

Description

TECHNICAL FIELD

The present invention relates to a novel disposable testing device for skin testing human subjects for immediate hypersensitivity (allergic) or delayed hypersensitivity (cell-mediated) immune reactions. The testing device comprises one or more separate needles each in combination with a small reservoir of antigen test reagent in a strip, sheet or patch format.

BACKGROUND ART

Skin testing for allergy has conventionally been performed by putting a small drop of the suspected allergen on the back or the forearm of the subject and then exposing the underlying tissue by pricking the skin with a needle. An inflammatory response occurring within about 10-15 minutes indicates allergy to the suspected substance. Commonly, allergy to between 5 and 20 suspected substances may be tested in this way at any one time. This test commonly called the "skin-prick test", has remained essentially unchanged in its design since it was first introduced over 70 years ago. The method, still widely used by specialists in the field of allergic disease, is not as popular with general practitioners since it takes up valuable consultation time in the surgery, is uncomfortable for the subject and is costly to provide, especially if it is only done occasionally. Prick testing also requires some technical skill and is quite labour intensive. However, it is the most reliable method of those used to diagnose allergy and gives a result within 10 to 30 minutes of starting the test.

In a similar manner, testing for cell-mediated immunity may be performed by either injecting a small quantity of antigen under the surface of the skin using a needle and syringe or by puncturing the skin and allowing antigen solution to passively infiltrate the puncture site. Such a testing device is known for example from document US-A-2 974 787. The skin reaction, which is an index of the patient's ability to mount an immune response to the test antigen, is usually measured many hours to several days later.

In the last 15 years, an alternative method of testing for allergy using an *in vitro* assay has been introduced. The assay requires the use of serum, the reagents used are costly, assays are only performed by specialist pathology laboratories, and several days may elapse before a result is known. Because of the cost, the number of tests which can be performed is often limited to 4 suspected allergens. Only in rare circumstances do such *in vitro* assays offer any advantages over skin tests, for

example where the skin of a patient with eczema is highly inflamed, or when the patient is taking a particular drug which interferes with the skin test response. The correlation between results from skin prick tests and *in vitro* tests is only about 70% and there are several reasons why such *in vitro* tests sometimes produce false negative and false positive reactions. Despite this, these assays are very popular (well over 100 million have been performed internationally), and despite several more companies entering the field recently and the introduction of minor changes in design and/or procedure, no major improvements have been made.

It would be desirable to adapt the skin test to make it more available and acceptable to both patient and physician, and to improve the speed and reliability of the diagnosis of immune-mediated responses. Reduction of the costs of both tests would also, of course, be welcome.

An object of the present invention is to refine the existing methods of skin testing for the diagnosis of both immediate and delayed immune reactions. The procedure when the device of the present invention is employed does not require any specialized technical expertise and is sufficiently simple to be used, without specialised training, by general practitioners (GPs). It is also more acceptable to patients than when conducted according to prior art techniques.

DISCLOSURE OF THE INVENTION

In accordance with the present invention there is provided a medical testing device comprising a needle able to penetrate the skin of a patient to introduce a test reagent under the skin of the patient to perform a test, having a hollow body which provides a sealed chamber enclosing the needle and a test reagent, said hollow body being manipulable by a user to reduce the volume of said chamber and to move the needle to extend beyond said body to penetrate to a predetermined depth the skin of the patient against which the device is held for the test and characterised in that said needle has a plurality of points or is fluted or grooved to enhance flow of the reagent to the skin.

Generally, the needle will be adapted to penetrate the skin about 1 to 2mm and may have a plurality of points or be fluted or grooved to enhance flow of the reagent to the skin. To limit the depth to which the needle penetrates the skin, it may be fitted with a collar or be of enlarged cross-section beyond its point or points.

In general, the reagent will be an antigen. However, other components or other reactive compounds may be included in the reagent. Different substances, or dilutions of the same substance with or without control substances such as the vehicle

alone, or standard solutions, such as a histamine solution, may be tested concurrently at different skin sites, when the medical testing devices of the invention are incorporated into strips or sheets. Individual patches, strips or sheets may be manufactured as part of a large sheet and separated into single patches, strips or sheets prior to use. In a format where multiple tests are involved, sufficient distance would be allowed between individual antigen/needle units to avoid one test substance interfering with an adjacent test substance. For example, in skin testing for immediate hypersensitivity, a minimum distance between units would be about 20mm.

