Trichomoniasis is a sexually transmitted infection caused by the protozoan parasite, *Trichomonas vaginalis*. It is the commonest curable sexually transmitted infection; the World Health Organization estimates that 170 million new infections occur each year.1 The highest prevalence of infection has been reported from resource constrained countries2–4 and in disadvantaged populations in developed countries.5 Infection with *T vaginalis* may facilitate the transmission of HIV6–7 and is associated with adverse pregnancy and perinatal outcomes.8 Thus, the control of *T vaginalis* infection is important in reproductive health settings and also in the control of HIV/AIDS.

Diagnosis of *T vaginalis* infection in most parts of the world is carried out by the saline wet preparation (“wet prep”) method, a technique which has not changed since it was first reported by Donné in 1836.9 However, this technique has a low sensitivity of 30–80%9–11 and requires trained and experienced microscopists. The gold standard in *T vaginalis* diagnosis—culture—has a higher sensitivity of 71–100%,12 but requires an incubator with a constant electricity supply and relatively expensive culture media, in addition to an experienced microscopist. Further, it can take up to 7 days for results to be obtained, and currently is outside the reach of many health settings. In recent times, the sensitivity of *T vaginalis* diagnosis has been much improved by the use of nucleic acid amplification technology.13 14 Non-invasive diagnostic material (self obtained swabs, tampons, and urine)15 16 appealing to patients, have also been used. Polymerase chain reaction (PCR) currently, however, is also outside the reach of many diagnostic centres in resource poor settings.

A less technologically demanding technique with good test performance characteristics is needed, especially in resource poor countries. We compared a latex agglutination test with culture and Donné’s wet prep technique for the diagnosis of *T vaginalis* infection.

**PATIENTS AND METHODS**

A total of 3807 consecutive women attending antenatal clinics in Kumasi, Ghana, were screened for vaginal infections between September 2002 and May 2003. Following informed consent, self administered vaginal swabs were screened for *T vaginalis* infection using the Kalon TV latex agglutination test (Kalon Biological, Surrey, UK). In this test, vaginal swabs were eluted by agitation in phosphate buffered saline. One drop of this eluate was mixed with a drop of test latex on a reaction zone on a black glass slide, and the slide manually rocked continuously for 2 minutes. Agglutination of the test, but not control latex, indicated presence of *T vaginalis* antigen.

All study subjects testing positive for *T vaginalis* on latex agglutination testing, and the following two consecutive women testing negative had two further vaginal swabs taken. The triplet of tests was not matched according to symptom presentation. The swabs were obtained by a nurse from the posterior fornix, after speculum insertion and were tested for *T vaginalis* by wet prep and culture. In the wet prep technique, the swab was agitated in 0.9% saline and a drop of this was observed under wet mount microscopy at ×100 for the characteristic morphology and motility of *T vaginalis*. Any observed trichomonad was confirmed at ×400. Culture was undertaken using the *T vaginalis* InPouch system (Biomed Diagnostics, San José, CA, USA) as previously described.17

Latex agglutination and wet prep microscopy were done on site within 10 minutes of specimen collection. Inoculation of the InPouch was also done on site within 10 minutes of specimen collection and incubated at 37°C within an hour of specimen inoculation. All three tests were read independently and blind to the results of the other tests by different technicians.

Test sensitivity, specificity, and predictive values were compared. Kappa statistic for tests agreement between latex and wet prep, and latex and culture was also determined.

**RESULTS**

Of the 3807 pregnant women, 206 (5.4%) were positive for *T vaginalis* on screening with the latex agglutination kit; 618 women (206 latex positives, 412 latex negatives) were selected for wet prep and culture testing. At presentation, 343 women (53.5%) were symptomatic for vaginitis (either vaginal discharge or itch) and 275 (44.5%), asymptomatic.
Table 1  Diagnostic comparison of latex agglutination, wet prep, and culture for detection of *Trichomonas vaginalis*  

<table>
<thead>
<tr>
<th><em>T. vaginalis</em> infection</th>
<th>Diagnostic test</th>
<th>Wet prep</th>
<th>Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Latex agglutination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>True positive*</td>
<td>171 (27.7%)</td>
<td>141 (22.8%)</td>
<td>170 (27.5%)</td>
</tr>
<tr>
<td>False positive</td>
<td>35 (5.7%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>False negative</td>
<td>2 (0.3%)</td>
<td>32 (5.2%)</td>
<td>3 (0.5%)</td>
</tr>
<tr>
<td>True negative†</td>
<td>410 (66.3%)</td>
<td>445 (72.0%)</td>
<td>445 (72.0%)</td>
</tr>
</tbody>
</table>

*Wet prep microscopy or InPouch culture positive.
†Both wet prep microscopy and InPouch culture negative.

Significantly more symptomatic subjects were positive on testing ($\chi^2 = 10.3$, $p = 0.001$); 64.5% of the 206 subjects tested positive with the latex as against 51% of the 412 testing negative, were symptomatic for vaginitis.

All but one of the latex positive samples was positive on culture, and all but one sample positive on latex agglutination testing was positive on wet prep. These two latex negative samples had discrepant results for wet prep and culture testing. Three samples with flagellates having characteristic morphology and motility of *T. vaginalis* in the direct smear did not grow in culture.

