

# Tv latex

## 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, Viikki *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

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

Store the reagents in a refrigerator at 4° to 8°C. DO NOT ALLOW TO FREEZE.

### ADDITIONAL REQUIREMENTS

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

### SPECIMEN COLLECTION

- 1) Treat all specimens as potentially infectious.
- 2) 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.
- 3) Discard the swab.
- 4) If 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

Appearance	Result
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

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## LIMITATIONS

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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.

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## EXPECTED RESULTS

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### *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.

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	Total	Latex		Microscopy		Culture	
		+	-	+	-	+	-
<i>T.vaginitis</i> positive	42	40	2	31	11	32	10
<i>T.vaginitis</i> negative	353	2	351	0	353		353
Sensitivity		95%		74%		76%	
Specificity		99%		100%		100%	

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### *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).

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## REFERENCES

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