The reagent may be conveniently contained within a capsule, reservoir or porous matrix or may contain an additive to form a paste or gel.

It is preferred to include a transparent layer in the device of the invention to both identify the reagent and to record details of the test. Thus, the transparent layer may be printed with identifiers of both the subject tested and of the test substances employed. It is preferably of a material which can be written on and has calibrations to enable the size of the skin reaction to be measured. It is preferably coated on the underside with a low-tack adhesive to secure the device to the skin in use. The adhesive also permits the transparent strip to be affixed to the patient's medical records.

After placement of the strip or patch on the skin, light direct finger pressure on each unit both releases the solution containing the antigen and causes the needle to penetrate the skin to a limited depth insufficient to draw blood. The antigen solution then infiltrates the site of the needle puncture causing a limited exposure of the intradermal or subcutaneous tissues to the antigen. The immunological response to such exposure is determined after the appropriate time, depending on the immune response involved.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a cross section of the skin test device in accordance with a first embodiment of the invention.

Figure 2 shows a second embodiment in cross section.

Figure 3 shows an alternate arrangement of a needle unit applicable to the invention and illustrated in a third embodiment.

Figure 4 shows a cross section of fourth embodiment of the invention.

Figure 5 shows a fifth embodiment in cross section.

Figure 6 shows various designs of needle points which can be used in the test devices of the invention.

Figure 7 shows the view from above of patch-like embodiments of the invention.

Figure 8 shows a view from above of the arrangement of a test device of the invention including a number of antigen testing units

Figure 9 is a side view of the embodiment of Figure 8.

Figure 10 is an exploded enlarged view of one of the antigen testing units of Figures 7, 8 and 9.

Figure 11 shows a view from above of the transparent layer of the test device of Figures 8 and 9.

BEST MODES FOR CARRYING OUT THE INVENTION

The following description relates to preferred embodiments of the invention as illustrated in the accompanying drawings and should not be construed as limiting on the claims.

The skin test device (17) of Figure 1 is made up of an antigen support layer (12) containing one or more (1 illustrated) capsules (2) containing antigen solution (1). Disposed to one side of the layer (12) is a compressible layer (11) and a cover (14). The layer (11) could be made of foam plastic, rubber or be of an air cell construction, and is adhered to support (12) and cover (14) is adhered to layer (11) by means of high-tack adhesive (15). The compressible layer (11) keeps capsule (2) and needle (3) separate when the device (17) is not in use, and keeps the needle above the plane of the patient's skin when uncompressed. It can also provide a physical mattress to house the capsule (2) and the needle (3). The cover (14) incorporates a needle (3) and ensures sterility and adds rigidity. The cover may be made of a material such as plastic, impregnated paper or metal foil. Its upper surface may be colour-coded and/or printed with the name(s) of the antigen(s) and with instructions for use of the device. Alternatively, it may be decorated to render the device more acceptable to children. The needle (3) which ruptures the capsule (2) prior to the needle penetrating the skin is provided with a collar (7) to restrict the depth of penetration of needle (3) into the skin, preferably to about 1 to 2mm, when the device (17) is in use. A transparent layer (10) and bottom cover (9) are disposed on the side of the support layer (12) opposite the needle (3) with a hole (18) in line with the needle (3). The bottom layer (9), seals, protects and ensures the sterility of the unit. It is removed prior to the start of the test. The removal of this layer exposes a layer of low-tack adhesive (16), shown bonded to the transparent layer (10). The purpose of the adhesive is to temporarily and lightly hold the device to the surface of the skin. The adhesive concerned should not be strong enough

to cause discomfort when the device is removed from the skin. Layer (10) is also secured to support layer (12) by means of low-tack adhesive (16). The layer could be made of plastic, cellulose, nylon or other transparent material which can be written on to outline the extent of a skin reaction and to record details of the subject - for example the name, unit number and date. This layer could also be printed with scale markings in mm to enable a skin reaction such as a wheal or flare response to be measured. Low-tack adhesive (16) permits the upper layers to be removed to allow the skin reaction to be viewed through the remaining transparent layer. When the skin reaction has fully developed, it can be measured from the scale or the outline of the reaction can be marked on the transparent layer which may then be removed and kept for record purposes.

