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(54) Title: METHOD FOR THE RAPID DIAGNOSIS OF TARGETS IN HUMAN BODY FLUIDS

(57) Abstract: More particularly, the present invention relates to a method for the detection of a target, e.g. pathogen in a human body fluid wherein a body fluid sample is collected with a swab member.

Method for the rapid diagnosis of targets in human body fluids

Description

Technical Field of the Invention

5 The present invention relates to a method for the detection of targets, e.g. pathogens and/or allergy-associated components in a human body fluid wherein a body fluid sample is collected with a swab member. The samples are transferred from the swab member to a sample analysis device, on which an analysis of the targets, e.g. by immunochemical or enzymatic means can
10 take place. The test result may be displayed within a short period of time and can be directly read out by the user. Further, a test kit for carrying out the method of the invention is provided.

Background of the Invention

15 Rapid, point-of-care analysis is becoming increasingly important in the diagnosis and treatment of various viral and other pathogenic microbiological agents (bacteria, others). Especially in the acute status of a infectious disease medical doctors have a need for immediate detection of
20 the causal agent for the symptoms observed.

Prior art discloses a rapid assay for HIV specific antibodies in saliva samples. A saliva sample is gained by means of a sampling stick. The saliva sample is diluted in a sample buffer and a lateral flow immunoassay is
25 dipped into the diluted saliva sample [United States Patent 5,714,341].

German Patent Nr. DE19622503 suggests to apply lateral flow immunoassays for the detection of illegal narcotics in saliva or sweat.

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Conjunctivitis, commonly known as red eye or pink eye, may be caused by several different agents including viruses, bacteria and allergens. Different etiologies require different treatments. Infectious conjunctivitis is typically contagious. Conjunctivitis is generally diagnosed clinically, by gross examination, and (during a routine eye exam) slit lamp biomicroscopy. This method does not provide information on the specific infectious agent. If specific (pathogen typing) diagnosis is necessary, swabs of the inferior fornix are sent for laboratory analysis to determine the type of pathogen. The preferred methods for laboratory analysis are cell culture with confirmatory direct immunofluorescence, ELISA or PCR. The disadvantage of this diagnostic strategy is that laboratory analysis needs typically between two and ten days, utilizes complex diagnostic equipment, and may require technical skill in both performing and interpreting results. This time period is problematic for a proper treatment of potentially infectious forms of conjunctivitis that cannot be specifically classified/connected with a certain pathogenic agent.

A publication by Uchio et al. (Ophthalmology 104 (1997), 1294-1299) discloses a method for the detection of adenovirus in eye fluid specimens. The method comprises collecting a sample of eye fluid and detecting the analyte on a paper disc by enzyme immunoabsorption. The detection, however, lacks specificity and sensitivity.

Thus, it is the objective of the invention to provide a sensitive and rapid non-invasive method for the detection of pathogens, e.g. bacterial or viral infectious agents in body fluids.

Summary of the Invention

In a first aspect, the present invention relates to a method for the detection of a target which is selected from pathogens and/or allergy-associated components in a body fluid comprising the steps:

(a) non-invasively collecting a body fluid sample with a swab member,

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(b) transferring the sample to a application zone on a sample analysis device and

(c) analysing the sample.

5 In a further aspect, the invention relates to a method for diagnosing conjunctivitis comprising the steps:

(a) non-invasively collecting an eye fluid sample with a swab member,

(b) transferring the sample to a application zone on a sample analysis device and

10 (c) analysing the sample.

In still a further aspect, the invention relates to a test kit comprising

(a) a swab member for non-invasively collecting a body fluid sample,

15 (b) a sample analysis device comprising a detection zone, wherein the detection zone contains reagents for determining the presence and/or amount of at least one target which is selected from pathogens and/or allergy-associated components.

In still a further aspect, the invention relates to a test kit comprising

20 (a) a swab member for non-invasively collecting an eye fluid sample,

(b) a sample analysis device comprising a detection zone, wherein the detection zone contains reagents for determining the presence and/or amount of at least one target which is selected from pathogens and/or allergy-associated components wherein the target is a causative agent or mediator of conjunctivitis or a plurality of such causative agents and/or mediators.

25

Description of the Drawings

30 Figure 1 shows a sample analysis device in the form of a chromatographic test strip comprising a plurality of different strip materials building an absorbent pad (1), an application zone (2), a detection zone (3) and a waste zone (4). The strip materials are arranged on an adhesive plastic backing

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(5). The absorbent pad (1) is providing for adding an elution medium in order to facilitate the transfer of the sample to the detection zone (3).

