 times higher compared to non-Indigenous Australians.<sup>4</sup> Also higher for non-remote Aboriginal communities.<sup>62</sup>

A large scale assessment of STI positivity estimated CT infection prevalence to be 11.5% in those aged 16-35 years and above, but exceeded 20% for those aged 16-19 years.<sup>63</sup> Estimates of NG infection prevalence among persons aged 16-35 years in the same study were also high (10.1%), and positivity was also strongly inversely associated with age, higher in men and women under 20 years of age (>20%). STI co-infections are common in remote Aboriginal communities, with CT/NG being the most frequent co-infection (2% of women and 4.1% of men aged 16-35 years and older), and highest in those aged 16-19 years (4.3% of women and 9.8% of men).<sup>63</sup> The incidence of combined CT/NG /TV has been reported to be highest in 16-19 year olds.<sup>60</sup> Studies have also shown relatively high rates of repeat co-infections, showing higher repeat NG positivity than repeat CT positivity (28.8% v. 18.1%,  $P < 0.01$ )<sup>64</sup> While practice guidelines recommend repeat testing in 3 months, difficulties with retesting have been found in a number of studies where only 15% of those with a positive test result were re-tested in the recommended time period of 2-4 months.<sup>64</sup> Also high levels of coinfection indicate a need for simultaneous testing.<sup>39</sup>

Additional strategies to improve coverage of STI testing are required to decrease the prevalence of STIs among young Aboriginal people and pregnant women.<sup>61</sup> Current management is based on a presumptive diagnosis of CT, NG or TV if a patient is symptomatic for a STI, based on signs and symptoms and patient history, the appropriate antibiotic treatment is provided to the patients. A urine sample and swab will be sent to a laboratory for testing from both symptomatic and at-risk patients. The mean interval between sample collection and treatment for patients seen at remote clinics is 22 days (SD 24 days), with a median time to treatment of 13 days at remote clinics (IQR = 7–27).<sup>65</sup> Treatment delays are greater with increasing remoteness, and are due to the time between receipt of specimen and reporting of results due to fewer courier services and distance from the clinic to the laboratory, and the time from receipt of results at the clinic to recall patients back to the clinic for treatment. Delays in actioning results were found to be due underutilisation of recall systems, the high mobility of the population between communities and high staff turnover which resulted in poor community knowledge.<sup>65</sup> As a results of delays, around 20% of patients diagnosed with a treatable sexually transmitted infections do not receive treatment.<sup>66</sup> On demand point of care (POC) tests would replace the current service as the test assay for CT/NG and TV are of equivalent standard to a laboratory conducted test,<sup>18 24</sup> with the processing of the specimen, and the result provided at the site of screening or testing (clinic) instead of the specimen transported off site to a central laboratory for processing which in a remote community may take 1-2 weeks to obtain a result. A single clinic visit would replace both the initial visit (where a sample would be provided sent away to a laboratory for analysis) and subsequent follow-up visit to obtain results (and treatment if necessary), as a test result and treatment if required, occur within one consultation. Time to treatment is significantly reduced<sup>67</sup> and contact tracing may be initiated promptly following a positive test result. Timely treatment is also important as POC tests reduce the possibility of loss to follow-up and decreases the incidence of complications like pelvic inflammatory disease due to delayed or no treatment.

STIs are also responsible for a range of adverse psychosocial consequences. For example, feelings of shame or reluctance to name partners must be considered in the context that individuals are members of small communities,<sup>55 68</sup> and the importance of connections to family and kin.<sup>69</sup> Additionally younger people are more likely to engage in risky behaviours, such as misuse of drugs and alcohol.<sup>70</sup> Individuals 15-34 years old age make the largest contribution, second to individuals 35-45 years old, to the health gap between Aboriginal and Torres Strait Islander and non-indigenous Australians.<sup>71</sup> Despite this younger people have lower use of health facilities which results in asymptomatic infections not being diagnosed. Coupled with high mobility, this highlights the advantages of POC testing for providing prompt diagnosis and management.

There is no change in safety or effectiveness using POC tests in health services in areas with high STI burden compared with transporting specimens to a centralised testing laboratory. On demand POC tests for STIs are a strategy that can improve health equity due to improvements in efficiency of delivery of treatment compared to standard treatment as time to treatment is reduced improving efficiency of treatment time, decreasing the risk of PID and reproductive complications. Efficiencies are also found in decreasing the risk of over treatment as only confirmed positive infections receive treatment and development of antimicrobial resistance may be mitigated with fewer unconfirmed cases receiving antibiotic treatment. Health system savings would be delivered due to reduced number of health care visits (subsequent visit for test results is voided), reduced staff follow-up time to locate and treat patients, reduced costs for specimen transfer to a central laboratory and savings over the long term will also be achieved due to less cases of PID and sequelae of untreated infection such as reproductive complications. Other benefits of earlier diagnosis are the potential to expedite notification of contacts at the time of the first consultation (rather than waiting for a result from the laboratory) which should reduce opportunities for re-infection and cross infection.

