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- (54) Benævnelse: **Indretning til visuel detektion af analyter i en flydende prøve**
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The invention relates to a device for visual detection of analytes in an analysis or liquid sample derived from the human or animal body according to the preamble of claim 1.

Devices for detection of analytes in a liquid sample, for example of drugs,
5 medicaments or antibodies as a sign for certain diseases in a body fluid or findings in terms of information of concentration are known in various versions. There is a particular interest in such devices which can also be used outside of a laboratory. They have to be portable and easy to operate as well as deliver a reliable result in a short amount of time. Particularly for carrying out tests regarding drug use or drug
10 abuse or similar by the police, a device is required which allows for such a test, also outdoors in different changing light conditions, weather conditions and temperatures. In DE 20 2014 002 369 U1, a device is proposed for this purpose, in which a test cassette can be inserted and which is provided with a light source, by means of which light is transmitted through the lower wall of the test cassette consisting of translucent
15 plastic as well as the test area of the test strip arranged in the test cassette and the test result is illuminated. The test cassette is designed for carrying out a lateral flow immunoassay, aptamer-based assay or enzyme immunoassay (EIA) and consists of a lower lid and an upper lid. Enclosed by these two lids, the test cassette contains a test strip, which is held in position inside a receptacle. In the upper lid, there is a filling
20 opening above the sample receiver of the test strip, through which a liquid sample to be examined can be introduced. Above the central test area of the test strip, there is a control window, through which the test result can be read. Such cassettes have proven effective in mobile use. However, the known cassettes are disadvantageous in that their production is complex and they take up a relatively large space.

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The invention seeks to remedy this problem.

DE19843094 A1 discloses test devices where porous matrix materials are applied to inert carriers. The inert carriers may be made of coated cardboard.

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The invention is based on the problem to provide a device for visual and metrological detection of analytes in a liquid sample, which is of simple construction, suitable for mobile use and which only takes up little space. According to the invention this problem is solved by a device having the features of claim 1.

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The invention provides a device for visual and metrological detection of analytes in a liquid sample which is of simple construction, suitable for mobile use and which only takes up little space. Due to the design of the device providing a support plate equipped with a test strip receptacle, in which a test strip provided with a sample receiving portion and a test section is arranged, which one test strip receptacle is at least partially closed via a cover layer non-detachably connected to the support plate, a very compact, compressed construction is allowed for. Preferably, the cover layer has a sample application window arranged at a distance from the control window, which allows for a sample application onto the sample receiving portion of at least one test strip.

Due to the fact that the support plate is made of cardboard, wherein existing test strip receptacles and/or reservoirs are formed by impressions, an environmentally friendly disposal of the device is achieved. For this purpose, the lid is preferably also made of cardboard. Alternatively, existing test strip receptacles and/or reservoirs can also be formed by recesses of an interlayer arranged between cover film and support plate.

In a development of the invention, at least two test strip receptacles each receiving a test strip are arranged in parallel to one another, which on one end open up into a shared reservoir, in which the sample receiving portions of the test strips are arranged and above which the sample application window of the cover layer is positioned. This allows for a simultaneous sample application on all sample receiving portions of the test strips opening up into the reservoir. The design of the reservoir also guarantees a sufficient supply of liquid sample as well as a homogenous distribution of the liquid on the sample receiving portion of the test strips preferably provided with a separation film (sample fleece).

In an embodiment of the invention, a sample receiving fleece is arranged in the area of the sample application window between cover layer and test strip. As a result, the liquid sample is applied to the test strip in a uniform manner.

In a further development of the invention, the cover layer is formed by a film, which is preferably substantially laminarly glued with the support plate and the test strips received by the support plate. As a result, the test strips are protected from contamination. In this regard, the film is preferably made of putrescible material. The at least one control window is preferably formed by one transparent area of the film each.

In a further embodiment of the invention, two pivotably connected support plates are arranged, which are each provided with test strip receptacles on one half of their surface, in a manner that in the folded state, the half of one support plate provided with test strip receptacles abuts on the half of the other support plate not provided with any test strip receptacles abutting thereon. As a result, an arrangement of test strips on both sides of the device is achieved, whereby the possible number of test strips is increased. At the same time, a thin design is achieved.