Figure 2 shows a plastic housing (6) containing the strip as shown in Figure 1. A sample application window (7) is provided for bringing a swab member into contact with the strip. The test result is displayed in the read out window (8).

Figure 3 shows a swab member or collection device for collecting a sample. The swab member comprises a plastic body (9) with a sample collection material (11) fixed on it and an opening (10) corresponding to a read out window when the swab member is operatively in contact with a test strip.

Figure 4 shows a test kit comprising a sample analysis device according to Figures 1 and 2 and a swab member according to Figure 3.

Detailed Description of preferred embodiments

The invention provides a sensitive and rapid method for the detection of targets, e.g. pathogens and/or allergy-associated components in samples collected by non-invasive means from a body fluid. The pathogens are selected from viruses, microorganisms, e.g. bacteria and parasites, e.g. amoebae or nematodes. The allergy-associated components are selected from allergens and anti-allergic components. The detection may comprise a direct detection of the target, e.g. the pathogen and/or the detection of antibodies against the target, e.g. the pathogen which are present in the fluid sample to be tested. Preferably, the method comprises a parallel determination of a plurality of targets.

The body fluid is preferably a fluid from a body surface selected from mucose membrane fluids (of the oral, nasal, vaginal, and ocular cavities) tears, secretions from glands and secretions from lesions or blisters, e.g. lesions or blisters on the skin. More preferably, the sample is selected from oral, nasal, ocular, genital and rectal fluids and secretions from skin lesions

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or blisters. Most preferably, the sample is an eye fluid. A significant advantage of the method is that results are provided within the medical consultation period, e.g. in few minutes. Preferably, the results are provided in a time period up to 20 minutes, more preferably up to 15 minutes. Also, as
5 the test is noninvasive, it poses very little risk to the patient. Thus the best available treatment can be applied on a timely basis for a specific pathogen. A further advantage over prior art methods is that only a few microliters of sample are required to perform an analysis. The sample is preferably about 0.1 μ l to about 100 μ l, more preferably about 0.2 μ l to about 20 μ l and most
10 preferably about 0.5 μ l to about 10 μ l.

The invention may be performed by means of a simple test kit. Handling of the test kit does not necessitate additional laboratory equipment, further handling of reagents or instrumentation. Another important advantage of the
15 invention described below is that the detection limit is typically 10 to 100 times lower than currently available diagnostic tests because samples do not require dilution before they are transferred to the analysis device. Therefore the disclosed method has proven to be more sensitive and accurate than methods of the prior art.

20 The invention discloses a non-invasive method for the rapid and point-of-care determination of pathogens from body fluids. The method is suitable for diagnosis in human beings and animals, e.g. pets or livestock animals. A preferred application is the detection of pathogens in eye fluid, e.g. human
25 eye fluid. In this embodiment the pathogen to be detected is a causative agent of conjunctivitis or a plurality of such causative agents. For example, the pathogen is selected from the group of adenoviruses, herpesviruses, chlamydiae, cytomegaloviruses and combinations thereof. More preferably, a plurality of pathogens are detected on a single sample analysis device. For
30 example, the sample analysis device may allow a simultaneous detection of a plurality of pathogens, particularly of at least two, of at least three, of at least four or of at least five pathogens selected from the group consisting of adenoviruses, herpesviruses, chlamydiae, cytomegaloviruses,

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pseudomonas, streptococci, haemophilus, staphylococci, amoebae, particularly Acanthamoeba and nematodes, particularly Onchocera volvulus. More preferably, the method comprises a simultaneous detection of adenoviruses, herpesviruses, chlamydiae, cytomegaloviruses and
5 Acanthamoeba.

In addition the invention provides a non-invasive method for the rapid and point-of-care determination of at least one allergy-associated component, particularly an allergen (e.g. pollen, dust, etc.) and/or an antiallergen,
10 particularly a component which is produced in the body in response to an allergenic challenge (e.g. IgE, histamine, etc.), in a body fluid as described above. More particularly, the invention relates to methods and devices for the diagnosis of allergy-associated components in eye fluid, e.g. human eye fluid. In a preferred embodiment, the determination of at least one allergy-
15 associated component may be combined with the determination of at least one pathogen as described above.

