Technology Brief

Update: Rapid tests for *Chlamydia trachomatis*

November 2011
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This brief was commissioned by Queensland Health, in its role as the Secretariat of the Health Policy Advisory Committee on Technology (HealthPACT). The production of this brief was overseen by HealthPACT. HealthPACT comprises representatives from health departments in all States and Territories, the Australian and New Zealand governments and MSAC. It is a sub-committee of the Australian Health Ministers’ Advisory Council (AHMAC), reporting to AHMAC’s Clinical, Technical and Ethical Principal Committee (CTEPC). AHMAC supports HealthPACT through funding.

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Register ID: WP072

Name of Technology: Rapid Chlamydia Test for Chlamydia trachomatis

Purpose and Target Group: For the rapid detection of Chlamydia infection in asymptomatic sexually active individuals in urine samples

Chlamydia continues to be one of the most prevalent sexually transmitted infection (STI), with the rate of notifications of infection in Australia continuing to grow (Figure 1).

Figure 1  Chlamydial infection notifications, Australia 2004-11
YTD = year-to-date, based on data sourced from the Australian National Notifiable Diseases Surveillance System (data downloaded 19 September 2011).

Since the 2009 prioritising summary, several reports on the diagnostic accuracy and acceptability of a range of chlamydia tests have been produced. This update provides an overview of the current state of point of care (POC) tests for chlamydia trachomatis (CT) infection when compared with the recognised diagnostic “gold standard”, nucleic acid amplification tests (NAATs).

2011 Effectiveness and Safety Issues:

Recently the British National Institute for Health Research conducted a systematic review of the diagnostic accuracy of rapid point-of-care tests (POC) for Chlamydia infection (Hislop et al 2010). This systematic review set out to include randomised controlled trials (RCTs) of both the diagnostic accuracy of POC tests, and the effectiveness of using these tests in terms of numbers of cases detected, treated and numbers of partners identified, notified, tested and treated. No comparative studies were identified that reported on the effectiveness of using POC tests, however the systematic review identified 11 RCTs that reported on diagnostic accuracy when POC...
tests were used to detect Chlamydia infection among sexually active adolescent and adult men and women (level III-2 diagnostic evidence). The POC tests that were identified were the Chlamydia Rapid Test (4 studies), Clearview Chlamydia (7 studies), Chlamydia Wand (2 studies), QuickVue (1 study), Magic Lite Chlamydia (1 study), and the SureCell Chlamydia test (1 study).

Of the 13 studies that reported diagnostic accuracy three used first void urine (FVU) samples, two used vaginal swab samples, four used endocervical samples, while three collected both endocervical and vaginal specimens, and one collecting endocervical and urethral samples. Polymerase chain reaction (PCR) was the reference standard (comparator) in eight of the 13 studies identified, with two studies using strand displacement amplification (SDA) as the reference standard, one of which used both SDA and PCR. The remaining three studies used ligase chain reaction (LCR) as the reference standard test, one of which also used transcription-mediated amplification (TMA) test.

Table 1 lists the key results reported in the systematic review for the various POC tests.

### Table 1: Key results for various POC Chlamydia tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Number of studies**</th>
<th>Number of specimen sets</th>
<th>Pooled sensitivity (%)</th>
<th>Pooled specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlamydia Rapid Test (vaginal swab specimens)</td>
<td>2</td>
<td>5</td>
<td>80</td>
<td>99</td>
</tr>
<tr>
<td>Chlamydia Rapid Test (first void urine samples)</td>
<td>2</td>
<td>4</td>
<td>77</td>
<td>99</td>
</tr>
<tr>
<td>Clearview Chlamydia test (various swab specimens)</td>
<td>4</td>
<td>8</td>
<td>52</td>
<td>97</td>
</tr>
<tr>
<td>Clearview Chlamydia test (cervical specimens only)</td>
<td>4</td>
<td>4</td>
<td>64</td>
<td>97</td>
</tr>
<tr>
<td>SureScreen Chlamydia Wand*</td>
<td>1</td>
<td>1</td>
<td>18.4</td>
<td>90.7</td>
</tr>
<tr>
<td>SureScreen Chlamydia Wand*</td>
<td>1</td>
<td>1</td>
<td>36.4</td>
<td>79.8</td>
</tr>
<tr>
<td>QuickVue Chlamydia test*</td>
<td>1</td>
<td>1</td>
<td>64.7</td>
<td>100</td>
</tr>
<tr>
<td>QuickVue Chlamydia test*</td>
<td>1</td>
<td>1</td>
<td>25</td>
<td>100</td>
</tr>
<tr>
<td>Magic Lite Chlamydia test (urethral specimens)*</td>
<td>1</td>
<td>1</td>
<td>72.1</td>
<td>99.6</td>
</tr>
<tr>
<td>Magic Lite Chlamydia test (cervical specimens)*</td>
<td>1</td>
<td>1</td>
<td>60.5</td>
<td>99.9</td>
</tr>
<tr>
<td>SureCell Chlamydia test*</td>
<td>1</td>
<td>1</td>
<td>62.9</td>
<td>100</td>
</tr>
</tbody>
</table>