Other developments and embodiments of the invention are indicated in the remaining dependent claims. Exemplary embodiments of the invention are shown in the drawings and are hereinafter described in detail. It is shown in:

Figure 1 the schematic representation of a device for visual detection of analytes in a liquid sample in an explosive view and

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Figure 2 the schematic representation of a test strip of the device of figure 1.

The device for visual detection of analytes in a liquid sample selected as an exemplary embodiment substantially consists of two support plates 1 pivotably connected to one another along their longitudinal side, onto which an interlayer 2 is respectively applied, which receives the test strips 3 and which is provided with a cover layer 4.

The support plates 1 in the exemplary embodiment are made of cardboard and are formed by a single cardboard blank centrally provided with a fold 11.

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The interlayer 2 in the exemplary embodiment is made of corrugated cardboard and coated with a transparent, fluid-tight film in order to prevent the sample liquid from penetrating the cardboard. Alternatively, the interlayer 2 can be provided with a waterproof, preferably environmentally friendly varnish. In the interlayer 2, a recess 21 is inserted, by which two test strip receptacles 12 are respectively formed, which open up into a reservoir 13. The test strip receptacles 12 receive test strips 3.

In figure 2, the test strip 3 is shown in an offset cross section. The test strip 3 has a support film 31, on which on one end a sample receiving portion 32 is arranged.

35 Immediately adjacent to and partially under the sample receiving portion 32 on the support film 31, there is an antibody coating 33 containing antibodies which are

conjugated with gold particles and match an analyte or an antigen of such analyte to be detected and can immunologically react. The antibody coating portion 33 is followed by a test section 34, which is designed in the form of a membrane, on which a test line 341 and a control line 342 are arranged at a distance from one another, which
5 are formed by an antigen contained in a reagent for the detection of a certain analyte and are invisible before application of a sample. The sample receiving portion 32 of the test strip 3 is arranged below the sample application window 42 and the test section 34 is arranged below the control window 41 of the cover layer 4 applied on the interlayer 2.

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When a lateral flow assay is carried out, the test line 341 shows the result of the test; the control line 342 indicates if a sufficient sample amount was applied, i.e. if the test is valid and if it was properly performed. On its end opposite the sample receiving portion 32, an absorber portion 35 is arranged on the test strip 3.

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The cover layer 4 in the exemplary embodiment is formed by a putrescible, coloured film, which is provided with transparent, clear, low-reflection control windows 41. At a distance from the control windows 41, a sample application window 42 is arranged, which is formed by a recess inserted in the cover layer 4. The sample application
20 window 42 is arranged in such a manner that it is positioned above the sample receiving portions 32 of both test strips 3. In the exemplary embodiment, a sample receiving fleece – not shown - is arranged between the test strips 3 and the sample application window 42 of the cover layer 4, which covers the sample receiving portions 32 of the two test strips 3.

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Before a test is carried out, no lines 341, 342 are visible. When a test is carried out, a sample volume of a sample liquid is applied through a sample application window 42 of the cover layer 4 onto the sample receiving portion 32 of each test strip 3. Due to capillary action, the sample liquid flows in the direction of test section 34. It first comes
30 into contact with the antibody coating section 33, in which there are antibodies conjugated with gold particles for the antigen of an analyte to be detected in a standardised (dosed) amount. The antibodies have a different binding activity for different analytes (drugs). The antibodies conjugated with gold particles are picked up by the sample liquid, which flows through the test section 34. If the sample liquid does
35 not contain the analyte to be detected, the antigens of the analyte flowing through the test section 34 and being present there in the area of the test line 341 are bound by

the antibodies picked up by the sample liquid and a visible test line 341 emerges, which has a red or brown colour due to the gold particles conjugated with the antibodies. If the sample liquid contains the analyte to be detected, its antigens are already bound by the antibodies in the area of the antibody coating section 33 of the test strip 3 and adsorption cannot take place in the test section 34, which is why no visible test line 341 emerges. The control line 342 indicates if the test is valid. In figure 2, the test line 341 emerges in colour, which is why the test is negative regarding the corresponding analyte.

10 The support plates 1 pivotably connected via the fold 11 are pivoted in a manner that their backs opposite the test strips 3 rest against each other. As a result, an approximately credit card sized device is achieved, which receives four test strips 3. When using common test strips, which allow for testing regarding three analytes, the detection of twelve analytes is thus allowed for with the inventive device of credit card
15 size in the exemplary embodiment.