**26. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:**

**Characteristics of patients eligible for the proposed service**

1. Health centre servicing >90% Aboriginal and Torres Strait Islander people.
2. Located in an area where STI positivity is greater than 10% as qualified by laboratory data
3. Have systems in place, or be willing to establish systems to support POCT using the GeneXpert including:
  - a. Installation of Ondas software
  - b. Internet connectivity
4. Service more than 200 clients annually
5. Demonstrated need for POC testing (i.e. transient population, high level of loss to follow-up, high STI burden)

**Management of patients**

Guidelines produced by the National Aboriginal Community Controlled Health Organisation (NACCHO) and The Royal Australian College of General Practitioners (RACGP)<sup>72</sup> recommend annual screening, however, state that local regional guidelines should be followed if available and where appropriate. Guidelines that support clinical practice in remote areas are the CARPA Standard Treatment Manual<sup>73</sup> and Women's Business Manual<sup>74</sup> in the Northern Territory, The Primary Clinical Care Manual<sup>75</sup> in Queensland and the Guidelines for Managing Sexually Transmitted Infections<sup>76</sup> in Western Australia. Screening recommendations for sexually transmitted infections vary slightly between states, however in remote and very remote communities with high prevalence of sexually transmitted bacterial infections, testing for CT and NG is recommended if a patient presents with signs and symptoms of a sexually transmitted infection, following a 'risk' exposure, and opportunistic screening or bi-annual screening is generally recommended for sexually active people aged 15-35 years. In the Northern Territory asymptomatic screening for TV is recommended for men and women, TV screening recommended for women only in Queensland, and in Western Australia testing for other non-notifiable diseases, e.g. genital herpes, TV and Mycoplasma genitalium is recommended based on history and/or examination findings.

Provision of POC testing means that a single clinic visit would replace an initial screening and subsequent follow-up visit to obtain results (and treatment if necessary), as both screening and treatment if required, could occur simultaneously. Time to treatment is significantly reduced<sup>67</sup> and prompt initiation of contact tracing following a positive test result reduces the risk of onward transmission. Timely treatment is important to reduce loss to follow-up and decrease the incidence of complications (such as pelvic inflammatory disease) that can occur due to delayed or no treatment. The proposed service reduces both staff consultation time and also time required for locating and following-up untreated patients who had a positive test result.

#### **Quality assurance**

It is envisaged that the management of quality assurance for POC testing for detection of CT/NG/TV infection would be co-ordinated under a quality assurance program such as the Quality Assurance for Aboriginal and Torres Strait Islander Medical Services (QAAMS) Program,<sup>77</sup> which follows Australian guideline recommendations for POC Testing.<sup>78</sup> QAAMS is funded by the Commonwealth Government Department of Health and is a partnership between the Community Point-of-Care Services unit at Flinders University (which is responsible for the overall management of the program) and the Royal College of Pathologists of Australasia (RCPA) Quality Assurance Programs Pty Ltd (which provides the external quality assurance component of the program).<sup>79</sup> QAAMS provides a framework to support on-site testing for haemoglobin A1c (HbA<sub>1c</sub>) and urine albumin:creatinine ratio (ACR) for diabetes patients attending Aboriginal medical services.<sup>79</sup> The quality assurance program is modelled on the Royal College of Pathologists of Australasia (RCPA) Quality Assurance Programs for laboratories with monthly internal quality control and six-monthly external quality assurance testing cycles.<sup>80</sup> Staff are also supported with regular education and training programs to ensure ongoing competency.<sup>77</sup> Review of the program has found the quality assurance program to be analytically sound,<sup>80</sup> and diabetes management using POCT to be clinically effective and culturally acceptable.<sup>81</sup>

#### **Specific item numbers to access the Medicare Benefits Schedule rebate**

Under the QAAMS program specific program item numbers have been allocated for POC testing for diabetes management listed as Item numbers 73839, 73840 and 73844. Access to the rebate is under the following circumstances;

- a) the service is rendered by or on behalf of a medical practitioner;
- b) the practitioner referred to in paragraph (a), or the organisation for which the practitioner works, is participating in the Quality Assurance in Aboriginal Medical Services Program; and
- c) the service is provided in accordance with that Program; and
- d) the practitioner referred to in paragraph (a) has determined the service to be necessary for his or her patient.

#### **Notification of infections to state health departments**

Development of secure systems and processes to replace central laboratory reported notifications with clinic based reporting of positive results are currently underway and include liaison with state health services to ensure information is in the appropriate format and complies with state regulations, information is secure, and timely. A pilot of the novel notification system has been successfully completed in late 2019 at a remote health service in South Australia with confirmed end-to-end transmission (from health service to SA Department of Health) of a positive CT/NG result fitting the requirements for notification. Further expansion of this system is underway across all involved jurisdiction during 2020.

#### **Antimicrobial resistance surveillance**

Gonococcal antimicrobial resistance (AMR) surveillance is conducted by reference laboratories in each state and territory. Testing laboratories supply state reference laboratories with clinical isolates for sensitivity testing to inform AMR surveillance. In 2017, 28% of gonorrhoea specimens underwent sensitivity testing. However, only a small number of isolates collected from remote regions of Australia are viable for culture once they reach reference laboratories (reported at 14% in remote WA).<sup>82</sup> POC testing provides an opportunity to enhance AMR surveillance by prioritising POCT positive NG specimens for culture, potentially improving the yield of viable isolates for subsequent sensitivity testing.

An additional benefit of POC testing is the potential reduction or elimination of the need for presumptive treatment, which can lead to inappropriate antibiotic use, and probable increased risk of development of NG antimicrobial resistance.

**Justification for targeting the proposed medical service at the above-mentioned population**

High rates of STIs in young Aboriginal and Torres Strait Islander peoples indicate an area of significant health disadvantage in Australia. Currently in remote communities, time to treatment is delayed due to remoteness of testing laboratory and difficulties recalling patients. Strategies are required to increase rates of screening and treatment and provision of POC testing would:

1. significantly reduce delays between the receipt of sample and diagnosis as patients would receive their results within two hours, resulting in improved uptake of treatment.
2. avoid over treatment and misuse of antibiotics in that only patients who test positive for NG and CT would be treated.
3. improve efficiency and reduce costs of service delivery and medical staff time as only one appointment is required if medication can be provided at the time or soon after time of diagnosis
4. reduce follow-up time and costs as more patients are treated at time of diagnosis
5. assist with tracing of contacts which can begin following receipt of results. Additionally, this should reduce the risk of re-infection to patients and/or partners.
6. improve case finding via normalisation of opportunistic screening of at-risk asymptomatic persons. Currently asymptomatic persons who have CT and NG infections may continue to be sexually active and contribute to the ongoing transmission of CT and NG infection.
7. reduce the burden of sexually transmitted infections over time in communities experiencing high rates of sexually transmissible infections.
8. decrease rates of untreated infections thereby reducing the risk of complications particularly for women such as PID and infertility, which have significant associated morbidity and related hospitalisations.