* indicates insufficient data to allow pooling of estimates  
** some studies reported several different POC tests, so the total number of studies will be greater than 13

Of all the POC tests assessed, the Chlamydia Rapid Test had the highest reported sensitivity. Overall the sensitivity for all the POC tests ranged from poor to reasonable (range 18.4% to 80%), indicating that the majority of the POC tests are unable to
correctly identify those individuals who actually have the infection. The majority of studies included in the systematic review reported excellent specificities, above 90 per cent, with only one study reporting a lower specificity (79.8%) when the SureScreen Chlamydia Wand was used, indicating that they are effective in ruling out the presence of infection in uninfected patients. In terms of overall diagnostic accuracy, the Chlamydia Rapid Test performed better than all of the other assessed POC tests, with a good sensitivity and excellent specificity (99%).

A large study conducted in the Netherlands analysed the performance of POC tests compared with NAATs in 722 women, aged 16 years or more, who attended a STI clinic (van Dommelen et al 2010). Each woman was asked to take six self-taken vaginal swabs. Swabs one and six were used to determine quantitative Chlamydia load, swab two was used for the NAAT (the COBAS Amplicor CT/NG), and swabs 3-5 were randomised across three different POC tests. The three POC test that were tested were the Biorapid Chlamydia Ag test, the QuickVue Chlamydia test, and the HandiLab-C, with sensitivities of the tests (for all test samples) reported as 17.1, 25.0 and 22.5 per cent respectively, and specificities reported as 93.7, 99.7, and 88.9 per cent, respectively. The authors concluded that the POC tests evaluated were not ready for widespread use, with a risk of infections being missed, and patients with false positive results being unnecessarily treated (level III-2 diagnostic evidence).

Atlas Genetics recently published the results of a new bench-top assay for Chlamydia trachomatis, known as Velox, with a time-to-result of less than 25 minutes (level III-2 diagnostic evidence). The reported sensitivity and specificity of this system was excellent at 98.1 and 98.0 per cent, respectively, when compared to NAATs (Pearce et al 2011). No further information on the diagnostic accuracy or availability of this test was able to be obtained for this update.

Emmerton et al (2011) reported the results of a trial to distribute Chlamydia self-collection postal specimen kits from Australian pharmacies. Community pharmacists were instructed to offer kits to clients aged 16 years or older who were fluent in English and had presented for a sexual health-related product or consultation. Over a 4-month period across four community pharmacies, 156 kits were distributed to clients with 18 persons submitting specimens for testing (12%). The authors considered the distribution of these kits to be “moderately successful” in facilitating access to the testing service by the targeted at-risk sector of the population, however, pharmacy participation and support was highly variable. No results from the small number of tests distributed were reported (Emmerton et al 2011).

Owens et al (2010) conducted a survey on internet sites offering STI self-testing kits, and found that Chlamydia testing kits were the most commonly offered test, being offered from 20 out of 23 international and US web-sites (an additional three wholesaler/distributor sites also offered the test for sale but did not offer any testing services per se). Only two of the six kits purchased by the authors for testing yielded correct test results (one for Neisseria Gonorrhoeae and the other for both Neisseria
Gonorrhoeae and Chlamydia trachomatis), with two of the six providing no results at all (Owens et al 2010).

Issues regarding the usability or acceptability of self-sample kits also can affect the effectiveness of home-collection or self-sampling kits, with a recent study on self-sample collection kits for Chlamydia testing conducted in two primary care practices in Wellington, New Zealand finding that only three out of 67 distributed kits returned samples for Chlamydia testing (Rose et al 2010).