In the method of the invention, a body fluid sample is non-invasively collected with a collection device or swab member, respectively. The
20 collection step preferably comprises wiping or dabbing the swab member over a surface of the body containing body fluid to be tested. Usually, the swab member is sterile. The swab member may be dry or pretreated with a fluid before the collection step. For example, using a gentle swirling motion, a sterile swab member may be applied to the body surface or mucous
25 membrane of concern and allowed to capture any pathogens and/or allergy-associated components contained in the body fluid.

The swab member may be a part which is separate from the sample analysis device and the sample is transferred by contacting the sample analysis
30 device with the swab member under conditions wherein at least a part of the sample on the swab member is transferred to the sample analysis device. In this embodiment, the swab member is preferably contacted with a sample application zone on the analysis device from which the sample is then

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transferred to the detection zone. The contact preferably comprises fixing the swab member in a contact position with the sample analysis device in which the sample collection zone of the swab member is in direct contact with the sample application zone of the analysis device. Thus, the swab member and/or the analysis device preferably comprises fixing means for providing a fixed contact between both parts in a predetermined position. Alternatively, the swab member may be an integrated part of the sample analysis device and the transfer comprises passing at least a part of the sample on the swab member to the detection zone on the sample analysis device.

The transfer of the sample from the swab member to the detection zone on the sample analysis device is preferably a direct transfer, i.e. the transfer takes place without pretreatment of the sample on the swab member. Preferably, the transfer comprises an elution of the sample from the swab member with an elution medium, e.g. a buffer or water. The elution medium may be added from an external source or may be provided e.g. as a reservoir within the analysis device. Further, the transfer is preferably a chromatographic and/or capillary transfer of fluid to the detection zone on the sample analysis device.

In a preferred embodiment, the sample analysis device comprises a chromatographic test strip, e.g. a lateral flow test strip. The sample analysis device may comprise a sample application zone, a detection zone, optionally a waste zone, optionally a carrier backing, optionally a housing and optionally an opening for result read out. The sample analysis in the detection zone may be carried out by standard means, e.g. by an immunological or enzymatic detection method. Preferably, the detection method comprises the use of test reagents capable of specifically binding the targets, e.g. pathogens to be tested or antibodies or other receptors against these targets, e.g. pathogens and subsequent visualisation of the bound entity, e.g. by enzymatic detection or by means of direct labelling groups, such as colloidal gold.

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In an especially preferred embodiment, the swab member is placed on a lateral flow test strip. With this step the collected specimen is transferred directly on an immunochromatographic or enzymatic test strip. The test strip consists of one or several capillary active fleeces or membranes. The detection process will be either started directly with sample transfer or may require an elution medium to be applied for sample analysis. Preferably this elution medium is simple tap water. In the case of an immunochemical test strip, the chosen elution medium moves towards a detection zone and thereby passes the contact site within the collection device. The analyte is diluted by the elution medium and carried with it to the detection zone. In the detection zone the analyte is determined by qualitative and/or quantitative methods, e.g. in an immunological binding reaction.

The test strip can be made of one single chromatographic material, or preferably several capillary active materials made of the same or different materials and fixed on a carrier backing. These materials are in close contact with each other so as to form a transport path along which a liquid driven by capillary forces flows from the start zone, passing the contact site of the swab and the detection zone, towards a waste zone at the other end of the strip.

Furthermore this invention is disclosing a device and test kit for the performance of the described method.

In the method of invention, it is possible to make use of different immunological testing procedures to detect bacterial or viral constituents on one or several immunological binding reactions. In a preferred embodiment, a chromatography test strip contains:

- an application zone.
- a conjugate zone containing at least one labeled binding partner that is able to migrate with the elution medium. The binding partner is capable of specifically binding to an analyte and to a further specific reagent in the detection zone.

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- 5 - a detection zone containing a first section for the detection of a first analyte, e.g. a test line, comprising an immobilized specific binding partner for the analyte, and optionally further sections for the detections of further analytes, and at least one control section, e.g. a control line comprising an immobilized specific binding partner of an indicator substance indicating the functionality of the test kit.

10 In a preferred embodiment, the specific binding partners for the analytes in the conjugate and the detection zone are monoclonal, polyclonal or recombinant antibodies or fragments of antibodies capable of binding to a pathogen. On the other hand, the specific binding partners may also be antigens capable of binding to antibodies against a pathogen or an allergen. Other types of binding partners are bioorganic macromolecules like aptamers or receptors. The conjugate zone may be located before, within or
15 after the sample application zone, seen in the running direction of the eluent liquid. The test line(s) is(are) located after the conjugate/application zone and the control line(s) is(are) located after the test line. Together, the test line(s) and control line(s) comprise the detection zone.