Instead of the interlayer 2 provided with recesses, the support plate 1 may also be provided with impressions, whereby the test strip receptacles 12 and the reservoir 13 are designed in the form of depressions in the support plate 1. As a result, the
20 production effort can be further minimised.

The inventive device is characterised by the fact that it allows for a test of a great number of analytes while having a compact size. Due to the manufacturing of the device substantially from cardboard material, an environmentally-friendly disposal of
25 this device for single use is also facilitated.

PATENTKRAV

1. Indretning til visuel detektion af analyter i en analyse- eller væskeprøve, som stammer fra den menneskelige eller animalske organisme, omfattende en bæreplade (1) med i
5 det mindste én teststrimmelholder (12), i hvilken en teststrimmel (3) forsynet med en prøvemodtagende del (32) og et testafsnit (34) er anbragt, hvilken i det mindste ene teststrimmelholder (12) er i det mindste delvis lukket via et dæklag (4), som er uaftageligt forbundet med bærepladen (1), hvilket dæklag (4) har kontrolvindue (41) i området ved testafsnittet (34) i teststrimlen (3) i den i det mindste ene teststrimmelholder (12), **kendete-**
10 **tegnet ved, at** bærepladen (1) er fremstillet af pap, hvor foreliggende teststrimmelholdere (12) og/eller reservoirer (13) er udformede ved indprægninger eller udsparinger (21) i et mellemlag (2) anbragt imellem dækfilmen (4) og bærepladen (1).

2. Indretning ifølge krav 1, **kendetegnet ved, at** dæklaget (4) har et prøvetilførselsvindue (42) anbragt i afstand fra kontrolvinduet (41), som gør det muligt at tilføre en
15 prøve til det prøvemodtagende afsnit (32) på i det mindste en teststrimmel (3).

3. Indretning ifølge krav 2, **kendetegnet ved, at** i det mindste to teststrimmelholdere (12), som hver især modtager en teststrimmel (3), er anbragt indbyrdes parallelt, som
20 ved én ende udmunder i et delt reservoir (13), i hvilket det prøvemodtagende afsnit (32) for teststrimlerne (3) er anbragt, og over hvilke prøvetilførselsvinduet (42) i dæklaget (4) er anbragt.

4. Indretning ifølge krav 2 eller 3, **kendetegnet ved, at** i området ved prøvetilførselsvinduet (42) er der imellem dæklaget (4) og teststrimlen (3) anbragt et prøvetilførselsfleece.
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5. Indretning ifølge ethvert af de foregående krav, **kendetegnet ved, at** dæklaget (4) er dannet af en film, som fortrinsvis er i det væsentlige plant limet til bærepladen (1) og
30 teststrimlerne (3) modtaget af bærepladen (1).

6. Indretning ifølge ethvert af de foregående krav, **kendetegnet ved, at** det i det mindste ene kontrolvindue (41) er udformet i hvert enkelt tilfælde af et transparent område i
35 dæklaget (4).

7. Indretning ifølge ethvert af de foregående krav, **kendetegnet ved, at** to vipbart forbundne bærelader (1) er tilvejebragt, som er forsynede med teststrimmelholdere (12) på en halvdel af deres overflade på en sådan måde, at i den foldede tilstand ligger den respektive halvdel af én bærelade (1), som er forsynet med teststrimmelholdere (12), an imod den halvdel, som ikke er forsynet med nogen teststrimmelholder (12) i den anden bærelade (1), som ligger an mod denne.

