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A5R PS C6Y 191 502 U1S 1521 A5R G1B

(56) Documents cited

WO 82/00090 GB 1234044 GB 1248197 Journal of Clinical Microbiology Vol 22 (4) page 686-7 British Journal of Venereal Diseases Vol 58 (6) page British Journal of Venereal Diseases Vol 59 (5) page 302-5

(58) Field of search

A5R G<sub>1</sub>B Selected US specifications from IPC sub-class

- (54) Amine tester for diagnosing bacterial vaginosis and vaginitis
- (57) An amine tester for diagnosing bacterial vaginosis and vaginitis which comprises a plastic or glass receptacle 1 containing an alkaline fluid or gel 5. A cotton-wool tipped swab 3 with a sample of vaginal discharge moves freely into and from the alkaline medium. Amines present are volatilised and detected by smell via a window or opening in the side of the receptacle 2.

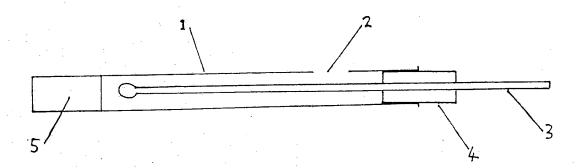


fig 1

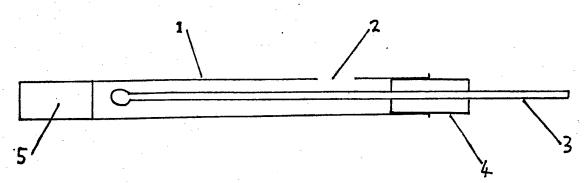


Fig 2

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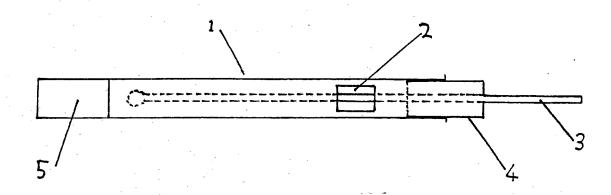
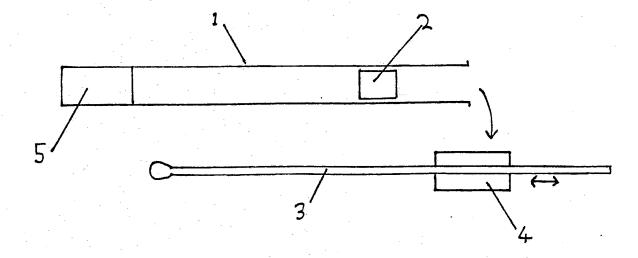
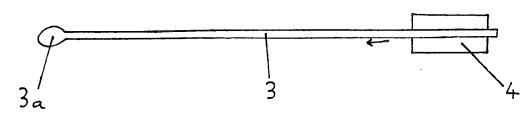


Fig 3

3





DFA

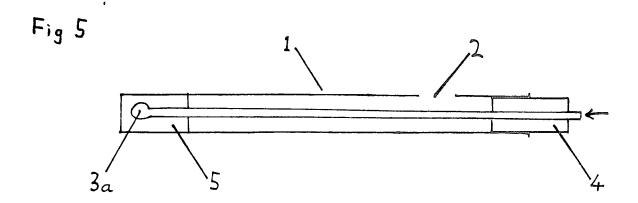
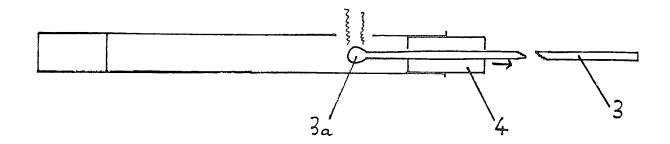


Fig 6



1.

AN AMINE TESTER FOR DIAGNOSING BACTERIAL VAGINOSIS AND VAGINITIS

This invention relates to a method of detecting amines in vaginal secretions, thus enabling the rapid diagnosis of bacterial vaginosis and certain other causes of vaginitis.

