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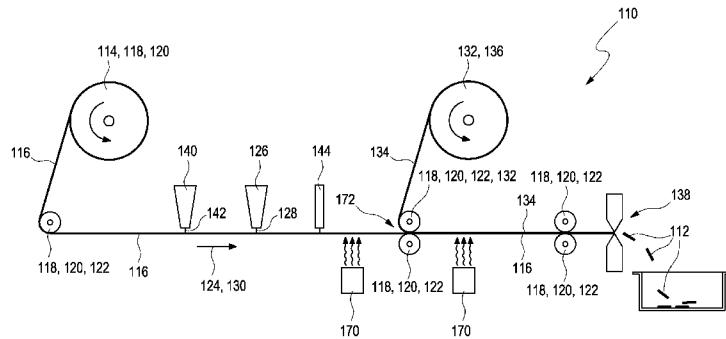


Fig. 1

(57) Abstract: A method and a production device (110) for producing a test element (112) are disclosed, the test element (112) being adapted for detecting at least one analyte in a body fluid. The test element (112) has at least one test chemical (142) adapted to perform at least one detection reaction in the presence of the analyte. The method comprises the following steps: a) a transport step, wherein a continuous substrate tape (116) is provided, the continuous substrate tape (116) being transported in a transport direction (124) parallel to a direction of extension (130) of the continuous substrate tape (116); b) an adhesive application step, wherein at least one continuous adhesive strip (154) is applied to the continuous substrate tape (116), by using a liquid adhesive (128) and a slot coating process, the continuous adhesive strip (154) being oriented parallel to the transport direction (124); c) a cover element application step, wherein at least one cover element (134) is applied to the continuous adhesive strip (154), thereby securing the cover element (134) to the continuous substrate tape (116); and d) an individualization step, wherein the continuous substrate tape (116) is individualized into single test elements (112).

Method and Device for producing a test element

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Field of the invention

The invention relates to a method and a device for producing a test element, the test element being adapted for detecting at least one analyte in a body fluid. Further, the invention relates to a test element producible by the method according to the invention and a use of a slot coating process, preferably a slot die coating process, for applying at least one adhesive strip to a test element for detecting at least one analyte in a body fluid. The method, the devices and the use according to the present invention preferably may be applied in the field of detecting one or more analytes such as glucose, lactate, triglycerides, cholesterol or other analytes, preferably metabolites, in body fluids such as blood, preferably whole blood, plasma, serum, urine, saliva, interstitial fluid or other body fluids, both in the field of professional diagnostics and in the field of home monitoring. However, other fields of application are feasible.

20 Related art

In the field of medical technology and diagnostics, a large number of devices and methods for determining the presence and/or the concentration of one or more analytes in body fluids are known. Without restricting the scope of the present invention, in the following, mainly reference is made to the determination of blood glucose concentrations.

For performing fast and simple measurements, several types of test elements are known, which mainly are based on the use of one or more test chemicals, i.e. on the use of one or more chemical substances, one or more chemical compounds or one or more chemical mixtures, adapted for performing a detection reaction for detecting the analyte. The test chemical often is also referred to as a test substance, a test reagent, a test chemistry or as a detector substance. For details of potential test chemicals and test elements comprising such test chemicals, which may also be used within the present invention, reference may be made to J. Hoenes et al.: The Technology Behind Glucose Meters: Test Strips, Diabetes Technology & Therapeutics, Vol. 10, Supplement 1, 2008, S-10 to S-26. Other types of

test elements and/or test substances are feasible and may be used within the present invention.

By using one or more test chemicals, a detection reaction may be initiated, the course of
5 which depends on the presence and/or the concentration of the at least one analyte to be determined. The detection reaction preferably may be analyte-specific. Typically, as may also be the case in the present invention, the test chemical is adapted to perform at least one detection reaction when the analyte is present in the body fluid, wherein the extent and/or the degree of the detection reaction typically depends on the concentration of the
10 analyte. Generally, the test chemical may be adapted to perform a detection reaction in the presence of the analyte, wherein at least one detectable property of at least one of the body fluid and the test chemical is changed due to the detection reaction. The at least one detectable property generally may be selected from a physical property and a chemical property.

15 In the following, without restricting potential other embodiments, reference will mainly be made to detection reactions in which one or more physical properties are changed due to the detection reaction, such as one or more of at least one electrical property and at least one optical property. Further, without restricting alternative solutions, reference will be made to detection reactions in which at least one optically detectable property of at least
20 one of the body fluid and the test chemical is changed due to the detection reaction. This at least one optically detectable property generally may be detected by detecting light propagating from the test chemical to a detector. This light, which may also be referred to as the detection light, generally may be light emitted by the test chemical itself and/or light which is elastically and/or inelastically scattered or reflected by the test chemical. Thus, the light
25 may be luminescence light, preferably fluorescence light, the generation of which may be excited by excitation light illuminating the test chemical. Additionally or alternatively, the light may be light which is reflected by the test chemical, such as by reflecting and/or scattering primary light. In the latter case, the test chemical preferably may be adapted to change at least one reflective property due to the detection reaction, preferably a color.

30 For deriving the concentration of the analyte, the progress of the detection reaction may be monitored, such as by measuring and/or monitoring a time development of at least one measurement value indicating the progress of the detection reaction. This measurement value generally may comprise an arbitrary measurement value which is linked to the detection reaction, such as an optical measurement value. As an example, in many measurement
35 setups, optical measurement values are monitored, such as a remission of a test field containing the test substance. Additionally or alternatively, electrical measurement values may

be recorded. By recording the time development of at least one measurement value, a measurement curve is provided, from which a concentration of the at least one analyte in the body fluid may be derived. Additionally or alternatively, a measurement value at a pre-determined point in time may be used for deriving the concentration of the analyte in the
5 body fluid. As outlined above, in addition or as an alternative to providing an information on a concentration of the analyte, an information on the presence and/or absence of the analyte may be provided.

10 A major challenge resides in the production of test elements. Typically, test strips or test tapes are used for detecting the analyte. Still, specifically in many home care applications, the user will have to perform a plurality of measurements per week or even per day, so, specifically in the field of home monitoring and Point of Care products for the professional market, pricing of the test elements is an issue. Therefore, a constant need for cost-efficient and, still, reliable manufacturing methods exists.