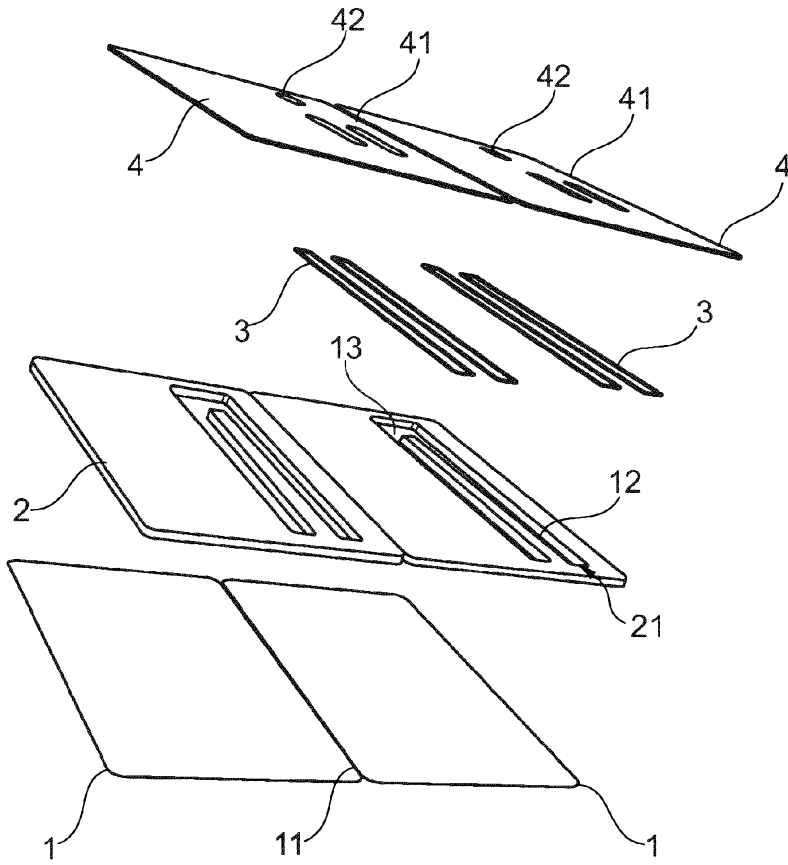


Fig. 1

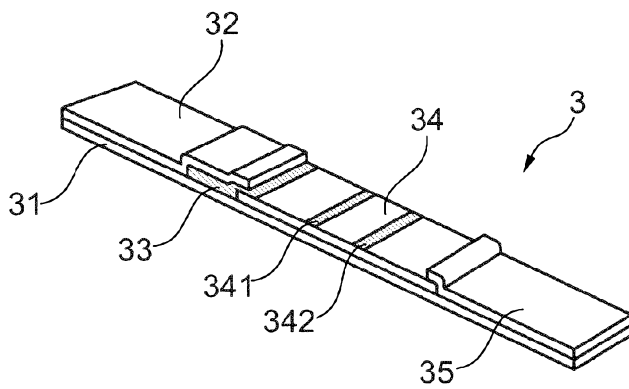


Fig. 2

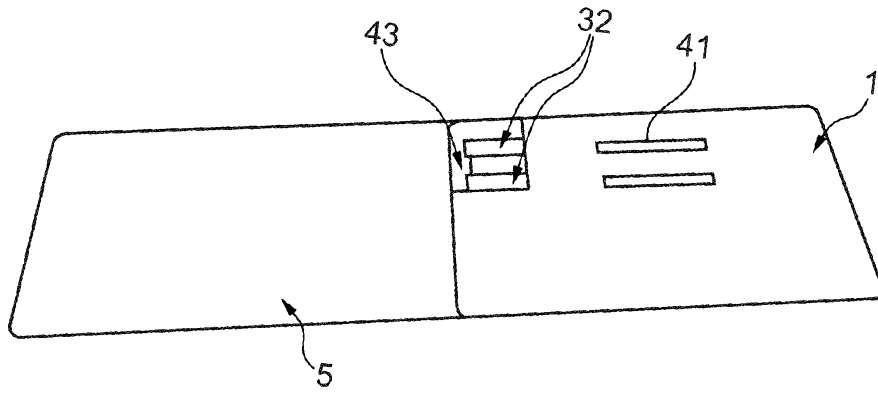


Fig. 3