In the embodiment of Figure 2, needle guides (8) are built into top layer (14). The needle (3) is adapted to fit guide (8) tightly by means of collar (7). Needle guide (8) also locates capsule (2) of antigen solution (1) between needle (3) and hole (18) in transparent layer (10). The device is sealed by bottom cover (9). Both top cover (14) and bottom cover (9) are affixed to transparent layer (10) by low-tack adhesive (16).

Figures 3 and 3a illustrate a further embodiment of the invention where as in the embodiments of Figure 1 and 2, a transparent layer (10) is bound to bottom cover (9) and the balance of the device by low-tack adhesive (16). In the embodiment of Figures 3 and 3a compressive layers (11) are provided above and below a support layer (13) which holds modified needle (3') and locates needle (3') above hole (18) in transparent layer (10). Compressive layer (11) away from the transparent layer (10) is thicker than the compressive layer (11) adjacent transparent layer (10) and carries capsule (2) of antigen solution (1) and locates it above needle (3') and hole (18). Needle (3') carries barbs (4) opposite the needle point which enable capsule (2) to be pierced to release the antigen solution (1). The device has a top cover (14). Layers (14) and (11) (thick), (11) (thick) and (13), and (13) and (11) (thin) are bound together with high-tack adhesive (15).

In the embodiment of Figure 4, the antigen solution (1) is contained in a reservoir (5) so shaped to correspond with a hub (19) in needle (3). Needle (3) has a hollow shaft (20) through which the antigen solution (1) can flow from the reservoir (5) to the skin test site. Needle (3) and reservoir (5) are surrounded by compressible layer (11) and covered by a top covering layer (14). The needle and reservoir are aligned over a hole (18) in transparent layer (10) which is bound to the compressible layer (11) and to bottom cover layer (9) by low-tack adhesive (16).

Figure 5 illustrates an embodiment of the invention similar to that described in Figure 1. In the device of Figure 5, a compressible porous matrix (6), such as glass fibre or plastic foam, containing the antigen solution replaces the capsule (2) and collar (7) of Figure 1. As the capsule (1) is absent, the support layer (12) of Figure 1 is not required in the embodiment described in Figure 5.

Figure 6 shows alternative needle configurations which may be used in the skin test device, to enhance the delivery of antigen to the skin. (a) depicts a needle with a grooved shaft, (b) depicts a needle with twin points, (c) depicts a needle with multiple points

Figure 7 depicts a preferred embodiment of the individual skin test units containing the same single antigen solution arranged in a sheet form, so that the single units can be individually separated.

The units of Figure 7 are illustrated in more detail in Figure 10. The antigen solution (1) is contained within a reservoir into which the needle (3) projects. The top covering layer (14) which could be made of a flexible material such as an ionomer resin, e.g., Surlyn (Registered Trade Mark) is domed at (14') to provide the space which the needle (3) and reservoir (5) occupy. A transparent layer (10) is provided adjacent the reservoir and has a hole (18) to permit the antigen solution to reach the skin when the device is in use. The device is sealed with a bottom layer (9).

Figure 8 illustrates a preferred embodiment of the invention where multiple antigen tests can be performed at the same time. A side view of the embodiment of Figure 8 is illustrated in Figure 9.

Figure 11 shows greater detail of the transparent layer shown in the previous figures, for the format of the skin test units shown in Figure 8. The embodiment illustrated is marked with a callibrated scale, enabling a skin reaction response to be recorded on this layer along with details of the subject or patient and test date.

The volume of antigen associated with each unit is sufficient for a single test. The aqueous solution of the antigen may contain components other than the antigen itself. Such components may be added, for example, to increase the stability of the antigen, reduce the non-specific binding of the antigen to surfaces, maintain solubility, reduce evaporation, protect against contamination by microorganisms or as a buffer. Examples of such added substances include ionic salts, non-reactive carrier proteins such as human serum albumin, non-ionic detergents, glycerol and anti-bacterial and anti-fungal agents.

The needle is to be constructed of a material to ensure sharpness, allow sterilisation and be easily manufactured. Some examples of such materials may be hard plastic, steel and nylon. To improve

the flow of the antigen solution into the puncture site, the needle penetrates the skin with several points and/or contains features, such as fluting or grooves.

