A latex agglutination test for the detection of *Trichomonas vaginalis*

**INTENDED USE**

To detect *Trichomonas vaginalis* antigens eluted from a vaginal swab as an aid to the diagnosis of trichomoniasis.

**INTRODUCTION**

*Trichomonas vaginalis* (Tv) is the causative agent of human trichomoniasis and is probably the commonest non-viral sexually-transmitted disease in the world with about 170 million new infections acquired each year (WHO, 1995).

Infections are usually described as extremely unpleasant but not dangerous however this may be re-evaluated in the light of recent studies. Epidemiological studies have linked trichomoniasis in women with a modest increases in the risk of HIV infection via heterosexual intercourse (Laga et al., 1993; ter Meulen et al., 1992), adverse pregnancy outcome (Hardy et al., 1984; Germain et al., 1994), and have suggested that it might be the cause of a few percent of cases of cervical neoplasia (Zhang et al., 1995; Zhang & Begg, 1994; Yap et al., 1995; Gram et al., 1992). Most recently, Viukki et al. 2000 found a six-fold increase in the incidence of cervical carcinoma in women infected with HPV who also had trichomoniasis.

**PRINCIPLE OF THE ASSAY**

The latex supplied with the kit is sensitised with rabbit anti-*T.vaginalis* IgG. For the test this latex is mixed on a slide with the eluate from a vaginal swab. Any Tv antigen present in the sample causes cross-linking (agglutination) of the sensitised latex. After mixing for three minutes the slide is read. Agglutination of the beads is indicative of Tv.

**KIT PRESENTATION**

- Test Latex in dropper bottle, contains sodium azide preservative (0.1%). 5 mL
- Positive Control in dropper bottle, contains sodium azide preservative (0.1%). 2.5 mL
- Negative Control in dropper bottle, contains sodium azide preservative (0.1%). 2.5 mL
- Sample Tubes, containing 500 µL phosphate buffer and sodium azide 100
- Wooden mixing sticks 100
- Reusable glass test slide 1

**ADDITIONAL REQUIREMENTS**

- Sterile swabs
- Micropipettes to deliver 50 µL and disposable tips.
- Disposable paper towels.

**SPECIMEN COLLECTION**

1) Take a high vaginal swab and elute into the sample tube. Do this by squeezing the swab vigorously onto the bottom of the tube in the liquid. Squeeze the swab on the side of the tube above the liquid to express as much liquid from the absorbent material as possible.

2) Discard the swab.

3) It the swab cannot be eluted within 30 minutes it should be stored frozen.

**TEST PROCEDURE**

1) Bring all reagents to room temperature.
2) Shake the test latex well immediately before use.
3) Add 50 µL of the swab eluate to a reaction zone on the glass slide.
4) Add one drop of test latex
5) Stir both liquids to a completely homogenous mixture that covers the whole surface of the reaction zone.
6) Tilt the glass slide with a rotating action continuously for three minutes.
7) After 3 minutes, read the degree of agglutination obtained.

**Procedural Note**

Use the Negative Control in an adjacent reaction zone in parallel with a test sample to distinguish between a weak positive and negative result.

Use the Positive Control to monitor the performance of the Test Latex. It is recommended to run the Positive Control the first time the kit is used and periodically when removed from storage.

**INTERPRETATION OF RESULTS**

Record the degree of agglutination as follows

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Result</th>
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</thead>
</table>
| The latex has agglutinated and much has collected around the edge of the reaction zone. | positive  
+++ |
| Agglutinated particles can clearly be seen against a background of granular latex. | positive  
++ |
| Agglutination can just be discerned when compared to the negative control. | positive  
+ |
| No agglutination compared to negative control | negative |
LIMITATIONS
Tv antigens can only be detected from the material that has been eluted into the sample tube. It is essential that the specimen is taken carefully and is then eluted thoroughly.

The results from this test are intended to be an aid to diagnosis only. Each clinician must interpret the results in light of the patient’s clinical history, symptoms and other diagnostic procedures.

EXPECTED RESULTS

Performance
In a clinical trial conducted in the STD clinic of a hospital in the UK, 395 women were examined for the symptoms of trichomoniasis; specimens were tested by wet mount microscopy and culture. A positive diagnosis was made on the basis of clinical symptoms plus a positive result by at least one of the laboratory tests. Swabs taken for the latex test were stored frozen and then tested blind on one occasion. The results obtained are shown below.

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Latex</th>
<th>Microscopy</th>
<th>Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>T.vaginitis positive</td>
<td>42</td>
<td>40</td>
<td>2</td>
<td>31</td>
</tr>
<tr>
<td>T.vaginitis negative</td>
<td>353</td>
<td>2</td>
<td>315</td>
<td>0</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>95%</td>
<td>74%</td>
<td>76%</td>
<td></td>
</tr>
<tr>
<td>Specificity</td>
<td>99%</td>
<td>100%</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

Prevalence
Trichomoniasis accounted for 2% (5 870/27 8081) of the diagnoses made for women attending genito-urinary medicine clinics in England in 1998 (Lamagni et al, 1999).

REFERENCES