20 Depending on the type of detection method, different binding partners are present in the different zones. In a sandwich immunoassay, it is preferred to have a labeled, non-immobilized analyte binding partner in the conjugate zone. The binding partner forms a complex with the analyte which is bound to the immobilized binding partner at the test line. In a preferred manner, the
25 label of the conjugate binding partner is an optically detectable label. Forming a complex at the test line concentrates and immobilizes the label and the test line gets visible for the bare eye, indicating a positive test result. Particularly preferred are direct labels, and more particularly gold labels which can be best recognized by the bare eye. Additionally, an electronically
30 photometrical read out device can be used to obtain more precise results and a semi-quantification of the analyte. Other labels may be latex, fluorophores or phosphorophores.

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In order to test ocular fluids, a sample may be collected with a sample collection device from the patient's eye by a health care professional. The sample collection device should be wiped or dabbed slightly several times between in the inferior fornix of the lower eye lid. If necessary the collection device may be wet with sterile physiological saline to decrease patient's discomfort. This procedure is well known in the ophthalmology practice as it is necessary for collecting specimens for conventional laboratory analysis. Generally the sample collection device comprises a capillary active material suitable for receiving a body fluid sample. In a preferred manner the sample collection material is made out of fibers on the basis of cellulose, polyester, rayon or calcium alginate. However, the sample collection device can also be designed as a microengineered mechanical structure containing microcapillaries and/or microchannels.

After the sample is collected, the collection device is fixed to the plastic housing containing the test strip (Figure 4) and thereby the collection applicator is slightly pressed on the application zone of the strip. The collection device remains in this position.

In an alternative embodiment, the sample is taken by a standard swab member as currently used in the physician's office or emergency rooms. This swab member is subsequently pressed into the application zone of the chromatographic test strip by means of an additional device similar to the sample collection unit.

In another preferred embodiment, the sample is taken by a swab member and the sample collection devices is pressed for only a short time into the application zone of the chromatographic test strip. A short period of time preferably means a time up to 20 seconds, particularly between 0.1 and 10 seconds. A transfer of the sample is happening within the contact period.

In the next step, an elution medium is applied by dipping the absorbent pad into the chromatographic liquid. The absorbent pad is made of a particularly

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well-absorbing material which delivers the liquid for the immunochemical or enzymatic reactions. Preferred elution media are water or buffer solutions that are conventionally used in immunoassays.

5 Alternatively the elution medium is contained in a reservoir which may be integrated within the analysis device, e.g. as an ampoule or a blister. The reservoir may be opened by fixing the swab member or sample collection device on the detection part of the device or by additional means.

10 After a time period of up to 15 minutes, preferably within two to five minutes, the result can be read out in the detection zone. The result is considered positive when at least a partial area of the test line and the control line shows a color change.

15 **Example**

Test kit for the detection of adenovirus from patient's eye swab

The structure of a test strip is depicted in Figure 1.

20

The polyester fleece for the absorbent pad was manufactured by Binzer, Hatzfeld, Federal Republic of Germany. The fleece is a polyester fleece reinforced with 10% curalon. The thickness ranges 1 and 2 mm, the absorbance capacity is 1800 ml/m².

25

The application/conjugate zone consists of 80 parts polyester and 20 parts viscous staple fibers at a thickness of 0.32 mm and an absorbing capacity of 500 ml/m². The fleece is impregnated with the following solutions and then dried: 100 mmol/l HEPES Buffer, pH 7.5, 100 mol/l NaCl, conjugate of gold particles and anti-Hexon antibodies at a concentration that has an optical density of 10 at 520 nm. Hexon is a protein that is common in the capsid of human adenoviruses. The gold sol was manufactured according to standard procedures (Fres. Nature Vol. 241, p. 20-22, 1973). Conjugation with the

30

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antibody was carried out according to prior art procedure (J. Immunol. Meth. Vol. 34, p. 11-31, 1980). The sample application takes place in the application/conjugate zone.

5 The detection zone consists out of a nitrocellulose (NC) membrane with a nominal pore size of 8 μm and a thickness of 100 μm produced by Schleicher & Schuell, Germany. The test line contains a Hexon specific antibody (not labeled) which is specific for a different epitope than the antibody immobilized on the gold. The control contains the same antibody
10 than the test line and binds any excess of Hexon specific gold. The control line will appear in any case even if Hexon is not present indicating that the test worked correctly.