**27. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):**

The current clinical management pathway is 'syndromic' which involves assessment of STI risk during a clinical assessment and health promotion counselling as appropriate (see page 33 for flowchart). Eligible patients are offered CT/NG and/or TV testing by the health service provider, and with patient agreement the appropriate urogenital specimens are collected.

**PART 6b – INFORMATION ABOUT THE INTERVENTION**

**28. Describe the key components and clinical steps involved in delivering the proposed medical service:**

The key steps of point-of-care testing (POCT) for detecting CT/NG (combined test) and/or TV infection are:

Step 1. Clinical consultation with patient, including medical history +/- examination

Step 2. Urogenital specimen collection and labelling of sample with patient details

Step 3. Electronic POC test request is generated from laptop for the specific patient (selected from clinic patient list or added as new patient)

Step 4. The work area is prepared, and the urogenital sample is added to the labelled POCT cartridge/s

Step 5. POCT request is selected and matched to POCT cartridge/s. POCT cartridge bar-code is scanned and cartridge/s is inserted into the POCT machine

Step 6. The test takes 90 minutes (for CT/NG) and 60 minutes (for TV) to produce a result (detected/not detected for CT, NG and TV)

Step 7. The result appears on the laptop screen and is delivered securely electronically into the corresponding clinic patient management system for matching with the patient record. Clinic staff then initiates management (including appropriate treatment and follow-up as necessary in accordance with CT and/or NG and/or TV infection treatment guidelines).

Step 8. All single use items are disposed of (including used POCT cartridge/s) as appropriate.

**29. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?**

As far as the applicant is aware, there is only one CT/NG trademarked assay system (Cepheid Xpert® CT/NG) distributed in Australia. The TV cartridge can be analysed on the same machine.

**30. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?**

N/A

**31. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):**

There is a limitation regarding the frequency of the test which is also the case with laboratory-based testing. Residual, non-viable CT/NG DNA remains positive for 3-4 weeks following effective treatment, thus repeat sampling to exclude re-infection should be undertaken at least one to 3 months following treatment for a positive test result.<sup>83</sup>

**32. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service:**

N/A

**33. If applicable, advise which health professionals will primarily deliver the proposed service:**

The proposed service will be provided by a nurse or Aboriginal and Torres Strait Islander Health Worker/Practitioner on behalf of a general practitioner, or by a general practitioner. All staff must receive training and be certified to conduct POCT, see (page 21, regarding QAAMS quality assurance program).

**34. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:**

N/A

**35. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:**

Delivery of the POC test is restricted to health professionals who have undertaken the standardised STI POCT training program delivered in-person and/or remotely through Flinders University International Centre for Point-of-Care Testing and demonstrated practical competency using the sample test kits.

**36. If applicable, advise what type of training or qualifications would be required to perform the proposed service as well as any accreditation requirements to support service delivery:**

Comprehensive training and quality management schemes to ensure reliability of test results have been developed in accordance with Australian Guidelines for Point-of-Care Testing.<sup>78</sup> Delivery of the POC tests is restricted to health professionals who have undertaken the standardised STI POCT training program delivered in-person and/or remotely through Flinders University International Centre for Point-of-Care Testing<sup>77</sup> and demonstrated practical competency using the sample test kits. Flinders University International Centre for Point-of-Care Testing also assess competency in performing POC testing every two years ensuring that upskilling and capacity building of the health workforce is maintained and provide an online and telephone support service to assist with any problems encountered using the machines.

The training, competency and quality systems are modelled on those used in the successful national QAAMS (Quality Assurance for Aboriginal and Torres Strait Islander Medical Services) POC testing program for diabetes management, which has been operating in indigenous medical services since 1999. This includes an ongoing comprehensive internal quality control (QC) and external quality assessment (EQA) testing program, consistent with quality processes undertaken in accredited laboratories. Quality testing samples are provided externally to sites, with quality control testing using one sample with a known bacterial load conducted monthly, while external quality assessment testing using a panel of 4 samples conducted six monthly.

**37. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select all relevant settings):**

- Inpatient private hospital
- Inpatient public hospital
- Outpatient clinic
- Emergency Department
- Consulting rooms
- Day surgery centre
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

Specify further details here:

- (b)** Health centre servicing >90% Aboriginal and Torres Strait Islander people.
- (c)** Located in an area where STI positivity is greater than 10% as qualified by laboratory data
- (d)** Have systems in place, or be willing to establish systems to support POCT using the GeneXpert including:
  - a. Installation of Ondas software
  - b. Internet connectivity
- (e)** Service more than 200 clients annually
- (f) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:**

The rationale for access to POC tests in a variety of health care settings is based on the need to offer Aboriginal and Torres Strait Islander patients attending health services in an area with a high STI burden on-demand rapid tests for CT/NG/TV to reduce the incidence and negative health effects of these STIs. All centres will have a demonstrated need for POC testing (i.e. transient population, high level of loss to follow-up, high STI burden or a long interval between testing and receipt of results).

**38. Is the proposed medical service intended to be entirely rendered in Australia?**

- Yes
- No – please specify below

**PART 6c – INFORMATION ABOUT THE COMPARATOR(S)**

**39. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service):**

Comparator medical service: laboratory-based CT/ NG and TV testing

Currently syndromic management of suspected STIs generally occurs in parallel with specimen collection and laboratory testing to confirm the diagnosis and appropriateness of treatment that was provided. However syndromic management will only pick-up ~30% of patients with infections.<sup>2</sup> Screening is also offered to asymptomatic 'at-risk' patients but treatment is withheld until receipt of a diagnosis confirming the presence of an infection.