The growth in rapid, or home-based, testing for Chlamydia infection was thought to hold promise with regard to the reduction of Chlamydia transmission by providing an effective testing platform on which to base further treatment, and, where necessary, notification of at-risk partners of index patients. However, due to the relatively low reported sensitivity (and possible inferior specificity), rapid tests are thought to be better-suited to settings where a substantial proportion of patients may be lost to follow-up, or where treatment after testing is delayed (Gift 2011). Furthermore, concerns have been raised about the ability of the general public to perform and interpret the results of self-tests, or seek appropriate treatment and notify partners (Skidmore 2010).

2011 COST IMPACT

The systematic review by Hislop et al (2010) also included a modelled cost-effectiveness analysis of two POC tests – ClearView and the Chlamydia Rapid Test. Two different outcome measures were analysed: (1) the cost-effectiveness with effectiveness measured as the number of true-positive cases identified, treated and their partners notified, and (2) cost-effectiveness with effectiveness measured as the number of cases correctly identified (i.e. true-positives and true-negatives) and treated (if necessary), and partners of positive cases notified. Using the first measure of cost-effectiveness, current practice was found to perform better than the two POC tests. Using the second measure, the Chlamydia Rapid Test was found to perform better than current practice with a marginal increase in costs. It is difficult, however to transfer the results of this analysis to the Australian and/or New Zealand context due to differences in prevalence rates, cost parameters, and other health system variables that would affect resource usage and outcome effects.

2011 SUMMARY OF FINDINGS

The recently published literature on POC tests for detection of Chlamydia infection has generally found the tests to be less accurate than the current gold standard NAATs. The range of home specimen collection and home tests that are currently available vary in their reported levels of user support, regulation and the diagnostic accuracy of these tests have been found to be poor. Furthermore, the ability of users of home testing kits to pursue appropriate medical treatment, post-diagnosis counselling and notify at-risk partners is also questionable. While rapid POC tests have value in
acceptability to patients, as well as in allowing the rapid identification and follow up treatment, the current state of the technology requires further development.

2011 HealthPACT Assessment:

From the evidence assessed it would suggest that the majority of point-of-care Chlamydia tests are capable of accurately identifying those individuals who do not have the infection but are poor at identifying those individuals who actually have the infection. There is currently little evidence to support that point-of-care testing may reduce the incidence of new Chlamydia infections. Therefore HealthPACT have recommended that information on this technology be noted and that no further research is warranted on rapid POC Chlamydia tests at this time.

2011 List of Studies Included

Total number of studies 3
Level III-2 diagnostic evidence 3 (including the systematic review)

2011 Sources of Further Information:


Gift, T. L. (2011). 'Nucleic acid amplification tests are more accurate and cost-effective than the Chlamydia rapid test for diagnosing genital chlamydia.' Evid Based Nurs 14(2): 45-46.


PRIORITISING SUMMARY 2009

REGISTER ID: 000429

NAME OF TECHNOLOGY: RAPID CHLAMYDIA TEST FOR CHLAMYDIA TRACHOMATIS

PURPOSE AND TARGET GROUP: FOR THE RAPID DETECTION OF CHLAMYDIA INFECTION IN ASYMPTOMATIC SEXUALLY ACTIVE INDIVIDUALS IN URINE SAMPLES

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- Yet to emerge
- Experimental
- Investigational
- Nearly established

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- Yes
- No
- Not applicable

INTERNATIONAL UTILISATION:

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>LEVEL OF USE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trials Underway or Completed</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>✓</td>
</tr>
<tr>
<td>Philippines</td>
<td>✓</td>
</tr>
</tbody>
</table>

IMPACT SUMMARY:

The University of Cambridge and Diagnostics for the real World (Europe) provides Chlamydia Rapid Test with the aim of detecting Chlamydia trachomatis infection. The technology would be available through general practitioners or sexual health clinics for Chlamydia infection in asymptomatic but sexually active individuals.

BACKGROUND

Worldwide Chlamydia trachomatis infection is a major public health problem and one of the most common sexually transmitted bacterial infections. The majority of testing for Chlamydia is conducted on symptomatic cases or as a result of contact tracing, and as such remains under-diagnosed. However, approximately 40-50 per cent of males and 70-85 per cent of females infected with Chlamydia are symptomatic (Vajdic et al 2005). If left undetected and untreated chlamydia infection may move into the upper
genital tract causing inflammation and scarring in the reproductive tracts of both males and females. The most common complications of chlamydia infection in women include pelvic inflammatory disease (PID), urethritis, cervicitis, tubal infertility, chronic pelvic pain and ectopic pregnancy, a cause of maternal death and morbidity in the first trimester. In untreated women, 10-40 per cent of chlamydia infections may result in PID, and of these, 20 per cent will become infertile. Chlamydia infection can be transmitted to the neonate at birth, causing conjunctivitis and pneumonia (Hocking & Fairley 2003; Walleser et al 2006; Watson et al 2002).