15 In order to manufacture test elements on a large scale, typically, lamination techniques are used. Test strips typically are manufactured on a large scale from a continuous or endless tape, wherein, typically, adhesive laminate foils are applied to an endless carrier tape, in order to provide an adhesive layer in the laminate setup. Further, hot-melt applications may
20 be used in order to apply single membranes or meshes to the test elements. Further, capillary-forming elements may be applied to the test elements, by using large-area gluing processes. In these gluing processes, base and cover elements of the capillary elements and/or wall elements, such as spacers in between the base and cover element, may be glued together. Further, additionally or alternatively, various layers of a layer setup may be joined
25 by a gluing process.

30 In US 2009 0263652 A1, a specific mixture of adhesives is disclosed, which may be used for manufacturing test elements. The adhesive mixture comprises an acrylic adhesive and a detergent. The adhesive is applied to a carrier foil by means of knife-coating methods.

35 Further, other application techniques for surfactants and test chemicals are known in the art. Thus, in EP 2 144 061 A1, a method for applying a surfactant to a surface of a sensor and, specifically, to a surface of a capillary element, is disclosed which uses piezo printing heads. Further, in WO 2004/113917 A2, a method for coating a test chemical mass, also referred to as a reagent coating mass, is disclosed. The coating mass is deposited by using a slot die coating process.

EP 0 297 389 A2 discloses a diagnostic test carrier, having at least two layers mounted in a spaced-apart manner, thereby providing an interspace in between these layers. The layers are connected by a plurality of hot melt regions, wherein gaps are provided between said hot melt regions. Through these gaps, a fluid transport into the interspace between the layers is enabled.

EP 1 291 650 A1 discloses a biosensor, the biosensor including a capillary having a channel with an inlet port for taking in a sample liquid, a membrane for promoting the movement of the sample liquid through the channel, and a reaction part containing a reagent that reacts with a component to be tested in the sample liquid whose movement has been promoted by the membrane.

US 2008/164142 A1 discloses a method for manufacturing a test sensor for detecting analytes in a body fluid. The method includes a screen printing process for depositing carbon electrodes including a method for selectively removing components that degrade the electrochemical performance from the surface of said carbon electrodes.

EP 1 612 554 A1 discloses a method of preventing the reuse of test strips for measuring an analyte such as glucose in a physiological fluid such as blood, interstitial fluid, or urine. The method comprises the steps of: inserting a test strip into a meter; detecting electrical continuity between a first electrical contact zone and a second electrical contact zone on said test strip and initiating a measurement sequence when said electrical continuity is present; applying a physiological sample to said disposable test strip; measuring a signal from said test strip that corresponds to an analyte concentration; and applying a voltage between said first electrical contact zone and said second electrical contact zone wherein said voltage is sufficient to destroy a frangible link between said first electrical contact and said second electrical contact.

Despite the advantages involved in the methods and devices disclosed in these prior art documents, a large number of disadvantages and technical challenges remains. These challenges widely are linked to the fact that a fine-patterning of structures and functional elements on the test elements has to be combined with a high-throughput manufacturing process. Thus, as an example, a precise positioning of test fields, capillary elements, cover elements, electrodes or membranes has to be integrated into a high-speed manufacturing process. Specifically, when applying one or more cover elements to a substrate by using an adhesive, a precise and, still, cost-efficient method for applying the adhesive to the substrate is an issue, specifically in case small-scale adhesive patterns or adhesive strips are

required, which is the case specifically in miniaturized test strips. Further, most known techniques, such as the above-mentioned lamination techniques, imply a manufacturing of one or more intermediate products, such as one or more intermediate tapes, having a liner covering the adhesive tape, wherein the intermediate products have to be spooled onto an 5 intermediate product reel. Before continuing the manufacturing process, the liner has to be removed from the intermediate product, which involves an additional manufacturing step and, thus, renders the manufacturing process complicated and costly.

Problem to be solved

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It is therefore an object of the present invention to provide methods and devices for manufacturing test elements involving one or more adhesives, which both are cost-efficient and suited for a large-scale manufacturing and, still, provide a sufficient level of precision even for miniaturized test strips having fine-patterned functional elements.

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Summary of the invention

This problem is solved by a method, a device, a test element and a use with the features of the independent claims. Preferred embodiments, which might be realized in an isolated 20 fashion or in any arbitrary combination, are listed in the dependent claims.

As used in the following, the terms "have", "comprise" or "include" or any arbitrary grammatical variations thereof are used in a non-exclusive way. Thus, these terms may both refer to a situation in which, besides the feature introduced by these terms, no further 25 features are present in the entity described in this context and to a situation in which one or more further features are present. As an example, the expressions "A has B", "A comprises B" and "A includes B" may both refer to a situation in which, besides B, no other element is present in A (i.e. a situation in which A solely and exclusively consists of B) and to a situation in which, besides B, one or more further elements or components are present in 30 entity A, such as element C, elements C and D or even further elements or components.

In a first aspect of the present invention, a method for producing a test element for detecting at least one analyte in a body fluid is disclosed. Generally, as used herein, a test element is an arbitrary element which is adapted for detecting one or more analytes in a body 35 fluid, wherein a quantitative and/or a qualitative detection may be performed. The test element may preferably be selected from the group consisting of an optical test element, which is adapted for detecting the analyte by using at least one optical detection method,

and an electrochemical test element, which is adapted for detecting the analyte by using at least one electrochemical measurement, such as the measurement of at least one voltage and/or at least one current. For potential setups of the test element, reference may be made to the prior art section above. Further, combined test elements providing electrochemical tests and/or optical tests may be feasible. Additionally or alternatively, other types of test elements may be used. The test element as discussed in the following disclosure preferably is a test strip, i.e. a strip-shaped test element, such as a test element having a strip length of 5 mm to 100 mm, preferably 10 mm to 50 mm, and a strip width of preferably 1 mm to 30 mm, preferably 3 mm to 10 mm. The thickness of the test strips preferably is below 2 mm, preferably below 500 μ m, and the test strips preferably are flexible, i.e. are deformable by hand.

The test element has at least one test chemical adapted to perform at least one detection reaction in the presence of the analyte. For a definition of the test chemical, for potential embodiments of the test chemical and for potential embodiments of the detection reaction, which e.g. may be an optical detection reaction and/or an electrochemical detection reaction, reference may be made to the prior art section above. Preferably, the test chemical is a dry test chemical. For potential compositions of the test chemical, reference may be made to the prior art documents cited above.