The chromatographic materials are in communication with each other in
15 order to create a fluid pathway.

A sample collection device is depicted in Figure 3. The sample collection material may consist of bibulous material such as highly purified cotton fibers which are fixed to the plastic device by ultrasonic welding. Alternative
20 materials may be polyester, rayon, polyamide or other fibrous polymeric materials.

A test kit for the detection of Adenovirus antigen (as described in the example above) was used in the Emergency Room of an Ophthalmologic
25 Hospital to diagnose the clinical picture of a "pink" eye. From every patient which has been tested with the test kit a second sample was taken and analysed in the laboratory.

The laboratory reference method used in this study was a combination of
30 cell culture and immunfluorescence (IF) detection (Rodrigues et al., Ophthalmology, 1979 Mar;86(3):452-64) which is the current "laboratory gold standard" for determining the presence of adenovirus in human ocular fluid.

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Within the testing period the following results have been achieved:

		Cell Culture/IF		
		+	-	
Adeno test kit	+	5	2	
	-	0	21	

5 These preliminary results are equivalent to a diagnostic sensitivity of 100 % and a diagnostic specificity of 91 %. These values are superior to diagnostic characteristics of other state of the art point-of-care devices.

Claims

1. A method for the detection of a target which is selected from pathogens
5 and/or allergy-associated components in a body fluid comprising the steps:
(a) non-invasively collecting a body fluid sample with a swab member,
(b) transferring the sample to a detection zone on a sample analysis
device and
10 (c) analysing the sample.
2. The method of claim 1 wherein the pathogen is selected from viruses,
microorganisms and parasites.
- 15 3. The method of claim 1 wherein the allergy-associated component is
selected from allergens and antiallergens.
4. The method of claim 1 wherein the body fluid is fluid from a body surface
selected from mucous membrane fluids, secretions from glands and
20 secretions from lesions or blisters.
5. The method of claim 4 wherein the sample is selected from oral, nasal,
ocular, genital, and rectal fluids, and secretions from skin lesions or
blisters.
- 25 6. The method of claim 5 wherein the sample is an eye fluid.
7. The method of claim 6 wherein the target is a pathogen which is a
causative agent of conjunctivitis or a plurality of such causative agents.
- 30 8. The method of claim 5 wherein the pathogen is selected from the group
consisting of adenoviruses, herpesviruses, chlamydiae, cytomegalo-
viruses, pseudomonas, streptococci, haemophilus, staphylococci,

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amoebae and combinations thereof.

5 9. The method of claim 6 wherein the target is an allergy-associated component which is a causative agent or a mediator of conjunctivitis or a plurality of such causative agents and/or mediators.

10. The method of claim 1 or 6, wherein the target comprises at least one pathogen and at least one allergy-associated component.

10 11. The method of claim 1 wherein the sample is about 0.1 μ l to about 100 μ l.

12. The method of claim 11 wherein the sample is about 0.5 μ l to about 10 μ l.

15 13. The method of claim 1 wherein the collecting step (a) comprises wiping or dabbing the swab member over a surface of the body containing body fluid to be tested.

20 14. The method of claim 1 wherein the swab member is sterile.

25 15. The method of claim 1 wherein the swab member is a part separate from the sample analysis device and the transferring step (b) comprises contacting the sample analysis device with the swab member under conditions wherein at least a part of the sample on the swab member is transferred to the sample analysis device.

30 16. The method of claim 1 wherein the swab member is an integrated part of the sample analysis device and the transferring step (b) comprises passing at least a part of the sample on the swab member to the detection zone on the sample analysis device.

17. The method of claim 1 wherein the transferring step (b) comprises fixing the swab member in a contact position with the sample analysis device.
18. The method of claim 1 wherein the transferring step (b) comprises an
5 elution of the sample from the swab member with an elution medium, e.g. a buffer or water.
19. The method of claim 18 wherein the elution medium is added from an external source or is provided within the analysis device.
10
20. The method of claim 1 wherein the sample analysis device comprises a chromatographic test strip.
21. The method of claim 1 wherein the sample analysis device comprises:
15 (i) a sample application zone,
(ii) a detection zone,
(iii) optionally a waste zone and
(iv) optionally a carrier backing.
22. The method of claim 21 wherein the sample analysis device further
20 comprises at least one of:
(v) a housing, and
(vi) an opening for result read out.
23. A method of claim 1 wherein the analysing step (c) comprises an
25 immunological or enzymatic detection.
24. A method for diagnosing conjunctivitis comprising the steps:
(a) non-invasively collecting an eye fluid sample with a swab member,
30 (b) transferring the sample to a detection zone on a sample analysis device and
(c) analysing the sample.