In remote communities, specimens collected from symptomatic and asymptomatic clients are transported (by air or road) to reference laboratories. Most of these laboratories use nucleic acid amplification tests (NAATs) to test for CT/NG/TV. These include commercially available assays such as the Aptima Combo 2 (Gen-Probe, San Diego, CA, USA) and Cobas<sup>®</sup> 4800 (Roche Diagnostics, Pleasanton, CA, USA) and in-house CT and NG assays. As remote primary health services are distant from the servicing pathology laboratory, samples may only be sent a once a week if air transport is limited and specimen transit time may be as long as eight days.<sup>84 85</sup> For some services who do not access the mail service the cost of transport is substantial and borne by the health service (personal communication).





must be done in a discrete and respectful way and hence it may take many days, weeks or months to deliver treatment. Sometimes patients are no longer in the community and additional staff time is taken to investigate where people have moved to, when they will be returning or based on provided information may even contact another community health centre who may attempt to locate the individual concerned.

4. A three-month recall is initiated for a follow-up test.

**42. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?**

- Yes  
 No

**(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted:**

The proposed medical service would be used instead of the comparator for diagnosis of CT/NG/TV infection. Practitioners would perform the proposed medical service under the same circumstances as they would order the existing tests and hence the clinical management algorithm would remain the same as current practice however treatment would be provided for the infection diagnosed rather than for the suspected syndrome.

**43. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline):**

The proposed medical service would be delivered under the same circumstances as the current clinical pathway; however the following changes would be expected:

1. All patients for whom POCT is conducted would receive a result on the same day as the initial consultation (ideally within 2 hours of providing a specimen for testing) and therefore could be treated if required on receipt of the result. Contact tracing and treatment of contacts could also be initiated at the same time. The ability to provide a test and result improves immediate clinical decision making.  
Patients who may have left the health service usually can be more easily located within the vicinity of the health service on the same day or following day depending on staff availability (compared to a two week interval) so we would expect resources for patient recall for STI treatment to be reduced, and success in uptake of treatment increased compared to the status quo.
2. Syndromic management practice could be replaced by evidence-based diagnosis and treatment, rationalising antibiotic treatment<sup>86</sup>

Benefits in providing screening/testing and immediate treatment cannot be underestimated due to the sensitive nature of STIs and opportunities to treat those with CT/NG/TV infections more efficiently and reduce the ongoing transmission and complications of these infections.<sup>67</sup> Improved access to both testing and treatment are required to reduce the high prevalence of STIs in remote communities<sup>87</sup> Improving the time delay between diagnosis and treatment will improve uptake and time to treatment,<sup>31</sup> especially where individuals have shown a previous reluctance to attend clinic.

Challenges noted are related to the high turnover of staff in remote area health services which require regular training and competency assessment in the use of POC testing. This places additional time demands on staff for training, processing and documentation of the test results, however staff using POC testing consider time to treatment an improvement in service provision.<sup>88</sup>

**PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME**

**44. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):**

The introduction of the proposed service does not envisage any potential patient risk. It is envisaged POC will replace the current laboratory test. Quality management (quality assurance and quality control) of the original trial<sup>67</sup> and expanded program is managed under the managed by the Flinders International Centre

for Point-of-Care Testing (ICPOCT) program, who also provide the Quality Assurance for Aboriginal & Torres Strait Islander Medical Services (QAAMS)<sup>77</sup> program for POC testing in diabetic management in remote communities. Flinders ICPOCT provides a range of education and support for staff which includes training on how to instruct patient's to provide the sample and for staff to be competent in sample handling, processing, recording patient details and the results in accordance with Australian Guidelines For Point-of-Care Testing (2015).<sup>78</sup> This program has been evaluated and shown to be analytically efficient and have operational benefits in providing diagnosis at the time of screening.<sup>27 80 88 89</sup>

Efficacy and diagnostic accuracy of POC test has shown to be equivalent to laboratory conducted testing in a number of trials.<sup>17 18 21</sup> Clinical effectiveness with the new proposed medical service will be seen in comparatively better health outcomes (due to improving the timeliness of treatment and reducing the time to treatment) than those associated with current laboratory testing. Results from the TTANGO trial among 16 -29 year old people with a positive chlamydia or gonorrhoea test across eleven health services, showed that among those who had a POCT, more than three quarters (78%) received treatment in <3 days compared to less than a third (30%) among those who had a laboratory test.<sup>31</sup> The mean time to treatment following the point-of-care test was 9 days (median: zero days, i.e. treated on same day as test), compared to a mean of 18 days (median: 8.7 days) following a standard laboratory test.<sup>31</sup> Earlier diagnosis and treatment of CT, NG and TV has the potential to reduce the risk of complications for the affected individual such as pelvic inflammatory disease.<sup>36</sup> Over treatment is avoided due to the provision of results.<sup>86</sup> Patient harms with regard to stigma are potentially reduced as results are provided soon after consultation are recall process is expedited and patients can receive treatment promptly.<sup>31</sup> Use of POC testing has been reported by clinical staff to aid in clinical decision making regarding treatment due to the turn-around time to diagnosis being more efficient and effective in delivering patient care compared to sending a specimen to a distant laboratory.<sup>90</sup>

Cultural acceptance of the use of POC testing from the perspective of both patients and health care workers has been reported. Clinicians using POC tests in Australian Aboriginal Medical Services were favourable towards the test particularly due to having results to manage patient's appropriately which meant they were more likely to return for follow-up and to be compliant with treatment.<sup>28 29 81</sup> For the management of STIs, staff were generally favourable towards the use of POC tests as they appreciated that the shorter time to diagnosis and treatment would improve management of STIs.<sup>19 30 88</sup>

Please advise if the overall clinical claim is for:

- Superiority
- Non-inferiority

**45. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:**

**Safety Outcomes:**

The proposed medical service is equivalent to other laboratory tests that involve sampling of urine or collection of cervical/vaginal swabs.