The method comprises the following method steps, which may be performed in the given order. However, other orders of the method steps are feasible. Further, two or more of the method steps may be performed simultaneously and/or overlapping in time. Thus, preferably, the method provides a continuous manufacturing process, in which at least method steps a) and b), optionally additionally method steps c) and/or d), may be performed simultaneously, such as in an in-line-process. Further, one or more of the method steps may be performed repeatedly or iteratively. Further, one or more additional method steps may be provided, which are not listed in the following.

The method comprises the following steps:

- a) a transport step, wherein a continuous substrate tape is provided, the continuous substrate tape being transported in a transport direction parallel to a direction of extension of the continuous substrate tape;
- b) an adhesive application step, wherein at least one continuous adhesive strip is applied to the continuous substrate tape, by using a liquid adhesive and a slot coating process, the continuous adhesive strip being oriented parallel to the transport direction;

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- c) a cover element application step, wherein at least one cover element is applied to the continuous adhesive strip, thereby securing the cover element to the continuous substrate tape; and
- d) an individualization step, wherein the continuous substrate tape is individualized into single test elements.

As outlined above, the transport step and the adhesive application step preferably are performed simultaneously and continuously. Thus, the transport step and the adhesive application step each may be a continuous process.

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As outlined above, in the transport step, a continuous substrate tape is provided. As used herein, the term continuous substrate tape refers to the fact that the continuous substrate tape provides a substrate for more than one test element, preferably for at least 10, at least 100, at least 1000 or even at least 10000 or at least 100000 test elements. Thus, preferably, the continuous substrate tape has a length, i.e. an extension along a direction of extension of the substrate tape, of preferably at least 1 m, more preferably at least 10 m, and most preferably at least 30 m. The continuous substrate tape may have a width perpendicular to the direction of extension of the substrate tape which, preferably, is at least 5 mm, more preferably at least 10 mm, such as 20 mm or more. This width may correspond to the length of the test elements, since, as will be outlined in further detail below, the individualization step d) preferably implies a cutting of the continuous substrate tape in a direction perpendicular to the extension of the substrate tape. Thus, with regard to preferred embodiments of the width of the continuous substrate tape, reference may be made to the preferred length of the test strips as given above.

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The transportation of the continuous substrate tape, as an example, may be performed by using one or more reels and/or one or more other types of transportation devices, such as rollers and/or transport wheels. The continuous substrate tape, as will be outlined in further detail below, may be provided by using at least one supply reel.

30

As outlined above, the transport direction is parallel to a direction of extension of the substrate tape. Thus, the continuous substrate tape may be spooled along a direction of extension, such that all sections of the continuous substrate tape successively or continuously may pass one or more application stations of a device for performing the method, as will be outlined in further detail below. Thus, the direction of lateral extension of the substrate tape and the transport direction may be the direction of the transport at the location of one

or more application stations of the device, such as at the location of an adhesive application device and/or a cover element application device, as will be outlined in further detail below.

5 As outlined above, in method step b), a liquid adhesive is applied. As used herein, the term "liquid" refers to the fact that the liquid adhesive is provided in an amorphous, deformable format, such as in a liquid form and/or as a paste. Preferably, the liquid adhesive is provided in a liquid form, such as in the form of a solution, an emulsion and/or a dispersion. Thus, the liquid adhesive preferably may comprise one or more solvents.

10 As used herein, the term slot coating process, which preferably implies a slot die coating process, generally refers to a process of applying a liquid or a paste to a substrate by using one or more slots, such as by using one or more dies, each die having one or more slots (slot die). Thus, as an example, the slot coating process, such as the slot die coating process, 15 may provide a slot perpendicular to the transport direction, wherein the transport direction preferably in this location is a horizontal direction. The liquid adhesive may pass the slot due to an external pressure and/or due to its own weight and may hit a surface of the substrate tape. Preferably, in this location, the substrate tape is in motion and immediately takes away the liquid adhesive applied to the surface, thereby continuously applying 20 additional liquid adhesive in a continuous film onto the surface.

The slot preferably may be part of a nozzle, preferably a die. Thus, the nozzle or die may comprise one or more shims having the shape of a slot, preferably a rectangular slot, with a longer side of the rectangle preferably being oriented perpendicular to the transport direction. Slot coating processes are generally known for other applications in the art, such as 25 from WO 2004/113917 A2.

As used herein, the term continuous adhesive strip generally refers to a strip-shaped element having precise boundaries parallel to the transport direction and, thus, preferably parallel to the long sides of the continuous substrate tape.

As used herein, the term cover element generally refers to an arbitrary element which is glued to the substrate tape by using the at least one continuous adhesive strip. The cover element preferably may be a continuous cover element, which, in the individualization step 35 and/or in an additional cover element singulation step, may be separated or individualized into individual cover elements for each test element. Examples of cover elements which may be used in the present invention will be given in further detail below.

As further used herein, the term "individualize" generally refers to the process of separating the continuous substrate tape, with one or more additional elements disposed thereon (such as the liquid adhesive and/or the cover element) into a plurality of test elements or 5 pre-products of the test elements. Thus, in step d), ready-to-use test elements may be generated and/or intermediate products of the test elements, which may optionally be subject to one or more subsequent finalization steps.

As outlined above, the method according to the present invention may comprise one or 10 more additional steps. Thus, the method may further comprise the step of applying the test chemical to at least one of the continuous substrate tape and the cover element. This method step may be performed during the transportation step, such as before or after the adhesive application step or even parallel to the adhesive application step. With regard to potential test chemicals or application methods for test chemicals, reference may be made to the 15 related art section above. As an example, the method as disclosed in WO 2004/113917 A2 may be used. Additionally or alternatively, knife-coating techniques and/or roller coating techniques and/or printing techniques may be used, preferably in a continuous process. Thus, generally, the application of the at least one test chemical preferably is performed in a continuous process.

20 The continuous adhesive strip preferably may have a width perpendicular to the transport direction of less than 5 mm, preferably less than 4 mm and, more preferably, of less than 3 mm. The continuous adhesive strip, as an example, may have a width perpendicular to the transport direction of at least 1 mm and less than 5 mm. Other dimensions are possible.

25 Generally, different dimensions of the continuous adhesive strip are feasible. Thus, as an example, the continuous adhesive strip may have a width perpendicular to the transport direction of 0.5 mm to 40.0 mm, preferably of 1.0 mm to 5 mm, more preferably a width of 1.0 mm to 3.0 mm and, most preferably, 2.0 mm. Other dimensions are feasible.