The application of this design may not be restricted to *in vivo* testing of the immune response to antigens. Another application of this device could be the delivery of biological or non-biological material into the skin for purposes other than for diagnosis. Such material could be of microbiological origin to function as a vaccine, immunoreactive material to stimulate an immune response, or a therapeutic drug or other substance. This type of application may require minor modification to the needle. For example, the needle in Figure 4 would have the outlet lower down the shaft towards the point to force more antigen into the puncture site rather than as shown, where the needle is designed to flood the site allowing passive infiltration.

It may also be preferred to incorporate into the layer in contact with the skin, as well as the weak adhesive, an absorbent band between antigen reservoir sites, so that excess antigen solution is not forced from one test site to an adjacent site giving rise to false positive reactions.

It may also be preferred to incorporate into the layer in contact with the skin a mild, topical, local anaesthetic which would not interfere with the skin test response, but would reduce the itching and minor discomfort associated with an immediate skin test reaction.

Gamma irradiation may be used for sterilisation of the devices of the invention.

INDUSTRIAL APPLICABILITY

Medical devices of the invention enable allergy and other skin tests to be readily performed by medical and paramedical personnel to provide a quick result and permanent record.

Claims

1. A medical testing device comprising a needle (3) able to penetrate the skin of a patient to introduce a test reagent under the skin of the patient to perform a test, having a hollow body (11) which provides a sealed chamber enclosing the needle and a test reagent, said hollow body being manipulable by a user to reduce the volume of said chamber and to move the needle to extend beyond said body to penetrate to a predetermined depth the skin of the patient against which the device is held for the test and characterised in that said needle has a plurality of points or is fluted or grooved to enhance flow of the reagent to the skin.

2. A device as claimed in claim 1, characterised in that said predetermined depth is about 1 to 2 mm.
3. A device as claimed in claim 1 or 2, characterised in that the cross-section of the needle is enlarged to prevent penetration of the skin beyond the predetermined depth.
4. A device as claimed in any one of claims 1 to 3, characterised in that the test reagent is an antigen.
5. A device as claimed in claim 4, characterised in that the test reagent further contains a stabiliser, preservative or buffer.
6. A device as claimed in any one of claims 1 to 5, characterised in that the test reagent is contained within a capsule or a reservoir.
7. A device as claimed in any one of claims 1 to 6, characterised in that the test reagent is contained within a porous matrix.
8. A device as claimed in any one of claims 1 to 7, characterised in that the test reagent contains an additive to form a paste or gel.
9. A device as claimed in any one of claims 1 to 8, further characterised by comprising a top layer deformable to reduce the volume of said chamber.
10. A device as claimed in any one of claims 1 to 9, further characterised by comprising at least one collapsible layer which permits the volume of said chamber to be reduced on application of pressure to said device.
11. A device as claimed in any one of claims 1 to 10, further characterised by comprising a transparent layer which, in use, is located against the skin.
12. A device as claimed in claim 11, characterised in that the transparent layer is capable of being written on so that the result of the test can be recorded thereon.
13. A device as claimed in claim 11 or 12, characterised in that the transparent layer is calibrated to enable the extent of the skin reaction to be measured.
14. A plurality of the devices as claimed in any one of claims 1 to 13, characterised by being in the form of a strip or sheet, each said



the flow of the antigen solution into the puncture site, the needle penetrates the skin with several points and/or contains features, such as fluting or grooves.

The application of this design may not be restricted to *in vivo* testing of the immune response to antigens. Another application of this device could be the delivery of biological or non-biological material into the skin for purposes other than for diagnosis. Such material could be of microbiological origin to function as a vaccine, immunoreactive material to stimulate an immune response, or a therapeutic drug or other substance. This type of application may require minor modification to the needle. For example, the needle in Figure 4 would have the outlet lower down the shaft towards the point to force more antigen into the puncture site rather than as shown, where the needle is designed to flood the site allowing passive infiltration.

It may also be preferred to incorporate into the layer in contact with the skin, as well as the weak adhesive, an absorbent band between antigen reservoir sites, so that excess antigen solution is not forced from one test site to an adjacent site giving rise to false positive reactions.

It may also be preferred to incorporate into the layer in contact with the skin a mild, topical, local anaesthetic which would not interfere with the skin test response, but would reduce the itching and minor discomfort associated with an immediate skin test reaction.