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Bacterial vaginosis is one of the commonest causes of abnormal vaginal discharge. The condition is underdiagnosed partly because of the lack of an easy and acceptable method of diagnosis. Genito-urinary medicine physicians make the diagnosis of bacterial vaginosis by examining stained preparations of vaginal discharge under the microscope and relating this to the patients symptoms. This is rarely performed by General Practitioners, Family Planning doctors, Gynaecologists and other health care workers because of the lack of time and expertise. An easier and more rapidly performed method of diagnosis is therefore required.

Bacterial vaginosis is a mixed infection with anaerobic bacteria and another bacterium, Gardnerella vaginalis, being present in varying concentrations. These bacteria produce chemical substances called amines which are present as "salts" in the vaginal discharge. The amines may be volatilised and hence freed from the "salts" by the addition of alkali. The volatilised amines have a pronounced fishy odour which is easily detected by smell. Certain other causes of vaginitis(e.g. Trichomonas vaginalis) may also produce amines and hence may be detected in the same manner.

The present invention provides an easy method of amine detection thus enabling rapid diagnosis of bacterial vaginosis and vaginitis.

According to the present invention there is provided an alkaline gel or fluid contained within a plastic or glass container which has an opening on one side. A cotton-wool tipped swab moves freely through a stopper which in turn fits onto the open end of the container. The swab can be forwarded through the stopper into the alkaline gel and withdrawn again through the stopper so that the cotton-wool tip is positioned below the opening or window in the side of the container.

A specific embodiment of the invention will now be described by way of example with reference to the accompanying drawing in which:-

Figure 1 shows a cross-sectional representation of the amine tester.

Figure 2 represents a surface view of the amine tester with the opening or window in full view.

Figure 3 shows the stopper with swab in place removed from the main body of the amine tester.

Figure 4 shows the swab fully forwarded through the stopper.

Figure 5 shows the stopper fitted onto the main body of the amine tester with the sw ab fully forwarded into the alkaline gel or fluid.

Figure 6 shows the swab withdrawn through the stopper and positioned so that the cotton-wool tip lies below the opening or window.

Referring to the drawing, the amine tester consists of a hollow plastic or glass container 1 with a small opening or window 2 on one side, as shown in figures 1 and 2. A cotton-wool tipped swab 3 moves freely through a stopper 4 which in turn fits onto the open end of the container. The stopper 4 with swab 3 in place can be easily removed from the main body 1 of the amine tester, as shown in figure 3. An alkaline gel or fluid 5 is situated at the bottom of the container.

Prior to the sampling of vaginal discharge, the swab 3 and stopper 4 are removed from the main body of the tester and the swab is forwarded fully through the stopper, as illustrated in figure 4. The tip 3a of the swab may be placed into vaginal discharge collected on a speculum at the time of clinical examination or alternatively the swab may be placed directly into the vagina by the patient. Having thus collected a sample of discharge onto the swab, the stopper with swab in place is refitted onto the open end of the container. If not already fully forwarded, the swab is advanced into the alkaline gel (figure 5 ) and then retracted through the stopper so that the cotton-wool tip 3a is positioned just below the opening 2, as shown in figure 6. Any amines present in the vaginal discharge and hence on the swab, will be volatilised by the alkaline gel and can be detected by placing the nose in close proximity to the opening.

## CLAIMS

- 1. An amine tester for diagnosing bacterial vaginosis and vaginitis comprising a receptacle containing an alkaline medium into which a moveable swab can be placed and withdrawn.
- 2. An amine tester as claimed in claim 1 wherein an opening is present in the side of the receptacle whereby volatilised amines can be detected by smell.
- 3. An amine tester as claimed in claim 1 or claim 2 wherein a moveable swab is guided into and withdrawn from the alkaline medium via the stopper of the receptacle.
- 4. An amine tester as claimed in any preceding claim, wherein the alkaline medium consists of a fluid or gel of sufficient alkalinity to volatilise any protonated amines present on the moveable swab.
- 5. An amine tester substantially as described in figures 1 to 6 of the drawings accompanying the description.