30 As outlined above, one or more continuous adhesive strips may be applied to the continuous substrate. Thus, as one advantage of the present invention, as will be outlined in further detail below, two or more continuous adhesive strips may be applied to the continuous substrate, even with a high precision, such as two or more continuous adhesive strips having the dimensions as given above, such as a width of 1.0 mm to 5.0 mm, preferably a width of less than 5.0 mm. Other dimensions are feasible.

As outlined above, the slot coating process preferably comprises a slot die coating process. Preferably, the slot coating process is adapted to apply a pressure of more than 1 bar to the liquid adhesive, such as a pressure of 1 to 2 bar. The liquid adhesive preferably may be supplied to a die of a die slot coater or slot die coating device via at least one tubing system and/or at least one pump.

In case a slot die is used in the slot coating process, preferably, the slot die has a width perpendicular to the transport direction of less than 5 mm, preferably a width of less than 4 mm and, more preferably, a width of less than 3 mm. For potential dimensions of the slot, reference may be made to the preferred width of the continuous adhesive strip as outlined above. Thus, the width of the slot die preferably corresponds to the width of the continuous adhesive strip. Preferably, the width of the slot die is at least 1 mm, such as 1 to 3 mm, preferably 2 mm.

As outlined above, preferably, the continuous substrate may be a flexible tape or foil. As an example, the continuous substrate tape may comprise one or more of: a plastic tape, such as a polyester tape; a membrane; a metal foil; a non-woven fabric, preferably a non-woven fabric containing glass fibers; a paper material; a textile; a micro-structured material. Additionally or alternatively, other materials and/or combinations of materials may be used. Additionally or alternatively, the continuous substrate tape may comprise a laminate tape, comprising one or more plastic materials and/or one or more additional materials. The flexible tape may be a transparent or intransparent tape. The continuous substrate tape preferably may have a thickness of 10 μm to 1 mm, more preferably a thickness of 20 μm to 50 μm and, most preferably, a thickness of 30 μm . Other dimensions are feasible.

The continuous substrate tape preferably may be provided by using at least one supply reel. As outlined above, additional transport elements may be provided, such as one or more transport wheels and/or one or more transport rollers.

Further embodiments refer to the cover element. Thus, as outlined above, the cover element generally may be or may comprise one or more elements which are secured directly or indirectly to the transport tape via the at least one adhesive strip. The cover element may be a passive cover element which simply provides a protection of the test element or parts thereof against detrimental influences, such as mechanical influences and/or environmental influences. Additionally or alternatively, however, the at least one cover element may be or may comprise at least one functional element. As used herein, the term functional element generally refers to an element providing one or more functions to the test element which

are related to the detection of the analyte in the body fluid. Thus, the functional element may be or may comprise a fluidic functional element, such as a fluidic transport element, more preferably at least one capillary element. As used herein, the term capillary element generally refers to an element which forms at least a part of a sidewall of a capillary channel for transporting liquids by capillary forces. Additionally or alternatively, the at least one functional element may be or may comprise at least one separation element, such as at least one separating membrane, such as for separating one or more components of the body fluid. Additionally or alternatively, the at least one functional element may comprise one or more spreading elements adapted for spreading the body fluid or at least one part thereof over a specific region or area. Thus, as an example, the functional element may be or may comprise at least one cover foil which is adapted to spread the body fluid or a part thereof over one or more electrodes and/or over one or more test fields, preferably by capillary forces and/or surface action. Again, additionally or alternatively, as outlined above, the cover element may comprise one or more substrate elements and one or more test chemicals applied thereto. Thus, the at least one functional element may be or may comprise at least one test chemical, preferably in the form of at least one test field. Thus, the test element generally may comprise one or more test fields comprising the at least one test chemical, wherein the test field may have a monolayer or a multilayer setup. The at least one test field may be applied directly or indirectly to the continuous substrate tape or the substrate of the test element made thereof, and/or may be applied directly or indirectly to the cover element.

Thus, summarizing, the cover element preferably may comprise at least one element selected from the group consisting of: a spreading element; a capillary element; an electrode; a cover foil; a reagent foil or test field comprising the at least one test chemical; a membrane for separating at least two components of the sample of the body fluid. Additionally or alternatively, other types of elements may be provided, preferably functional elements.

The cover element may be applied to the adhesive strip in an individualized form and/or in a continuous format. Thus, individual cover elements, such as one or more cover elements per test element, may be applied to the continuous adhesive strip, before individualization. Additionally or alternatively, the at least one cover element may be provided in a continuous process. Thus, preferably, the at least one cover element is a continuous cover element or comprises a continuous cover element, the continuous cover element being continuous in the direction of the extension of the substrate tape and/or in the transport direction. Thus, as an example, the at least one cover element may comprise at least one continuous

cover foil or continuous cover tape, such as at least one continuous plastic tape and/or at least one continuous laminate tape.

As outlined above, the method according to the present invention preferably is performed in a continuous process. Thus, preferably, method steps a) and b) and, optionally, steps c) and/or d), are performed continuously, such as in an in-line-process, more preferably in a reel process. Thus, as an example, the at least one cover element may be provided by using at least one supply reel.

Further embodiments refer to the test chemical which may be used within the present invention. For potential embodiments of the test chemical, reference may be made to the prior art documents listed above. Other types of test chemicals may be used alternatively or additionally. Thus, as an example, the at least one test chemical may comprise at least one optical test chemical, wherein the at least one optical test chemical is adapted to perform at least one optical detection reaction in the presence of the analyte, wherein at least one optically detectable property of at least one of the optical test element and the body fluid changes due to the optical detection reaction. As an example, the at least one optically detectable property may be or may comprise a fluorescence property and/or a phosphorescence property and/or a luminescence property. Additionally or alternatively, the at least one optically detectable property may be or may comprise a reflection property of the test chemical, preferably of a test field comprising the test chemical, such as at least one remission and/or at least one color. As an example, the at least one test chemical may comprise one or more enzymes, such as glucose oxidase and/or glucose dehydrogenase. Additionally or alternatively, other components may be comprised, such as one or more dyes and/or colorants. Further, one or more additional elements may be comprised, such as co-enzymes and/or mediators.