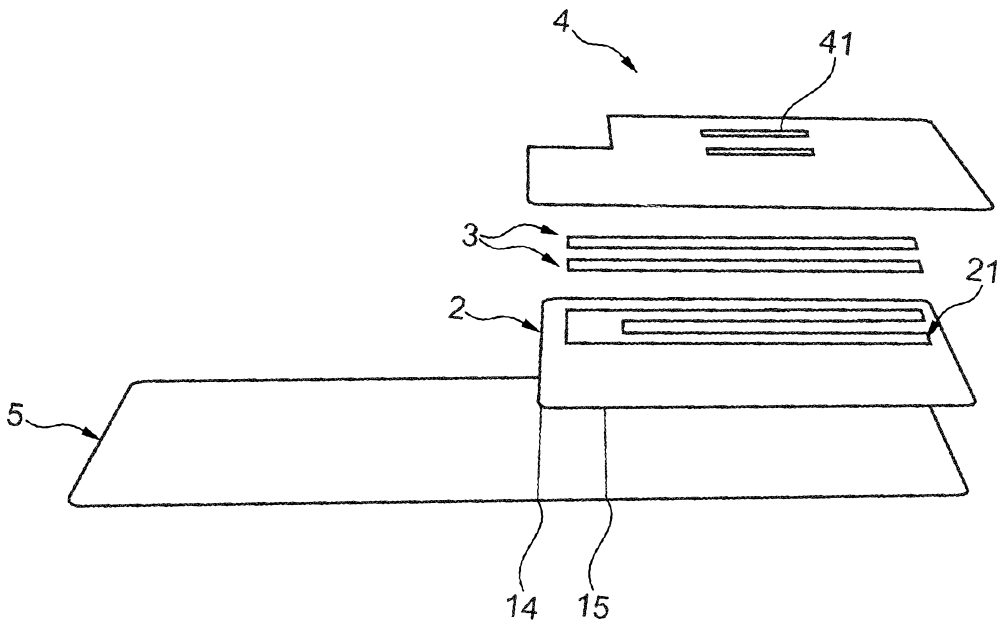


Fig. 4

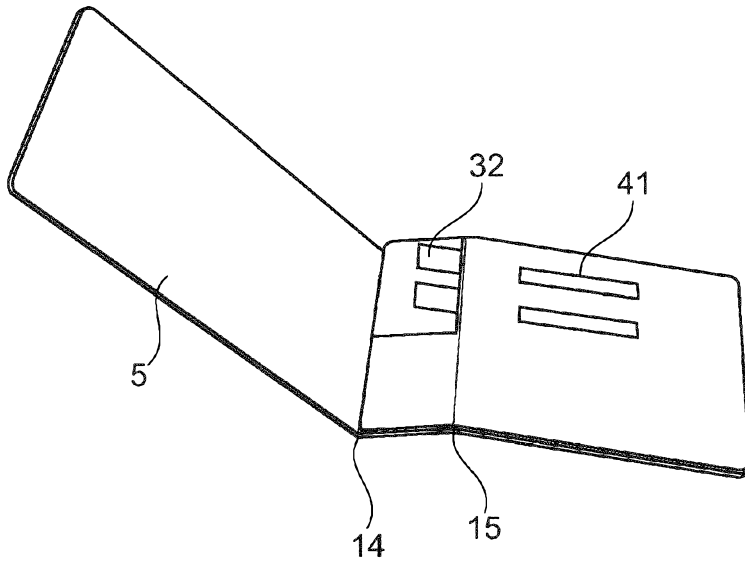


Fig. 5

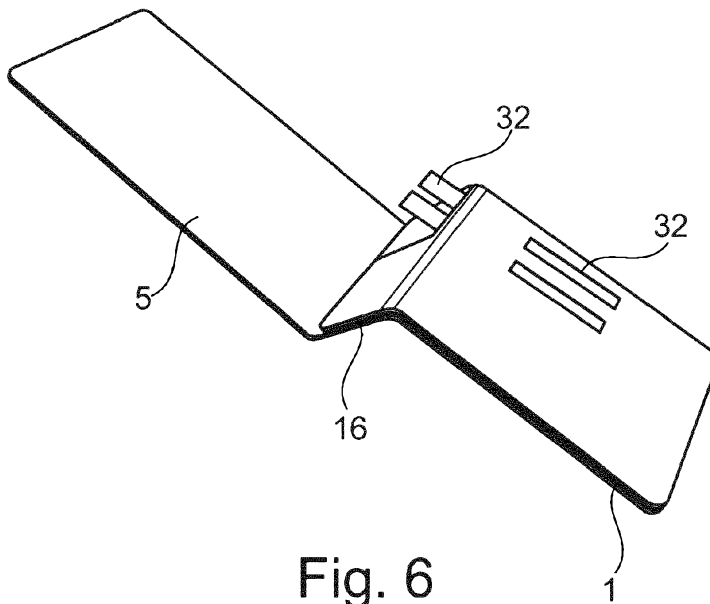


Fig. 6