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25. The method of claim 24 wherein the sample is analysed for the presence of a pathogen which is a causative agent of conjunctivitis or a plurality of such causative agents.
- 5 26. The method of claim 25 wherein the sample is analysed for the presence of a pathogen selected from the group consisting of adenoviruses, herpesviruses, chlamydiae, cytomegaloviruses, amoebae and combinations thereof.
- 10 27. The method of claim 24 wherein the sample is analysed for the presence of an allergy-associated component which is a causative agent or a mediator of conjunctivitis or a plurality of such causative agents and/or mediators.
- 15 28. The method of claim 24 wherein the sample is analysed for the presence of a pathogen which is a causative agent of conjunctivitis or a plurality of such causative agents and at least one allergy-associated component which is a causative agent or a mediator of conjunctivitis or a plurality of such causative agents and/or mediators.
- 20 29. A test kit comprising
- (a) a swab member for non-invasively collecting a body fluid sample,
 - (b) a sample analysis device comprising a detection zone, wherein the detection zone contains reagents for determining the presence
- 25 and/or amount of at least one target which is selected from pathogens and/or allergy-associated components.
- 30 30. A test kit comprising
- (a) a swab member for non-invasively collecting an eye fluid sample,
 - (b) a sample analysis device comprising a detection zone, wherein the detection zone contains reagents for determining the presence
- and/or amount of at least one target which is selected from pathogens and/or allergy-associated components wherein the

pathogen is a causative agent of conjunctivitis or a plurality of such causative agents and wherein an allergy-associated component which is a causative agent or a mediator of conjunctivitis or a plurality of such causative agents and/or mediators.

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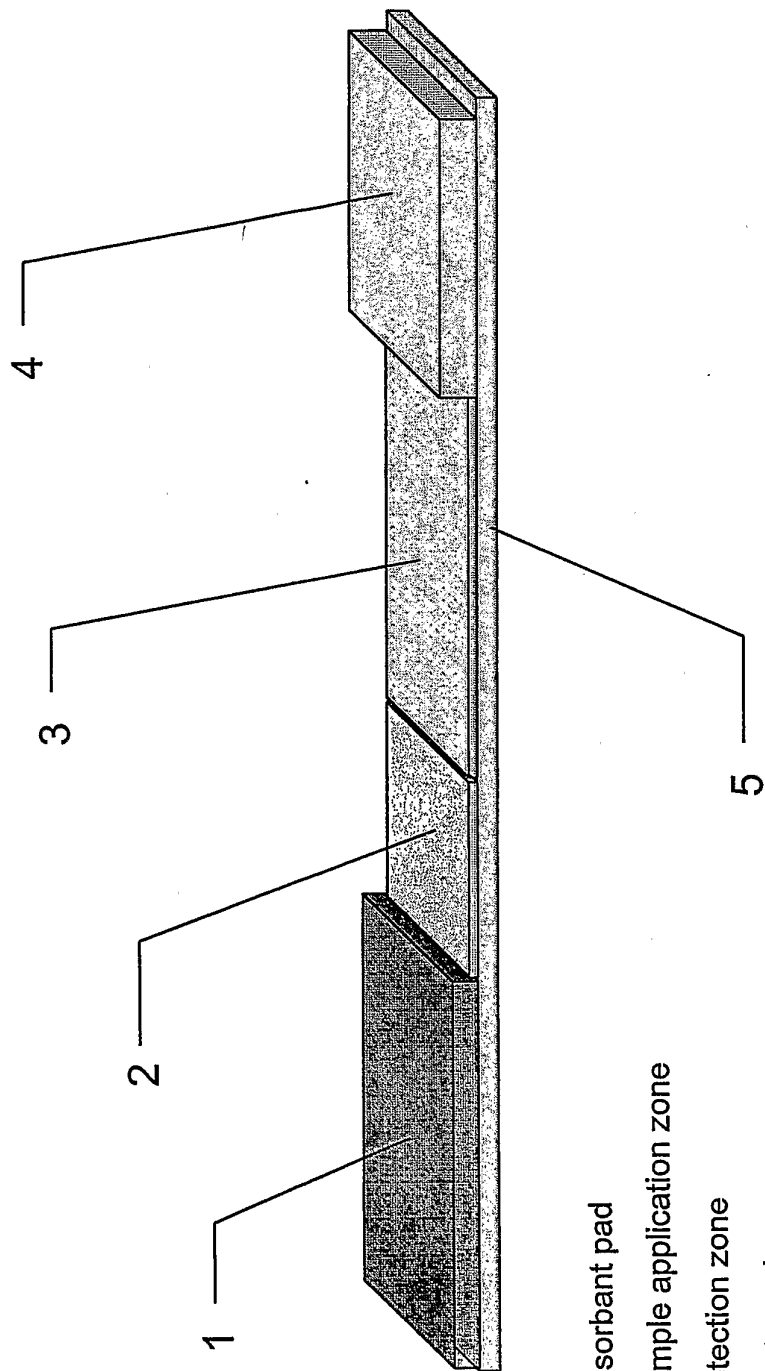
31. The test kit of claim 30 wherein the pathogen is selected from the group consisting of adenoviruses, herpesviruses, chlamydiae, cytomegaloviruses, streptococci, pseudomonas, staphylococci, haemophilas, amoebae and combinations thereof.