Additionally or alternatively to the use of at least one optical test chemical, the at least one test chemical may be or may comprise at least one electrochemical test chemical. The electrochemical test chemical may be adapted to perform at least one electrochemical detection reaction in the presence of the analyte. At least one electrically detectable property of at least one of the electrochemical test chemical and the body fluid may change due to the electrochemical detection reaction. Again, the at least one electrochemical test chemical may be or may comprise at least one enzyme, such as glucose dehydrogenase and/or glucose oxidase. Additionally or alternatively, other components may be present, such as one or more co-enzymes and/or one or more mediators. The at least one electrically detectable property may be at least one property which may be detected by using one or more elec-

trodes, as is known in the art. Thus, the at least one electrically detectable property may be or may comprise a current and/or a voltage. Thus, the at least one test chemical may be applied to at least one working electrode of the test element, wherein at least one counter electrode and/or reference electrode may be provided. A current and/or a voltage between 5 the working electrode and the at least one further electrode may be measured, in order to determine the at least one electrically detectable property. For further details, reference may be made to the related art listed above.

10 Thus, generally, the method and the production device according to the present invention preferably may be used for manufacturing optical test elements, for manufacturing electrochemical test elements or for manufacturing hybrid test elements, providing both means for optical measurements and means for electrochemical measurements.

15 In case at least one electrochemical test chemical is used, the method according to the present invention may further comprise the method step of applying at least one electrode to at least one of the continuous substrate tape and the cover element. The electrochemical test chemical may be applied to the electrode. Thus, one or more electrodes may be provided directly or indirectly on the continuous substrate tape and/or on the cover element. The substrate tape and/or the cover element may be provided with the one or more electrodes 20 already deposited thereon, such as by providing one or more intermediate products. Additionally or alternatively, the application of the one or more electrodes may fully or partially take place during the method according to the present invention.

25 As an example, the continuous substrate tape may comprise one or more conductive layers in a patterned fashion and/or in an unpatterned fashion. The one or more conductive layers, as an example, may comprise one or more metal layers such as metal layers comprising one or more metal materials selected from the group consisting of Ag, Al, Au, Pt, Pd, Ni and Cu, as pure materials and/or as a component of an alloy or Cermet. Additionally or alternatively, other metals may be used. In addition or alternatively, other types of conductive materials having electrically conductive properties may be used, such as one or more electrically conductive organic materials, preferably electrically conductive polymers, 30 and/or conductive coatings as will be known to the skilled person.

35 For applying the at least one electrode, known techniques may be used. Thus, the at least one electrode preferably comprises one or more metal electrodes, such as one or more electrodes made of gold. For applying the metal, known techniques such as physical vapor deposition and/or chemical vapor deposition, preferably sputtering techniques, may be

used. Additionally or alternatively, other application techniques may be used, such as lamination techniques. For patterning the one or more electrodes, typical patterning techniques may be used. The patterning may take place during deposition of the one or more metals and/or may take place in a subsequent step. Thus, as an example, a patterning by using 5 ablation techniques may be performed, such as one or more laser ablation techniques and/or etching techniques.

As outlined above, for applying the at least one electrochemical test chemical to the at least one electrode or to at least one of the electrodes, known deposition techniques may be 10 used. Thus, knife-coating, printing, roller blading, dispensing, screen printing or other techniques may be applied.

As outlined above, preferably, at least method steps b) and c) are performed in a continuous process. Thus, preferably, the process implies an in-line-application. As an example, 15 the full process may be an in-line-process, without generating an intermediate product, which might be spooled onto a reel. However, additionally or alternatively, one or more intermediate products may be generated during the process, and the process might be interrupted by intermediately storing the intermediate product. Preferably, however, a continuous process is used, preferably a reel process.

20 Further embodiments refer to the liquid adhesive. Preferably, the liquid adhesive has a viscosity of 20 mPas to 10000 mPas. As an example, the liquid adhesive may have a viscosity of more than 100 mPas, such as a viscosity of 100 mPas to 1000 mPas. Other viscosities are feasible.

25 The continuous adhesive strip and/or the liquid adhesive may have various properties, such as electrical properties. Thus, the continuous adhesive strip may have electrical properties selected from the group of electrically insulating properties and electrically conductive properties. Thus, the at least one continuous adhesive strip and/or the at least one adhesive strip on the test element may be used for electrically connecting two or more conductive 30 elements. As an example, when using one or more continuous adhesive strips having electrically conductive properties, the at least one adhesive strip formed thereby may be used in a layer setup for electrically connecting electrical leads or other electrical elements in different layers of the layer setup.

35 In order to provide electrically conductive properties, the liquid adhesive may comprise one or more electrically conductive components, such as metal particles and/or electrically

conductive carbon particles. As an example, the liquid adhesive may comprise one or more matrix components and/or binders and, in addition, one or more filler materials having electrically conductive properties, such as metal particles and/or carbon particles. Other ways of rendering the liquid adhesive electrically conductive are known to the skilled person and may be used in addition.

Additionally or alternatively, at least one liquid adhesive and/or at least one continuous adhesive strip may be used having electrically insulating properties. These elements may, as an example, be used in case no electrical connection has to be provided via the continuous adhesive strip or the adhesive strip formed thereby, or in case an electrical insulation has to be provided by the continuous adhesive strip on the adhesive strip formed thereby, such as an electrical insulation between neighboring electrically conductive layers of a layer setup. The test element even may comprise a combination of one or more electrically conductive adhesive strips and one or more electrically insulating adhesive strips.

15 The continuous adhesive strip and/or the liquid adhesive may have various properties, such as thermal properties. Thus, the continuous adhesive strip may have thermal properties selected from the group of thermally insulating properties and thermally conductive properties. Thus, the at least one continuous adhesive strip and/or the at least one adhesive strip on the test element may be used for thermally connecting two or more adjacent elements. As an example, when using one or more continuous adhesive strips having thermally conductive properties, the at least one adhesive strip formed thereby may be used in a layer setup for thermally connecting elements in adjacent layers of the layer setup.

25 In order to provide thermally conductive properties, the liquid adhesive may comprise one or more thermally conductive components, such as metal particles. As an example, the liquid adhesive may comprise one or more matrix components and/or binders and, in addition, one or more filler materials having good thermally conductive properties, such as metal particles. Other ways of rendering the liquid adhesive thermally conductive are known to the skilled person and may be used in addition.

35 Additionally or alternatively, at least one liquid adhesive and/or at least one continuous adhesive strip may be used having thermally insulating properties. These elements may, as an example, be used in case no thermal connection or heat transfer has to be provided via the continuous adhesive strip or the adhesive strip formed thereby, or in case an thermal insulation has to be provided by the continuous adhesive strip on the adhesive strip formed thereby, such as an thermal insulation between neighboring layers of a layer setup. The test

element even may comprise a combination of one or more thermally conductive adhesive strips and one or more thermally insulating adhesive strips.

