
Candida latex

A latex agglutination test for the detection of vaginal *Candida*.

INTENDED USE

To detect *Candida spp* antigens eluted from a vaginal swab.

The kit is supplied for research use only. Not for use in diagnostic procedures. The results obtained should be considered as provisional until confirmed by an alternative method and should not be used in isolation but together with all the information available to the researcher.

INTRODUCTION

Candida vaginitis is an extremely common medical problem for women. It is important to differentiate this from other causes of vaginitis for effective treatment. Diagnosis is normally based on history and examination and should be supplemented by microscopy, culture of vaginal specimens, or both. However these two laboratory-based procedures have drawbacks. Culture takes at least 48 hours, thus providing only a retrospective diagnosis and the relatively low numbers of yeast carried by some healthy women as a normal constituent of their vaginal flora are detected. Microscopy requires instrumentation and the sensitivity is very dependent on the expertise of the microscopist.

This rapid test is designed to eliminate the need for microscopy, and can give a result in a clinical setting, whilst the patient is still present, thereby assisting in the formulation of the diagnosis.

PRINCIPLE OF THE ASSAY

The latex supplied with the kit is sensitised with goat IgG raised to a mixture of *Candida albicans* A, *Candida albicans* B and *Candida torulopsis*. For the test, latex is mixed on a slide with the eluate from a vaginal swab. Any *Candida* antigen present in the sample causes cross-linking (agglutination) of the sensitised latex. After mixing for two minutes the slide is read. Agglutination of the beads is indicative of *Candida*.

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 polyester swabs, individually wrapped
- 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 two minutes.
- 7) After 2 minutes, read the degree of agglutination obtained.

Procedural Notes

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.

Only use polyester swabs as indicated in the "additional requirements". Cotton swabs from other may give false positive reactions owing to contamination with environmental yeasts.

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

Candida 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 (1)

87 women attending GP surgeries in the UK were suspected of having vaginal candidiasis. Specimens were examined by microscopy, culture and the Candida latex test. Women with positive swabs by microscopy and culture were diagnosed as having vaginal candidiasis. The results obtained are shown below.

vaginal candidiasis	Latex test		
	<i>positive</i>	<i>negative</i>	<i>total</i>
Positive	24	6	30
Negative	0	57	57
<i>Total</i>	24	63	87
Sensitivity of latex test			80%
Specificity of latex test			100%

Performance (2)

In a second study of 137 women attending a vaginitis clinic, 77 were diagnosed as having acute candidiasis. Of these, the latex test detected 56/77 = Sensitivity 72.7%.

When the test was used on a panel of asymptomatic, healthy women a false positive rate of 5.6% was found.

BIBLIOGRAPHY

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