**Clinical Effectiveness Outcomes:**

*Analytical validity*

Sensitivity, specificity, PPV, NPV comparable to reference standard

*Clinical utility*

Management (therapeutic efficacy)

Treatment pathway expedited, reduced time from diagnosis to treatment

Reduced unnecessary treatment

Individual health outcomes

Reduced period of infectiousness

Reduced complications of CT and NG and TV

Population health outcomes

Reduced disparity in health outcomes

Reduced ongoing transmission of CT/NG/TV among those at risk

Reduced prevalence of CT/NG/TV

Cost-effectiveness

Current preliminary estimations using a health system perspective over 10 years indicate that point of care is cost saving. Using POC testing for detection of CT and NG infection in women 15-29 years, over 10 years based on current testing rates the mean cost of POC is less than **REDACTED** per person and is less expensive compared to standard care and provides benefit in quality of life. The main drivers of cost effectiveness are staff time saved in follow-up of patients and time to treatment decreasing the incidence of PID.

## PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

### 46. Estimate the prevalence and/or incidence of the proposed population:

#### Chlamydia

A recent meta-analysis of CT prevalence studies among and Torres Strait Islander peoples indicates an overall pooled prevalence of 11.2% (12.7% and 7.7% for women and men respectively); subgroup analysis revealed higher prevalence estimates among Aboriginal people living in regional areas (17.1%), pregnant females (16.8%) and young Aboriginal people aged 12-29 years (16.2%).<sup>61</sup> This is generally consistent with a recent large scale (almost 13,500 patients across 68 remote communities in central and northern Australia) assessment of STI positivity as part of the 'STRIVE'1 study, where CT prevalence was estimated to be 11.5% in those aged 16-35 years and above, but exceeded 20% for those aged 16-19 years.<sup>39</sup>

**Table 5. CT Prevalence studies cited in meta-analysis by Graham et al<sup>61</sup>**

Author/year	Age range, yrs	Location	Prevalence	95% Confidence interval
Hart, 1992	Not stated	Urban	19.6	10.2–32.4
Hart, 1993	Not stated	Urban	5.2	1.4–12.8
How and Bowditch, 1994	14-33	Remote	0.0	0.0–5.2
Mein and Bowden, 1997	13-53	Remote	29.6	20.0–40.8
Skov et al., 1997	12-40	Remote	4.1	2.5–6.2
Bowden et al., 1997	13+	Remote	7.9	4.2–13.5
Miller et al., 1999	12-40	Remote	7.9	6.9–8.9
Bowden et al., 1999	12-73	Remote	11.00	9.2–13.0
Kildea and Bowden, 2000	20-45	Remote	30.00	25.6–35.6
Miller et al., 2001	12+	Remote	10.5	8.6–12.8
Knox et al., 2002	Not stated	Remote	11.5	8.2–15.6
Garrow et al., 2002	Not stated	Remote	21.3	10.7–35.7
Miller et al., 2003	15+	Remote	8.4	7.4–9.5
Latif and Smith, 2004	15-30	Remote	10.00	4.2–15.2
Mak et al., 2004	14-51	Remote	45.00	41.1–56.2
Panaretto et al., 2006	Pregnant women	Regional	14.4	10.9–17.8
Lenton et al., 2007	Not stated	Remote	10.5	2.5–21.7
Su and Skov., 2008	15+	Remote	2.5	2.1–3.0
Spurling et al., 2009	15-54	Urban	5.0	1.9–10.7
Buhrer-Skinner et al., 2009	Not stated	Regional	15.00	3.2–37.9
Forrest et al., 2009	Not stated	All	1.3	1.0–1.6
Fairbairn et al., 2010	16-35	Regional	8.9	5.5–13.6
Franklin et al., 2010	15–63	Urban	6.7	1.8–16.2
Templeton et al., 2010	14–20	Regional	16.3	10.0–25.5
Kwan et al., 2012	Not stated	All	8.0	5.0–12.0
Goller et al., 2012	16–39	All	8.4	7.4–9.7
Silver et al., 2012	14–34	Remote	14.3	6.7–25.4
Buhrer-Skinner et al, 2013	19–28	Remote	30.8	9.1–61.4
Rahman et al., 2014	14–79	Remote	2.4	1.0–4.9
Ward et al., 2014	16–29	All	14.8	13.0–16.7
Maher et al., 2014	16+	Urban	14.00	6.3–25.8
O'Connor et al., 2014	15+	All	17.1	14.7–19.7
Silver et al., 2015	16+	Remote	11.1	10.6–11.6

Li and McDermott, 2015	15+	Remote	9.2	7.8–10.9
Guy et al., 2015	16+	Remote	11.5	10.9–12.0
Tuttle et al., 2015	17-40	Regional	20.00	11.6–30.8

## Gonorrhoea

A recent meta-analysis of NG prevalence studies among Aboriginal and Torres Strait Islander peoples indicates an overall pooled prevalence of 12.5% (10.7% and 8.1% for Aboriginal women and men respectively). In this instance, subgroup analysis revealed that the highest pooled prevalence of NG was among Aboriginal people living in remote areas (12.6%) and young Aboriginal people aged 12-29 years (11.9%).<sup>61</sup> This data is largely consistent with NG positivity derived from the 'STRIVE' study- indicating NG prevalence of 10.1% (9.4% in women, 11.4% in men) among the 13,480 patients aged 16-35 years of age. Gonorrhoea positivity was strongly inversely associated with age, higher in men and women under 20 years of age (>20%).<sup>39</sup>Error! Bookmark not defined.