The continuous adhesive strip, preferably in an adhesive or wet state, may have a thickness, i.e. an extension perpendicular to a surface of the continuous substrate tape, of 2 μm to 150 μm , preferably of 10 μm to 100 μm , more preferably of 5 μm to 50 μm , and most preferably of 10 μm to 20 μm , such as 15 μm . Other dimensions are feasible.

In a further embodiment, the method may further comprise one or more drying steps, wherein the continuous adhesive strip is fully or partially dried in the drying step. As used herein, the term drying generally refers to a full or partial solidification of the liquid adhesive in the liquid adhesive step, such as by fully or partially removing one or more solvents from the liquid adhesive and/or by initiating one or more chemical reactions within the liquid adhesive, such as cross-linking reactions. In the latter case, the at least one chemical reaction may be initiated by internal factors, such as one or more initiators contained within the liquid adhesive, and/or may be initiated by one or more external influences, such as heat and/or electromagnetic radiation, as will be outlined in further detail below.

The at least one drying step may be performed before or after the cover element application step. In case at least one drying step is provided before the cover element application step, preferably, the at least one liquid adhesive is not fully cured or dried during the at least one drying step, such that a stickiness or adhesive properties of the continuous adhesive strip remain even after the drying step. Additionally or alternatively, the at least one drying step may be performed fully or partially after the at least one cover element application step, such as by heating and/or setting and/or curing via electromagnetic radiation. Thus, preferably, a full or partial solidification of the at least one continuous adhesive strip takes place after the application of the at least one cover element, preferably before performing the at least one individualization step.

As outlined above, the at least one drying step may optionally comprise exerting one or more influences to the continuous adhesive strip and/or the liquid adhesive. Thus, as an example, the drying step may comprise one or more of: a heating of the adhesive strip; an exposure of the adhesive strip to hot gas, such as hot air; an exposure of the adhesive strip to electromagnetic radiation, preferably electromagnetic radiation in the ultraviolet spectral range. Additionally or alternatively, other types of heating processes may be performed, such as simple setting processes, such as by leading the continuous substrate tape with the continuous adhesive strip and the cover element disposed thereon via at least one setting

distance, in order to provide sufficient time for full or partial setting of the adhesive. Additionally or alternatively, the drying step may imply a drying by using at least one heating channel and/or at least one heating plate. Thus, as an example, the continuous substrate tape with the continuous adhesive strip and the cover element disposed thereon may be led over at least one heating channel and/or over at least one heating plate. As an example, temperatures of 30 °C to 150 °C may be applied to the continuous adhesive strip, such as temperatures of 40 °C to 100 °C. Other temperatures are feasible.

For further improving the adhesion of the at least one cover element to the at least one continuous substrate tape, pressure may be applied. Thus, as an example, the cover element may be pressed onto the continuous adhesive strip or vice versa. For continuously pressing the cover element to the continuous adhesive strip and/or the continuous substrate tape, various pressurizing techniques may be used. Thus, as an example, one or more pressurizing rollers may be used, such as one or more rollers pressing the cover element onto the continuous adhesive strip or vice versa, by using a rigid support, and/or one or more roller clearances or nibs through which the setup comprising the continuous substrate tape, the continuous adhesive strip and the cover element is led during a continuous process. Other options are feasible.

Further optional embodiments refer to the type of the liquid adhesive. Generally, the liquid adhesive may be or may comprise an arbitrary type of liquid adhesive, such as one or more cross-linkable monomers, oligomers or polymers and/or such as one or more polymers containing one or more solvents. As an example, epoxy resins may be used. As a further example, acrylic liquid adhesives may be used. Thus, as an example, the liquid adhesive may be or may comprise a contact adhesive and/or a bonding emulsion. Further, additionally or alternatively, the liquid adhesive may be or may comprise a dispersion, preferably an aqueous dispersion. As an example, transfer adhesives may be used which typically are used in the field of adhesive tapes, specifically double-sided adhesive tapes. The liquid adhesive may have a basic material, such as an acrylate. As an example, a dispersion of an acrylate may be used as a basic material of the liquid adhesive, as is the case for Ucecryl® adhesives, as available by Cytec Surface Specialties SA/NV, Brussels, Belgium, such as the Ucecryl® adhesives described in US 2009 0263652 A1. Additionally or alternatively, one or more of the following liquid adhesives on the basis of an acrylate dispersion may be used: a helmitin® liquid adhesive, such as helmitin 35038; a swift®tak adhesive, such as swift®tak 2050; a technicoll® adhesive, such as technicoll® 9220 and/or technicoll® 921; all available by Ruderer Klebetechnik GmbH, Zorneding, Germany.

The liquid adhesive, such as one or more of the above-mentioned liquid adhesives and, more specifically, a liquid adhesive based on an acrylate dispersion, may comprise one or more additives. Thus, as an example, specifically for liquid adhesives based on an acrylate dispersion, one or more adhesives may be added, selected from the group consisting of: an

5 electrically conductive material, specifically a metal and/or graphite, more specifically one or more of gold, silver or graphite dispersed within the liquid adhesive; a thermally conductive material; one or more additives for adjusting rheological properties, such as more thickeners; an anti-foaming agent. Other additives are feasible.

10 Generally, the liquid adhesive may provide various properties, with regard to one or more of rheology, thermal conductivity and electrical conductivity. Thus, the liquid adhesive may be selected from the group consisting of: an electrically conductive liquid adhesive; and electrically insulating liquid adhesive; a thermally conductive liquid adhesive; a thermally insulating liquid adhesive.

15 As outlined above, the term liquid adhesive generally refers to the adhesive in a non-dried or only partially dried state. Thus, in this state, one or more solvents may still be present and/or the liquid adhesive at least partially is in a non-cross-linked state. Contrarily, in the 20 final test element, after individualization of the test elements, the test element may comprise one or more adhesive strips in which the adhesive is in a fully or partially dried state, such as in a state in which the at least one solvent is fully or partially removed and/or in a state in which the adhesive is fully or at least partially cross-linked.

25 As outlined above, the at least one liquid adhesive may comprise one or more solvents, in order to provide a solution, a dispersion or an emulsion. Therein, polar and/or non-polar solvents may be used. The content of the one or more solvents may further be used to adapt the viscosity of the liquid adhesive, in order to optimize the coating properties of the liquid adhesive during the slot coating process. As a most preferred example, specifically for reasons of toxicity and/or compatibility with other ingredients, water-based liquid adhesives 30 may be used, such as water-borne emulsions.