Gamma irradiation may be used for sterilisation of the devices of the invention.

INDUSTRIAL APPLICABILITY

Medical devices of the invention enable allergy and other skin tests to be readily performed by medical and paramedical personnel to provide a quick result and permanent record.

Claims

1. A medical testing device comprising a needle (3) able to penetrate the skin of a patient to introduce a test reagent under the skin of the patient to perform a test, having a hollow body (11) which provides a sealed chamber enclosing the needle and a test reagent, said hollow body being manipulable by a user to reduce the volume of said chamber and to move the needle to extend beyond said body to penetrate to a predetermined depth the skin of the patient against which the device is held for the test and characterised in that said needle has a plurality of points or is fluted or grooved to enhance flow of the reagent to the skin.
2. A device as claimed in claim 1, characterised in that said predetermined depth is about 1 to 2 mm.
3. A device as claimed in claim 1 or 2, characterised in that the cross-section of the needle is enlarged to prevent penetration of the skin beyond the predetermined depth.
4. A device as claimed in any one of claims 1 to 3, characterised in that the test reagent is an antigen.
5. A device as claimed in claim 4, characterised in that the test reagent further contains a stabiliser, preservative or buffer.
6. A device as claimed in any one of claims 1 to 5, characterised in that the test reagent is contained within a capsule or a reservoir.
7. A device as claimed in any one of claims 1 to 6, characterised in that the test reagent is contained within a porous matrix.
8. A device as claimed in any one of claims 1 to 7, characterised in that the test reagent contains an additive to form a paste or gel.
9. A device as claimed in any one of claims 1 to 8, further characterised by comprising a top layer deformable to reduce the volume of said chamber.
10. A device as claimed in any one of claims 1 to 9, further characterised by comprising at least one collapsible layer which permits the volume of said chamber to be reduced on application of pressure to said device.
11. A device as claimed in any one of claims 1 to 10, further characterised by comprising a transparent layer which, in use, is located against the skin.
12. A device as claimed in claim 11, characterised in that the transparent layer is capable of being written on so that the result of the test can be recorded thereon.
13. A device as claimed in claim 11 or 12, characterised in that the transparent layer is calibrated to enable the extent of the skin reaction to be measured.
14. A plurality of the devices as claimed in any one of claims 1 to 13, characterised by being in the form of a strip or sheet, each said

device containing a different réagent.

Patentansprüche

1. Medizinische Testvorrichtung mit einer Nadel (3), welche in die Haut eines Patienten eindringen kann, um ein Testreagens unter die Haut des Patienten einzuführen und einen Test durchzuführen, und mit einem Hohlkörper (11), der eine dichte Kammer aufweist, welche die Nadel und ein Testreagens einschließt, wobei der Hohlkörper durch einen Benutzer manipulierbar ist, um das Volumen der genannten Kammer zu verkleinern und die Nadel zu bewegen, damit sie sich über den genannten Körper hinaus erstreckt und bis zu einer vorgegebenen Tiefe in die Haut des Patienten eindringt, gegen welche die Vorrichtung für den Test gehalten wird, dadurch gekennzeichnet, daß die Nadel eine Mehrzahl von Spitzen aufweist oder geriffelt oder gekerbt ist, um den Fluß des Reagens in die Haut zu verbessern. 5 10 15 20
2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die genannte vorgegebene Tiefe etwa 1 bis 2 mm beträgt. 25
3. Vorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß der Querschnitt der Nadel vergrößert ist, um ein Eindringen in die Haut über die vorgegebene Tiefe hinaus zu verhindern. 30
4. Vorrichtung nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß das Testreagens ein Antigen ist. 35
5. Vorrichtung nach Anspruch 4, dadurch gekennzeichnet, daß das Testreagens ferner einen Stabilisator, ein Konservierungsmittel oder einen Puffer enthält. 40
6. Vorrichtung nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß das Testreagens in einer Kapsel oder einem Reservoir enthalten ist. 45
7. Vorrichtung nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß das Testreagens in einer porösen Matrix enthalten ist. 50
8. Vorrichtung nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß das Testreagens ein Additiv enthält, um eine Paste oder ein Gel zu bilden. 55
9. Vorrichtung nach einem der Ansprüche 1 bis 8, ferner gekennzeichnet durch eine Deck-

schicht, die verformbar ist, um das Volumen der genannten Kammer zu vermindern.