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32. A test kit of claim 30 wherein the allergy-associated component is selected from the groups of allergens or antiallergens.

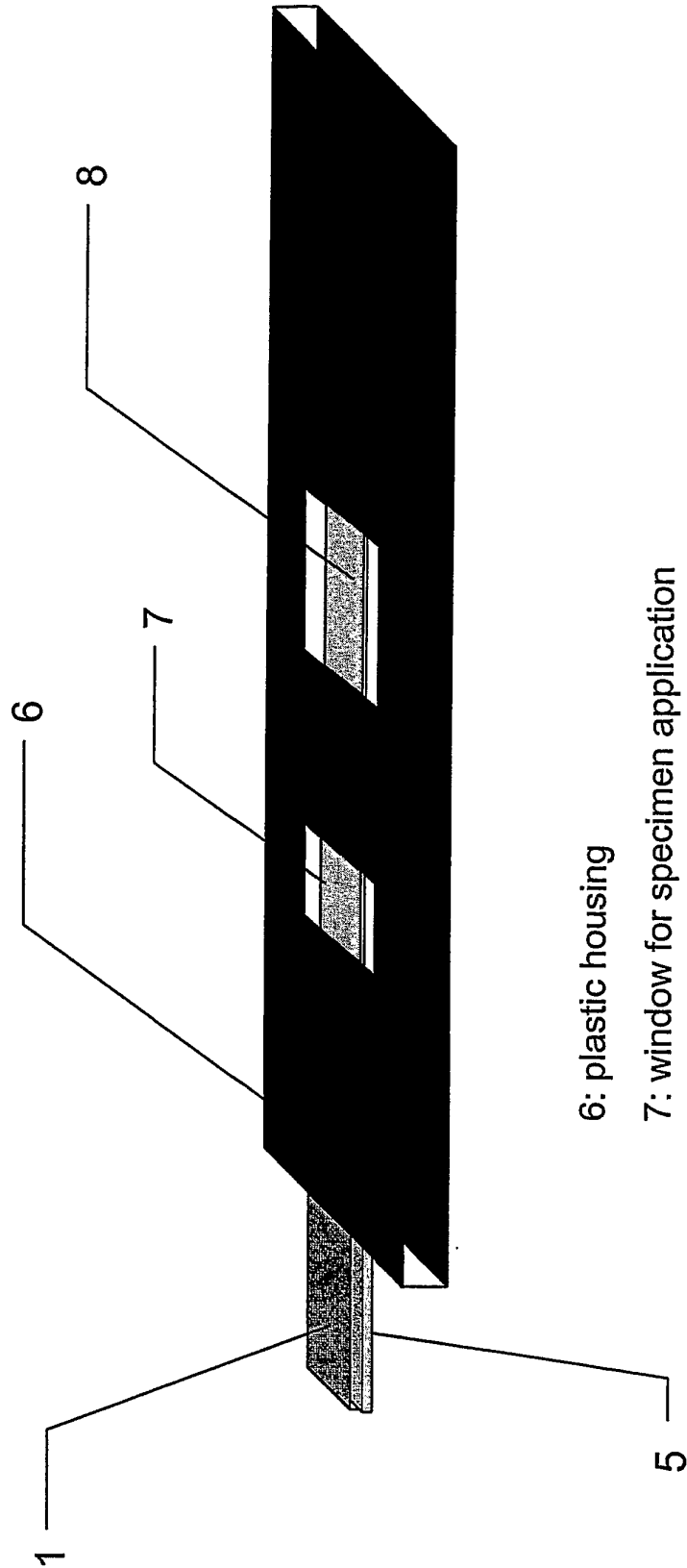
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Fig. 1