When the occurrence of co-infection was examined in the STRIVE study- the most frequent combination was CT and NG (2% of women and 4.1% of men aged 16-35 years and older), and highest in those aged 16-19 years (4.3% of women and 9.8% of men aged).<sup>39</sup>

**Table 6. NG Prevalence studies cited in meta-analysis by Graham et al<sup>61</sup>**

Author/year	Age range, yrs	Location	Prevalence (%)	95% Confidence interval
Hart, 1992	Not stated	Urban	42.9	34.1–52.0
Hart, 1993	Not stated	Urban	14.5	7.5–24.4
How and Bowditch, 1994	14-33	Remote	7.2	2.4–16.1
Skov et al., 1997	12-40	Remote	11.7	9.1–14.9
Bowden et al., 1997	13+	Remote	2.1	0.4–5.7
Mein and Bowden, 1997	13-53	Remote	30.9	21.1–42.0
Mak et al., 1998	15+	Remote	34.2	31.0–37.6
Miller et al., 1999	12-40	Remote	10.00	8.8–11.1
Bowden et al., 1999	12-73	Remote	17.00	14.8–19.3
Kildea and Bowden, 2000	20-45	Remote	27.00	22.5–32.2
Miller et al., 2001	12+	Remote	44.5	36.3–52.9
Knox et al., 2002	Not stated	Remote	11.8	8.5–15.0
Garrow et al., 2002	Not stated	Remote	27.7	15.6–42.6
Miller et al., 2003	15+	Remote	8.4	7.4–9.5
Latif and Smith, 2004	15-30	Remote	14.00	4.6–13.5
Mak et al., 2004	14-51	Remote	66.00	63.1–76.9
Panaretto et al., 2006	Pregnant women	Regional	2.9	1.3–4.5
Su and Skov., 2008	15+	Remote	4.2	3.6–4.8
Fairbairn et al., 2010	16-35	Regional	9.4	5.8–14.1
Templeton et al., 2010	14–20	Regional	2.3	0.7–8.1
Campbell et al., 2011	25+	Remote	3.6	2.5–5.1
Silver et al., 2012	14–34	Remote	21.00	11.5–32.7
Kwan et al., 2012	Not stated	All	3.00	0.0–6.0
Rahman et al., 2014	14–79	Remote	10.3	7.0–14.3
Maher et al., 2014	16+	Urban	1.9	0.0–9.4
Guy et al., 2015	16+	Remote	10.1	9.6–10.6
Silver et al., 2015	16+	Remote	11.1	10.7–11.6
Li and McDermott, 2015	15+	Remote	2.6	1.8–3.5

**Table 7. TV Prevalence studies 7**

There are not a lot of prevalence studies for TV in Australia and prevalence is low in urban Australia however higher rates have been reported in remote communities.

Author/year	Age range, yrs	Location	Prevalence	95% Confidence interval
Smith et al91	25-34 year	remote	26	
Smith et al91	<25yrs		33	
Smith et al91	>35		15	
Panaretto et al., 2006	Pregnant women	Regional	7.2	4.5–9.7
Ryder, 2012	Not stated	Rural and remote, NSW	8.4	5.9-11.1
Silver et al., 2014	16+	Remote	17.6	not provided

**Table 7. Concurrent infections prevalence studies 8**

Author/year	Age range, yrs	Location	Prevalence	95% Confidence interval
Panaretto et al., 2006	Pregnant women	Regional	20.2	16.5–23.9
Silver et al. 2014			CT 11.1, NG 9.5, TV 17.6	

**47. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:**

Existing guidelines recommend annual screening (WA biannual) screening for CT and NG in those who are sexually active and aged less than 35 years (<39 years in remote Queensland). If positive for CT or NG by POC test, an additional follow-up test after treatment at 3 months is recommended to exclude re-infection. Patients presenting with clinical symptoms of STIs are may also be offered testing. Guidelines for TV vary nationally with opportunistic screening recommended for men and women in the Northern Territory, for women only in Queensland and if clinically indicated based on symptoms or history in Western Australia.

**48. How many years would the proposed medical service(s) be required for the patient?**

Based on the recommendations for screening to be focussed on those aged 15-39 years, the proposed medical service would be required for approximately 25 years per patient, with additional testing as required.

**49. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:**

We estimate 16,065 individual patients will utilise the CT/NG POC test who will at the same consultation also utilise the TV POC test.

As per current STI guidelines, an individual may utilise a POC test more than once in a year. This includes when symptomatic; as part of screening when asymptomatic (e.g. as part of an adult health check, antenatal visit or cervical cancer screen); or as a retest at 3 months following an initial positive result. Currently 15% of patients receive an additional test within 6 months.

**50. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:**

Based upon both tests being done simultaneously and the implementation of POC testing for CT/NG and TV being scaled up from the current baseline of 31 health services (year 0) to 75 services over the next 5 years, we estimate the following:

Year 1 (38 health services): 18900 CT/NG POC tests and 18,900 TV POC tests  
 Year 2 (46 health services): 23,200 CT/NG POC tests and 23,200 TV POC tests  
 Year 3 (53 health services): 26,600 CT/NG POC tests and 26,600 TV POC tests  
 Year 4 (63 health services): 30,300 CT/NG POC tests and 30,300 TV POC tests  
 Year 5 (75 health services): 34,600 CT/NG POC tests and 34,600 TV POC tests

Estimates presented here as to the numbers of individuals and numbers of tests reflects currently available data and will be updated as additional data becomes available. Additional information around the impact of increasing both coverage and retesting rates will be provided.