10. Vorrichtung nach einem der Ansprüche 1 bis 9, ferner gekennzeichnet durch mindestens eine zusammenlegbare Schicht, die es erlaubt, das Volumen der genannten Kammer beim Anlegen eines Drucks an die Vorrichtung zu verkleinern.
11. Vorrichtung nach einem der Ansprüche 1 bis 10, ferner gekennzeichnet durch eine durchsichtige Schicht, die beim Gebrauch auf der Haut angeordnet wird.
12. Vorrichtung nach Anspruch 11, dadurch gekennzeichnet, daß die durchsichtige Schicht beschreibbar ist, so daß das Testergebnis darauf aufgezeichnet werden kann.
13. Vorrichtung nach Anspruch 11 oder 12, dadurch gekennzeichnet, daß die durchsichtige Schicht kalibriert ist, damit das Ausmaß der Hautreaktion gemessen werden kann.
14. Mehrzahl von Vorrichtungen nach einem der Ansprüche 1 bis 13, dadurch gekennzeichnet, daß sie in Form eines Streifens oder einer Platte vorliegen, wobei jede Vorrichtung ein anderes Reagens enthält.

Revendications

1. Dispositif de test médical comprenant une aiguille (3) capable de pénétrer dans la peau d'un patient pour introduire un réactif de test sous la peau du patient pour réaliser un test, ayant un corps creux (11), qui fournit une chambre scellée renfermant l'aiguille et un réactif de test, ledit corps creux étant manipulable par un utilisateur en vue de réduire le volume de ladite chambre et en vue de déplacer l'aiguille pour la pousser au-delà dudit corps afin de pénétrer à une profondeur prédéterminée dans la peau du patient contre laquelle le dispositif est maintenu pendant le test, et caractérisé en ce que ladite aiguille possède une pluralité de pointes, ou bien est nervurée ou rainurée pour favoriser l'écoulement du réactif à la peau.
2. Dispositif selon la revendication 1, caractérisé en ce que ladite profondeur prédéterminée est d'environ 1 à 2 mm.
3. Dispositif selon la revendication 1 ou 2, caractérisé en ce que la coupe transversale de l'aiguille est agrandie pour empêcher la péné-



- tration dans la peau au-delà de la profondeur prédéterminée.
4. Dispositif selon l'une quelconque des revendications 1 à 3, caractérisé en ce que le réactif de test est un antigène. 5
 5. Dispositif selon la revendication 4, caractérisé en ce que le réactif de test contient de plus un stabilisateur, un conservateur ou un tampon. 10
 6. Dispositif selon l'une quelconque des revendications 1 à 5, caractérisé en ce que le réactif de test est contenu à l'intérieur d'une capsule ou d'un réservoir. 15
 7. Dispositif selon l'une quelconque des revendications 1 à 6, caractérisé en ce que le réactif de test est contenu à l'intérieur d'une matrice poreuse. 20
 8. Dispositif selon l'une quelconque des revendications 1 à 7, caractérisé en ce que le réactif de test contient un additif pour former une pâte ou un gel. 25
 9. Dispositif selon l'une quelconque des revendications 1 à 8, caractérisé en ce qu'il comprend une couche supérieure déformable pour réduire le volume de ladite chambre. 30
 10. Dispositif selon l'une quelconque des revendications 1 à 9, caractérisé en ce qu'il comprend au moins une couche aplatissable qui permet au volume de ladite chambre d'être réduit à l'application d'une pression audit dispositif. 35
 11. Dispositif selon l'une quelconque des revendications 1 à 10, caractérisé de plus en ce qu'il comprend une couche transparente qui, en utilisation, est située contre la peau. 40
 12. Dispositif selon la revendication 11, caractérisé en ce que l'on peut écrire sur la couche transparente de sorte que le résultat du test peut y être enregistré. 45
 13. Dispositif selon la revendication 11 ou 12, caractérisé en ce que la couche transparente est calibrée pour permettre de mesurer l'étendue de la réaction dermique. 50
 14. Pluralité de dispositifs selon l'une quelconque des revendications 1 à 13, caractérisé en ce qu'elle est sous forme d'une plaque ou d'une feuille, chaque dispositif contenant un réactif différent. 55