- 1: absorbant pad
- 2: sample application zone
- 3: detection zone
- 4: waste pad
- 5: carrier backing

Fig. 2



6: plastic housing

7: window for specimen application

8: window for result read out

Fig. 3

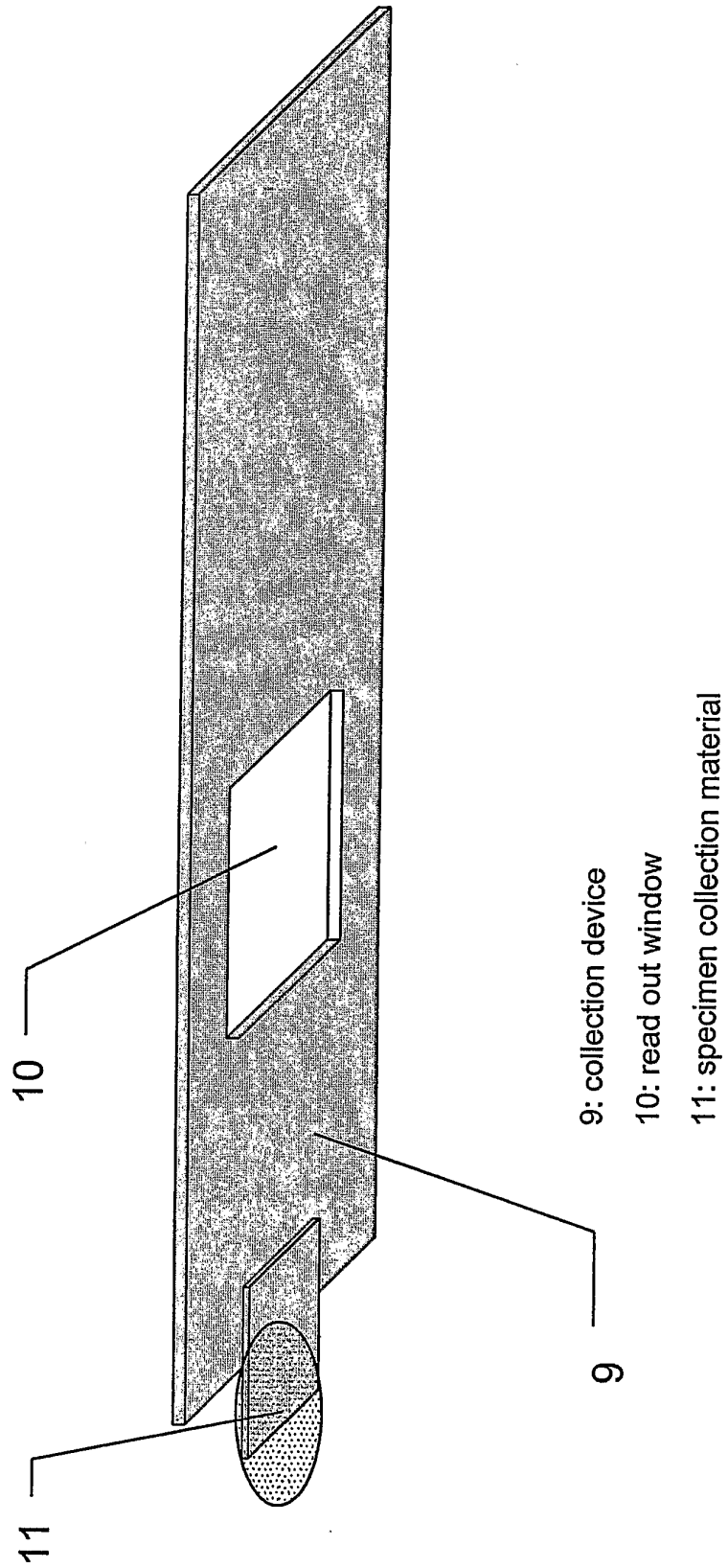


Fig. 4