The Rapid Chlamydia urine test requires subjects to provide a urine sample, collected using the FirstBurst urine collection device which collects the first 4-5 ml of urine. The urine is diluted with distilled water and centrifuged. The supernatant is discarded and the pellet is extracted by the sequential addition of the three kit solutions. A fraction of the extracted sample is added to a tube which contains lyophilised amplification and detection reagents. After mixing, the test strip is added to the solution and incubated at room temperature for 25 minutes (Figure 2). The test strip is embedded with a monoclonal antibody to chlamydial lipopolysaccharide. If chlamydia is present in the sample a line appears on the test strip (Nadala et al 2009).

![Image of the Rapid Chlamydia test](Wellcome Images)

Figure 2 The Rapid Chlamydia test, showing test strip with a result line indicating the presence of chlamydia (printed with permission Wellcome)

It has been proposed that the Rapid Chlamydia urine test will enable a test and treat regimen, with patients undergoing the test, obtaining the result and if needed receiving treatment all in the one clinic visit. Testing by polymerase chain reaction (PCR) may take hours or even days and the return rate of positive patients to clinics for treatment is approximately 65 per cent (Nadala et al 2009). Although there are other rapid chlamydia tests on the market, they lack sensitivity in comparison to PCR.
CLINICAL NEED AND BURDEN OF DISEASE

In Australia and New Zealand, the rate of chlamydia infection has been steadily increasing for a number of years, with chlamydia now the most common notifiable disease. Notification rates are likely to be an underestimate of the true rate of chlamydia infection as the majority of tests are performed on symptomatic patients (40-85% of infected individuals may be asymptomatic) or as a result of contact tracing (Vajdic et al 2005).

In Australia, there were 73.5 per 100,000 population notifications of chlamydia infection in 1999, the first year that all states and territories reported notification data. This number has increased every year and in 2008 the notification rate was 273.8 per 100,000. The Northern Territory recorded the highest number of notifications in all years, however this is likely to be due a high number of chlamydia infections of the eye (Communicable Diseases Australia 2009). True prevalence data are difficult to obtain. An Australian systematic review identified 40 studies that used PCR to identify individuals infected with chlamydia. The mean overall prevalence of genital chlamydia infection was 4.6 per cent, 95% CI [4.4, 4.8], which the authors considered indicated an over-sampling of high-risk groups in the included studies. Mean community-based rates were similar for non-Indigenous males and females (1.5% and 1.4%, respectively). Mean community-based rates for Indigenous men and women were 7.5 per cent (95% CI [6.4, 8.6]) and 8.7 per cent (95% CI [7.9, 9.7]), respectively. The overall mean estimate for adolescents and young adults was 3.3 per cent, 95% CI [2.8, 3.9] (Vajdic et al 2005).

A recent Australian study reported on the medical records of women (mean age 27.7 years, range 12.2 -80.7 years) using the Melbourne Sexual Health Clinic from 2003 to 2007. All new clients to the clinic underwent a chlamydia test, regardless of their reason for visiting the clinic or whether they were symptomatic for chlamydia infection or not. Over the 5-year period, 10,498 chlamydia tests (PCR) tests were performed and an overall prevalence of 5.9 per cent (95% CI [5.5, 6.4]) was reported. Women less than 25 years had the highest rate of positive tests at 8.1 per cent. The authors report that the positive chlamydia tests are increasing by 12 per cent per year (O'Rourke et al 2009).

As reported in a previous summary\(^1\), an Australian prevalence survey of chlamydia among young women (aged 18-35 years) was conducted in Melbourne between March 2003 and June 2004. Of the 11,001 households chosen at random, 979 women were eligible and interviewed and of these, 657 provided a urine. A total of six cases of chlamydia were detected (five aged 18-24 years and one aged 25-35 years), with an overall prevalence of 0.9 per cent. The prevalence was 3.7 per cent (95%CI [1.2, 8.4], n=135) in the 18-24 years group and 0.2 per cent (95%CI [0.0, 1.1], n=489) in the 25-35 years group.