## PART 8 – COST INFORMATION

### 51. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

Estimated cost of service is based on a health service conducting 300 tests per year<sup>1</sup>

GeneXpert including cartridge for CT/NG <sup>2</sup>	Non consumables	Consumables	Antimicrobial testing if NG positive <sup>3</sup>	Reporting and quality control costs CT/NG <sup>4</sup>	Cost of CT/NG POC test	Cartridge for TV	Reporting and quality control costs TV <sup>4</sup>	Cost of TV POC test <sup>5</sup>
REDACTED	REDACTED	REDACTED	REDACTED	REDACTED	REDACTED	REDACTED	REDACTED	REDACTED

Abbreviations CT Chlamydia trachomatis, NG Neisseria gonorrhoea, TV Trichomonas vaginalis

1. It is assumed testing for both CT/NG and TV will occur consecutively.
2. Estimated cost is based on purchase of GeneXpert (less expensive than rental cost) and depreciated over 8 years. Rental of GeneXpert would increase GeneXpert cost by 13%. Cost includes an annual delivery cost of cartridges which contains the assay for NAAT testing. The costs of reporting notifiable infection are not included which would be covered by the organisation overseeing health service reporting and quality assurance.
3. If NG is detected at the clinic, another specimen will be requested and send to the laboratory for antimicrobial susceptibility testing. Assumed 8% positivity.
4. Internal quality control tests are performed monthly and include clinic costs for training and ongoing annual competence testing, performing the QC and documentation. External QC costs are not included. A breakdown of costs is available if required.
5. Cartridge and staff time cost to perform test and QC for TV. External QC costs are not included and would be covered by the organisation overseeing health service reporting and quality assurance.

Further breakdown of costs is available on request. Costs for Cepheid GeneXpert could also be provided in confidence.

### 52. Specify how long the proposed medical service typically takes to perform:

CT/NG 90 minutes and TV 60 minutes

### 53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

Category 6 - PATHOLOGY SERVICE	Group PXX-Point of Care Tests
MBS [item number XXX]	
Proposed item descriptor: Detection of CT ( <i>Chlamydia trachomatis</i> ) and NG ( <i>Neisseria gonorrhoeae</i> ) via point of care testing performed for the diagnosis of CT or NG infection in patients at high risk.	
(Item is subject to restrictions in rule PR.9.1 of explanatory notes to this category)	
Fee: <b>To be determined</b>	

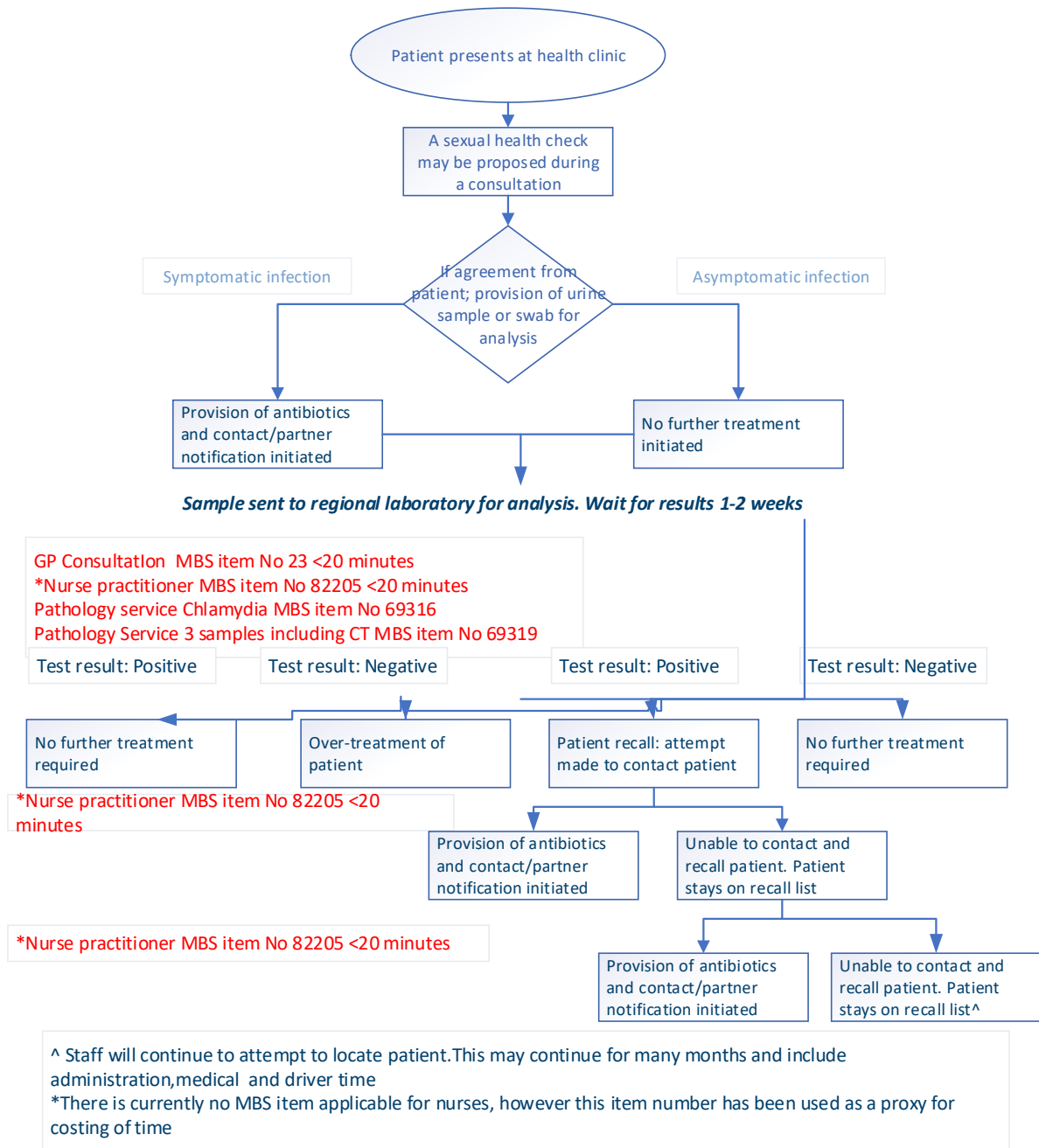
Category 6 - PATHOLOGY SERVICE	Group PXX-Point of Care Tests
MBS [item number XXX] Proposed item descriptor: Detection of CT ( <i>Chlamydia trachomatis</i> ) and/or NG ( <i>Neisseria gonorrhoeae</i> ) via point of care testing performed following previous CT or NG infection in patients at high risk. (Item is subject to restrictions in rule PR.9.1 of explanatory notes to this category)  Fee: <b>To be determined</b>	