The liquid adhesive may further comprise one or more additional components which do not directly imply adhesive properties. Thus, as an example, the liquid adhesive may comprise at least one surface-active additive, preferably at least one surfactant and, more preferably, at least one hydrophilic surfactant. The at least one surface-active additive may be mixed into the liquid adhesive. Additionally or alternatively, the method may further com-

prise at least one step of applying at least one surfactant to a surface of the continuous adhesive strip, preferably at least one alcoholic surfactant.

The slot coating process may further imply the use of a die, as outlined above. Thus, the die may comprise one or more shims. The slot coating process may imply the use of a die being separated from a surface of the continuous substrate tape by 10 μm to 1.0 mm, such as by 20 μm to 200 μm , preferably by 30 μm to 90 μm . Other distances are feasible.

The method may further comprise one or more steps of applying at least one continuous liner to the continuous adhesive strip. As used herein, the term continuous liner generally refers to an intermediate cover which is applied to the surface of the continuous adhesive strip in order to form an intermediate product, wherein the continuous liner is removed from the continuous adhesive strip before applying the at least one cover element onto the continuous adhesive strip. Thus, the at least one continuous liner may be or may comprise one or more plastic tapes. However, as outlined above, preferably, the process is performed as an in-line-process, preferably as a continuous process, without generating one or more intermediate products.

As outlined above, preferably, the process is a high-throughput process. Thus, the continuous substrate tape preferably is transported in the transport direction at a transport speed of 1 m/min to 150 m/min, preferably of 10 m/min to 100 m/min, more preferably of 20 m/min to 80 m/min, and, most preferably, of about 40 m/min.

The adhesive application step preferably, as outlined above, is performed during a continuous transportation of the continuous substrate tape, preferably at a constant speed. Thus, preferably, both the transport step and the adhesive application step are preferably performed continuously and in parallel, such as by using an in-line-process.

Further embodiments refer to the individualization step. As outlined above, preferably, the individualization step may comprise a cutting of the continuous substrate tape, preferably with the continuous adhesive strip and the cover element disposed thereon, in a cutting direction perpendicular to the transport direction. Thus, test strips may be generated or intermediate products of the test strips, which may be ready to use or which may be subject to one or more additional manufacturing steps. For the cutting step, known cutting techniques may be used, such as die cutting and/or cutting by using one or more knives or cutter rollers and/or by using one or more laser cutting tools.

In a further aspect of the present invention, a production device for producing a test element for detecting at least one analyte in a body fluid is disclosed. Generally, the production device may be adapted to perform the method according to one or more of the embodiments disclosed above and/or according to one or more of the embodiments disclosed in further detail below. Thus, for potential definitions, optional embodiments or other details of the production device, reference may be made to the respective disclosure of the method. Thus, the production device may comprise one or more devices for performing one or more of the method steps.

10 The production device comprises at least one of each of the following elements:

- I. a tape transport device, the tape transport device being adapted for providing a continuous substrate tape, the tape transport device being adapted to transport the continuous substrate tape in a transport direction parallel to a direction of extension of the continuous substrate tape;
- II. an adhesive application device, the adhesive application device being adapted for applying at least one continuous adhesive strip to the continuous substrate tape, by using a liquid adhesive and a slot coating process, the continuous adhesive strip being oriented parallel to the transport direction;
- III. a cover element application device, the cover element application device being adapted for applying at least one cover element to the continuous adhesive strip, thereby securing the cover element to the continuous substrate tape; and
- IV. an individualization device, the individualization device being adapted for individualizing the continuous substrate tape into single test elements.

25 For potential embodiments of the tape transport device, reference may be made to the disclosure of the method above. Thus, the tape transport device preferably may comprise one or more rollers and/or one or more transport wheels. As an example, the at least one tape transport device may comprise one or more reels, such as one or more supply reels, for providing a supply of the continuous substrate tape.

30 Further, with regard to the adhesive application device, reference may be made to the options disclosed above. Thus, as will be outlined in further detail below, the adhesive application device preferably comprises at least one slot coater, preferably at least one die slot coater.

35 The cover element application device generally may comprise one or more arbitrary devices adapted for providing the at least one cover element in a stepwise and/or continuous

fashion. Thus, the at least one cover element may be provided in an individualized format, such as by providing one or more dedicated cover elements to each test element. Additionally or alternatively, the at least one cover element may be provided in a continuous process, such as by providing one or more tape-shaped processes. Thus, as an example, as will 5 be outlined in further detail below, one or more supply reels may be provided for applying the at least one cover element to the at least one continuous adhesive strip and/or the continuous substrate tape. As outlined above, one or more pressurizing elements may be provided, for pressing the cover element to the continuous substrate tape and/or the continuous adhesive strip or vice versa.

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Further, the individualization device generally may be or may comprise one or more devices adapted for individualizing the continuous substrate tape into single test elements or, which shall also be comprised by this option, into intermediate test elements, which may be subject to one or more additional finalization steps. As outlined above, the individualization device preferably may be or may comprise at least one cutting device, such as at 15 least one knife and/or at least one cutting roller and/or at least one blade or laser cutting device. Combinations of these devices are feasible.

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The production device may further be adapted to perform a reel process, wherein the at least one continuous substrate tape is supplied by at least one supply reel. Additional elements may be provided. As outlined above, the process preferably is performed in an in-line-fashion, such that the test elements are the final product of the in-line-process. However, alternatively, intermediate products may be formed. Thus, the at least one continuous substrate tape with the continuous adhesive strip and the cover element disposed thereon 25 may be stored as an intermediate product, such as by spooling this intermediate product onto an intermediate product reel. The at least one individualization process may be a separate process which is subsequently performed, by using the reel of the intermediate product. However, preferably, an in-line-process is used, without using an intermediate product.

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The production device may further comprise at least one test chemical application device. The test chemical application device may be adapted to apply the at least one test chemical to at least one of the continuous substrate tape and the cover element. Thus, as an example, the at least one test chemical application device may be embodied by using one or more of the above-mentioned options, such as by using one or more printing techniques and/or one 35 or more of a roller coating and/or a knife coating technique. Additionally or alternatively, other types of deposition techniques may be used, such as one or more of a dispensing

technique and/or a printing technique. As an example, reference may be made to WO 2004/113917 A2.