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\(^1\) Screening for chlamydia in pharmacies
35 years group. All women who tested positive were asymptomatic (Hocking et al 2006).

Prevalence data for New Zealand are difficult to obtain. Annual testing for chlamydia within the Waikato District Health Board region rose from approximately 18,000 tests conducted in 1998 to 23,338 tests in 2002, and remained at that level until 2006. In 1999, 7.7 per cent of tests were positive, however this rate rose to 11.3 per cent in 2005 but declined again in 2006 to 9.6 per cent (Morgan 2008). A later study again conducted in the Waikato region, reported that there were 21,104 Chlamydia tests carried out during Feb-Oct 2008. Of these, 10,847 (51.4%) tests were tests on 15-24 year olds, 82.3 per cent of whom were female. Using census data for the region, these figures represent 22.2 per cent of the region’s 15-24 year olds, which was made up overwhelmingly of 37 per cent of the region’s young females compared to 7.7 per cent amongst males. Overall 15.8 per cent of tests from 15-24 year olds were positive, 14.4 per cent in females and 23.0 per cent in males ($p<0.001$), with positivity double amongst Māori (24.2% vs. 12.5%; $p<0.001$) (Morgan & Bell 2009).

New Zealand laboratory surveillance indicates an overall increase in the rate of reported chlamydia infection over time (Figure 3). In the quarter from April to June 2009, 37,678 chlamydia tests were conducted with 2,708 (7.2%) testing positive from 2,562 patients. Sixty-six per cent of all positive tests were aged 15-24 years. The Waikato region reported testing 7,379 samples for chlamydia with 768 being positive (10.4%) from the same number of patients. Seventy-five per cent of all positive tests were aged 15-24 years. Almost the same figures were reported from Bay of Plenty laboratories. The overall rate of chlamydia infection in these regions for the quarter April to June 2009 was 211.4 per 100,000 population (STI Surveillance Team 2009).

![Figure 3](image-url)
**DIFFUSION**

The Rapid Chlamydia Test is not currently available in Australia.

**COMPARATORS**

The gold standard diagnostic test for *Chlamydia trachomatis* currently in use in Australia and New Zealand is PCR. PCR is highly specific and sensitive, especially in comparison to culture, and will only identify *Chlamydia trachomatis* and not *Chlamydia pneumoniae* or *Chlamydia psittaci* (psittacosis) infection. The PCR test amplifies a fragment of specific DNA from the cryptic plasmid of chlamydia, and is capable of detecting only one chlamydia cell in the sample. The PCR test for *Chlamydia trachomatis* can be performed on first void urine in males and females, avoiding the need for urethral swabs, however endocervical swabs are also suitable. For swabs, a specific PCR swab specimen collection transport kit must be used (Ferguson 2005). Samples for PCR testing must be sent to a certified pathology laboratory.

**SAFETY AND EFFECTIVENESS ISSUES**

The Rapid Chlamydia test was first trialled in the UK for women attending a sexual health clinic (site one) or two genitourinary medicine clinics over a six-month period. All women over the age of 16 years attending the clinics were invited to attend. All participating women provided a self-collected vaginal swab and a first-void urine sample (FVU). At sites two and three, women also provided a clinician-collected vaginal swab. The majority of women attending site one were asymptomatic (98.2%) and were attending for contraception or reproductive health services. Many of the women (67%) attending sites two and three, however, reported symptoms including vaginal discharge (46%), lower abdominal pain (23%) or pelvic inflammatory disease (3%). Urine samples were divided, with one half sent for PCR chlamydia testing at an independent laboratory and the other subjected to the Rapid Chlamydia test (level III-2 diagnostic evidence). A total of 1,349 women took part in the study. The mean age of participants varied between the clinics: site 1 (n=663), mean age 18.5 years (range 16-27.4 years); site 2 (n=385) mean age 25.4 years (range 16-49.7 years) and site 3 (n=301) mean age 27.8 years (range 17.1-54.8 years).