Category 6 - PATHOLOGY SERVICE	Group PXX-Point of Care Tests
MBS [item number XXX] Proposed item descriptor: Detection of TV ( <i>Trichomonas vaginalis</i> ) via point of care testing performed for the diagnosis of TV infection in patients at high risk. (Item is subject to restrictions in rule PR.9.1 of explanatory notes to this category)  Fee: <b>To be determined</b>	

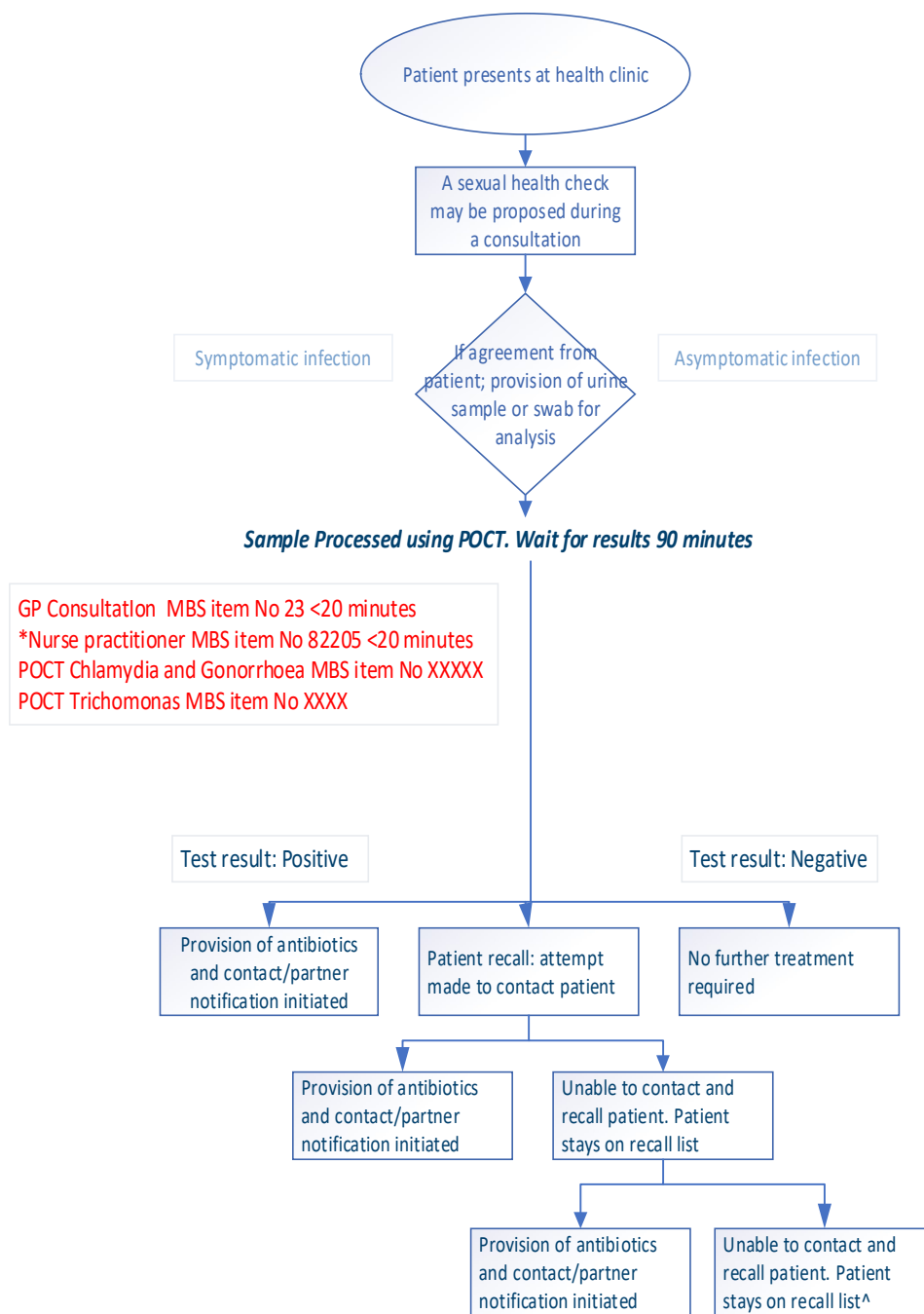
The 'Item is subject to restrictions in rule PR.9.1 of explanatory notes to this category' has been added as an example where there is oversight of POC testing by the Quality Assurance in Aboriginal Medical Services (QAAMS) Program.

**Appendix:**

**Q 27. Clinical pathway before intervention**



**Q. 43 Clinical management pathway with proposed medical service**



GP Consultation MBS item No 23 <20 minutes  
 \*Nurse practitioner MBS item No 82205 <20 minutes  
 POCT Chlamydia and Gonorrhoea MBS item No XXXXX  
 POCT Trichomonas MBS item No XXXX

\*Nurse practitioner MBS item No 82205 <20 minutes

^ Staff will continue to attempt to locate patient.  
 \*There is currently no MBS item applicable for nurses, however this item number has been used as a proxy for costing of time

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