Using an expanded gold standard for the comparison, patients were considered to have *T. vaginalis* infection when either wet prep microscopy or InPouch culture were positive. They were considered negative for infection when both wet prep microscopy and InPouch culture were negative. Table 1 shows the diagnostic comparison and table 2 test performance.

The kappa index which measures agreement between tests was 0.93 (95% CI 0.91 to 0.94) for latex and culture, and 0.88 (95% CI 0.86 to 0.90) for latex and wet prep.

**DISCUSSION**

In this diagnostic comparison, the test performance of the wet prep and culture are in conformity with other published studies. Sensitivity of the latex agglutination test compares favourably with culture and is superior to the wet prep. Moreover, the test is simple to perform, requires no equipment other than a glass slide and mixing stick and gives a result in less than 3 minutes. This study is the second evaluation of the latex agglutination test and the first to be conducted in Africa. Carney et al in their evaluation of this kit in the United Kingdom in 1988 reported a sensitivity and specificity of 95.2% and 99.4% respectively using wet prep and culture as reference standards. In spite of these encouraging results, the test has not been widely used.

Recent reports suggest that *T. vaginalis* enhances the transmission of HIV, and that symptomatic *T. vaginalis* infection increases the amount of HIV shed in semen. Moreover treatment of *T. vaginalis* infection significantly lowers the vaginal and seminal HIV viral load in dually infected subjects. Given the high prevalence of *T. vaginalis* infection, its control could have a significant impact on the HIV epidemic in Africa, and may reduce the incidence of adverse pregnancy outcome.

Two ingredients important in the control of sexually transmitted infections are accurate diagnosis and prompt treatment. Properly done, this will reduce the reservoir of infection and thus reduce the incidence of infection. In many health settings worldwide, wet mount microscopy is the preferred option for prompt diagnosis of trichomoniasis. This method, though timely and enabling patients to receive same day treatment, has a poor sensitivity and patients could remain infected and untreated. Culture, with a much better sensitivity, does not allow same day treatment, and patients, especially if asymptomatic for infection may continue to transmit infection. In many developing countries where the cost of return to the health facility can be substantial, patients may not bother to return for their culture results, thus prolonging infection, leading to further transmission and the possibility of sequelae. Partner notification efforts would also be defeated. This latex agglutination kit allows for prompt laboratory diagnosis of infection and treatment. With a sensitivity of 98.8% and a kappa index of 0.93 it compares favourably with culture, and its use could be more cost effective than culture. It provides same day results (test takes 2 minutes), thus saving time and costs due to incubation. At a present cost of £1 ($1.56) per test it compares with other rapid tests made for reproductive health settings. In resource poor settings where the cost of purchasing microscopes for wet prep and culture examinations may be prohibitive, and where trained and skilled personnel are unavailable, this latex agglutination test can fulfill such need. We have trained secondary school graduates to perform the test correctly. The kit as presently manufactured contains everything that is needed and no further purchases are needed.

In analysing a model of treatment interventions for trichomoniasis, Bowden and Garnett indicate that identifying individuals with both symptomatic and asymptomatic infection and giving appropriate treatment could be the most efficient method of controlling *T. vaginalis* infection. This would be greatly augmented by a good screening tool that would detect most infections and allow prompt treatment. Currently available diagnostic tools do not allow this. The *T. vaginalis* latex agglutination test could fill that void. In high *T. vaginalis* endemic areas, which unfortunately are also often

Table 2  Performance of the three diagnostic tests and 95% confidence intervals  

<table>
<thead>
<tr>
<th></th>
<th>Latex agglutination</th>
<th>Wet prep</th>
<th>Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (%)</td>
<td>98.8 (95.9 to 99.9)</td>
<td>81.5 (74.9 to 87.0)</td>
<td>98.2 (95.0 to 99.6)</td>
</tr>
<tr>
<td>Specificity (%)</td>
<td>92.1 (89.2 to 94.5)</td>
<td>100 (99.2 to 100)</td>
<td>100 (99.2 to 100)</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>83.0 (77.2 to 87.9)</td>
<td>100 (97.4 to 100)</td>
<td>100 (97.4 to 100)</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>99.5 (98.3 to 99.9)</td>
<td>93.3 (90.7 to 95.4)</td>
<td>99.5 (98.1 to 99.9)</td>
</tr>
</tbody>
</table>
Present diagnostic tests for *T vaginalis* in resource poor settings are either insensitive or too expensive.

The *T vaginalis* latex agglutination test is a 2 minute test and its performance compares favourably with culture, the current gold standard in *T vaginalis* diagnosis.

It is a simple to use kit, requires no equipment, and is suitable for developing country settings.

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**Key messages**

- Present diagnostic tests for *T vaginalis* in resource poor settings are either insensitive or too expensive.
- The *T vaginalis* latex agglutination test is a 2 minute test and its performance compares favourably with culture, the current gold standard in *T vaginalis* diagnosis.
- It is a simple to use kit, requires no equipment, and is suitable for developing country settings.

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**REFERENCES**


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**CONTRIBUTORS**

YAS, HAW, and DM designed the study; BKO and KAD trained the nurse-midwives and supervised clinical aspects of the study; YAS trained and supervised laboratory aspects of the study; data analysis was done by YAS and HAW; the manuscript was drafted by YAS, HAW and DM and written by YAS; all authors have reviewed and approved the final version of the paper.

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Comparison of latex agglutination, wet preparation, and culture for the detection of 
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