There was no significant difference between vaginal swab collection methods when compared to PCR. The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for self-collected swabs was 81.5, 98.7, 84.6 and 98.4 per cent, respectively. The sensitivity, specificity, PPV and NPV for clinician-collected swabs for the same women was 77.8, 99.2, 89.4 and 98.1 per cent, respectively. The difference in performance of the Rapid Chlamydia test between self- and clinician-collected vaginal swabs was not significant ($p=0.096$). When self-collected swabs from all centres were compared to the gold standard PCR, the
sensitivity, specificity, PPV and NPV values were 82.7, 98.8, 85.8 and 98.5 per cent, respectively. When only the asymptomatic subjects from all three sites were considered, the Rapid Chlamydia test had an overall sensitivity of 80.5 per cent when compared to PCR. It is unclear from the study why a vaginal swab was the preferred method of testing as opposed to testing of the urine sample. The majority of women (95.9%) were comfortable collecting their own vaginal swab. Self-collected swabs were the preferred method of sample collection for 40.7 per cent of women, with 37.5 per cent preferring a urine sample. The remaining 27.7 per cent of women did not express a preference. Seventy-five per cent of women were prepared to wait between 30 minutes and two hours for test results, with only 6.9 per cent preferring to wait less than 30 minutes (Mahilum-Tapay et al 2007).

In order to reduce or slow the steadily increasing rate of chlamydia infection in the population, it has been suggested that more widespread and systematic testing and treatment of males would reduce the infective pool and prevent transmission to females. Therefore a test which makes it quicker and easier to test males via a urine sample rather than a painful urethral swab may be advantageous. Males over 16 years (n=1,002) were recruited over a 12-month period at two of the sites described in the above study (one sexual health clinic, one genitourinary clinic) (level III-2 diagnostic evidence).

To optimise the urine collection method, participants were randomised to provide two urine samples using two different methods. One group provided a urine sample using the FirstBurst collection device, then after a two hour interval the second sample was collected using a conventional cup. The second group reversed the order of sample taking. The FirstBurst collection device, regardless of whether the sample was taken first or second, provided a sample with a significantly higher bacterial load when compared to the conventional cup device (p<0.0001). To further analyse the optimal collection mode, 31 chlamydia positive males provided a urine sample using the FirstBurst collection device and fractionation system, which allowed four distinct fractions from the one urine void. The importance of collecting the first fraction for chlamydia testing, and thus optimising bacterial load, is emphasised by the results. The first fraction (4.6ml) contained a mean bacterial load of 38,561 plasmids/ml with the number decreasing significantly with the second, third and fourth fractions yielding 5,219, 1,669 and 270 plasmids/ml.

The performance of the Rapid Chlamydia test using both FirstBurst and cup urine specimens were compared to the gold standard PCR in 534 randomly collected samples. PCR detected chlamydia infection in 34 of the FirstBurst urine samples (positivity rate 6.4%) and in 33 of the cup collected samples (6.2%). The Rapid Chlamydia test had a sensitivity of 82 per cent when the FirstBurst sample was used compared to a sensitivity of 47 per cent for the cup collected samples. The overall
specificity of the Rapid Chlamydia test was high at 98.8 per cent (Wisniewski et al 2008).

Having established the optimal collection conditions for urine samples from males (collecting the first 4-5ml of a urine sample using the FirstBurst collection device), Nadala et al (2009) enrolled 1,277 young males (>16 years) attending the same two clinics described by Wisniewski et al (2008) (level III-2 diagnostic evidence). The majority of men attending site one were asymptomatic and were attending for contraception or reproductive health services. However, 62 per cent of subjects (467/749) enrolled at site two reported symptoms including urethral discharge (21%) and painful or difficult urination (23%). In addition, three per cent of participants were attending the clinic after being identified via contact tracing. Of those eligible, 1,211 provided a usable urine sample. Samples were tested for the presence of chlamydia using the Rapid Chlamydia test and the reference standard, PCR. Twenty participants were identified as positive for chlamydia infection by PCR at site one (4%) and 90 (12%) at site two. The overall sensitivity and specificity of the Rapid Chlamydia test was 81.8 and 98.5 per cent, respectively (Table 2).

Table 2  Performance of the Rapid Chlamydia test compared to PCR

<table>
<thead>
<tr>
<th>Site</th>
<th>Sensitivity (%) [95 % CI]</th>
<th>Specificity (%) [95 % CI]</th>
<th>PPV (%) [95 % CI]</th>
<th>NPV (%) [95 % CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (n=454)</td>
<td>90.0 [86.3, 98.8]</td>
<td>98.2 [96.4, 99.2]</td>
<td>69.2 [48.2, 85.7]</td>
<td>99.5 [98.3, 99.9]</td>
</tr>
<tr>
<td>2 (n=757)</td>
<td>80.0 [70.2, 87.7]</td>
<td>98.7 [97.4, 99.4]</td>
<td>88.9 [80.0, 94.8]</td>
<td>97.3 [95.8, 98.4]</td>
</tr>
<tr>
<td>Total (n=1211)</td>
<td>81.8 [73.3, 88.5]</td>
<td>98.5 [97.5, 99.1]</td>
<td>84.1 [75.8, 90.5]</td>
<td>98.2 [97.2, 98.9]</td>
</tr>
</tbody>
</table>

The authors reported a significant difference between the PPV and NPV values obtained at the two sites ($p=0.009$ and $p=0.028$, respectively), which may reflect differences in prevalence of chlamydia infection between the two sites. The likelihood ratios of a positive and negative result from the chlamydia test from both sites and sites combined are summarised in Table 3.

Table 3  Positive and negative likelihood ratios for test results with Rapid Chlamydia test

<table>
<thead>
<tr>
<th>Site</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (n=454)</td>
<td>50.0</td>
<td>0.102</td>
</tr>
<tr>
<td>2 (n=757)</td>
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<td>0.202</td>
</tr>
<tr>
<td>Total (n=1211)</td>
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<td>0.185</td>
</tr>
<tr>
<td>Adjusted total (range)</td>
<td>43.1 (15.0-55.1)</td>
<td>0.184 (0.177-0.477)</td>
</tr>
</tbody>
</table>

Of the 20 participants found to be positive for chlamydia at site one, 18 (90%) were asymptomatic at presentation. At site two, 28 (31%) of those found to be positive had
no symptoms. Of these asymptomatic men, 16/18 (89%) and 20/28 (71%) tested positive for chlamydia using the Rapid Chlamydia test, giving an overall test sensitivity of 78 per cent (36/46) for asymptomatic men. The combined sensitivity for symptomatic men testing positive at both sites was higher at 84 per cent.

The majority of participants preferred giving a urine sample (89%), with seven per cent preferring a swab and four per cent willing to provide either. However as participants were not asked to provide a swab, this preference may not be valid. The majority of subjects (96%) indicated that they were willing to wait an hour or more for test results with only four per cent unwilling to wait an hour.

**COST IMPACT**

The Wellcome Trust were contacted via email for pricing information, however no reply was received by the evaluators. In the previous summary in 2006, which described the use of a dipstick assay for trachoma using the same principles, Diagnostics for the Real World aimed to have a two-tiered price range. Developing countries would be able to access the FirstBurst Trachoma test for approximately 70 cents per dipstick test, however prices would be higher in developed countries such as Australia (personal communication University of Cambridge, May 2006).

The fee for the MBS item number 69316, which covers the detection of chlamydia by any method, is $28.85.

**ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified/raised in the sources examined.

**OTHER ISSUES**

The Rapid Chlamydia urine test may be of benefit to rural and remote communities that do not have access to pathology laboratory testing. Although samples for PCR testing can be transported from these communities to regional centres the turnaround time for results is extended. The Rapid Chlamydia urine test enables a rapid diagnosis and a treatment regimen may be put in place immediately without a return visit.

**SUMMARY OF FINDINGS**

Initial studies with the Rapid Chlamydia test combined with either the FirstBurst collection device or vaginal swabs for women, appears to have good sensitivity and specificity for the rapid detection of chlamydia, depending on the prevalence of chlamydia in the tested population. The Rapid test has the advantage that results can be given to the patient within a short time frame and if found to be positive, patients can be given immediate treatment. The targeting and testing of young males may be an effective way in which to reduce the infective pool and to halt the increase in chlamydia infection rates.
HEALTHPACT ACTION:
The rapid Chlamydia test may be of use in rural and remote areas and in public hospital settings. Whether or not this test may be useful for screening populations remains to be ascertained. However, based on initial promising results from studies, the rapid increase in infection rates and the need to reduce the number of new Chlamydia infections in the population by identifying asymptomatic individuals HealthPACT have recommended that this technology be monitored for further information in 12-months time.

NUMBER OF INCLUDED STUDIES
Total number of studies 3
Level III-2 diagnostic evidence 3

REFERENCES:


**Search Criteria to be used:**

Chlamydia Infections
Patient Satisfaction
Polymerase Chain Reaction
Urinalysis
Chlamydia trachomatis
Bacterial/analysis
Point-of-Care Systems