As outlined above, the at least one adhesive application device preferably may comprise at least one die slot coater. For potential embodiments of the die slot coater, reference may be made to the disclosure of the method as given above. The adhesive application device preferably may be adapted to apply at least two continuous adhesive strips to the continuous substrate tape. Thus, as an example, at least two parallel continuous adhesive strips may be applied to the continuous substrate tape. The adhesive application device preferably may comprise at least one pressurizing device adapted to apply a pressure of more than 1 bar to the liquid adhesive. Thus, the adhesive application device may comprise a tubing system and at least one pump for supplying the liquid adhesive, such as for supplying the liquid adhesive to at least one nozzle and/or die. The adhesive application device preferably may comprise at least one slot die, such as at least one shim, preferably a shim providing an opening of a rectangular shape. The slot die preferably may have a width perpendicular to the transport direction of less than 5 mm, preferably of less than 4 mm and more preferably a width of less than 3 mm. Most preferably, the slot die has a width of at least 1 mm, such as a width of 1 to 3 mm, preferably a width of 2 mm. For further potential embodiments, reference may be made to the disclosure of the method above.

20 The cover element application device preferably may comprise one or more supply reels. As outlined above, the cover element may be applied to the continuous adhesive strip by using a continuous process and/or by using one or more cover elements in an individualized format.

25 As outlined above, the process may further imply the use of one or more electrodes and, thus, may further imply the application of one or more electrodes. Thus, the production device may further comprise at least one electrode application device, wherein the electrode application device is adapted to apply at least one metal electrode to at least one of the continuous substrate tape and the cover element. For potential application techniques, reference may be made to the deposition techniques listed above. The production device may further comprise at least one patterning device, such as a patterning device which is adapted to pattern the electrodes from a continuous metal layer.

.35 The production device may further comprise at least one surfactant application device, wherein the surfactant application device may be adapted to apply at least one surfactant to a surface of the continuous adhesive strip. For applying the surfactant, reference may be

made to known deposition techniques. Thus, as an example, reference may be made to EP 2 144 061 A1 and the printing techniques disclosed therein, additionally or alternatively, other types of application devices may be provided, such as one or more printing devices and/or one or more roller coating or knife coating devices and/or one or more dispensing devices.

As outlined above, the tape transport device preferably is adapted for high-speed production. Thus, as an example, the tape transport device may be adapted to transport the continuous substrate tape at a transport speed of 1 m/min to 150 m/min, preferably of 10 m/min to 100 m/min, more preferably of 20 m/min to 80 m/min, and most preferably of about 40 m/min. These speeds preferably may be generated by known roller techniques and/or reel techniques, such as in a reel-to-reel or a simple reel process, preferably an in-line-process.

In a further aspect of the present invention, a test element for detecting at least one analyte in a body fluid is disclosed. The test element has at least one substrate and at least one cover element mounted to the substrate via at least one adhesive strip. The test element further has at least one test chemical adapted to perform at least one detection reaction in the presence of the analyte. The test element is producible by the method according to the present invention, by using the method in one or more of the embodiments disclosed above or as disclosed in further detail below. Preferably, the test element comprises at least one capillary element, such as at least one capillary element for transporting a sample of the body fluid from at least one application position to at least one measurement position, such as to the at least one test chemical. The test element preferably is a test strip.

In a further aspect of the present invention, a use of a slot coating process, preferably a slot die coating process, for applying at least one adhesive strip to a test element for detecting at least one analyte in a body fluid is disclosed. For optional embodiments of the use and/or the test element, reference may be made to the method and/or the production device as disclosed above or as disclosed in further detail below.

The method, the production device, the test element and the use according to the present invention provide a large number of advantages over known methods and devices. Thus, preferably, the application of the liquid adhesive or adhesive mass may take place directly in a continuous process, such as in an in-line application. The application of the liquid adhesive may take place in a contactless way, by using the slot coating process, preferably the slot die coating process, also referred to as a slot die coating process. Preferably, the

process may fully or partially be embodied as a reel process, by using one or more supply reels and/or reels for spooling one or more optional intermediate products.

Surprisingly, by using the slot coating process, a high-precision application of the continuous adhesive strip is feasible, even at a very low width of the continuous adhesive strip. Thus, continuous adhesive strips of as low as 1 mm or even less may be manufactured, which is not feasible in other application techniques. Thus, for typical lamination techniques as widely used for applying adhesive laminates, an adhesive strip width of 5 mm or more typically forms a lower limit.

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Further, the method and the production device according to the present invention provide a high flexibility. Thus, one or more continuous adhesive strips having the same or different width, position or thickness may be applied. Further, a flexibility regarding a drying exists. Thus, one or more optional drying steps may be implemented, wherein the process may 15 also be performed without any drying at all.

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Further, as outlined above, the order of the method steps, which may correspond to the order of the various elements and devices within the production device, specifically in a transport direction, is highly flexible. Additional applications may be added and/or one or more applications may be combined into one or more steps. Thus, the application of the adhesive and the production of the at least one continuous adhesive strip may also be combined with an application of the at least one test chemical and/or with other process steps. Thus, a combined application device for applying the liquid adhesive to the continuous substrate tape and for applying the test chemical to the continuous substrate tape, such as a 25 device having a plurality of nozzles or slots, may be used.

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Further, as outlined above, the step of generating intermediate products, such as intermediate products having one-sided or two-sided adhesive tapes, may be omitted. Thus, the manufacturing costs may be reduced additionally. Similarly, a step of providing an adhesive tape may be omitted. This step, which typically may be found in lamination processes, typically implies the substeps of: coating a carrier foil, drying the carrier foil with the adhesive, applying a liner to the surface of the adhesive, providing an appropriate cutting process for providing the adhesive tape in an appropriate format. All these process steps may be eliminated, such that the throughput may be increased and the costs of the manufacturing process may be reduced. Still, despite these advantages, the positioning accuracy 35 of the applied continuous adhesive strip, regarding its geometry (position and/or width) is

comparable to or even better than the results achieved by using conventional lamination techniques.

Further, as outlined above, as opposed to conventional lamination techniques, the production of continuous adhesive strips by using slot coating is less limited with regard to the width of the continuous adhesive strips. Thus, continuous adhesive strips having a width of as little as 1 mm may be generated. Further, simple test runs may be performed, for generating test tapes having the continuous substrate tape with the continuous adhesive strip disposed thereon, with or without a subsequent drying of the adhesive.

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Further, astonishingly, it turned out that the slot coating process is well suited for liquid adhesives of various types. Thus, as opposed to conventional applications of a slot coating process for high-viscous masses, such as in applying surface layers in paper technology and/or for coating reagent pastes, the slot coating process astonishingly also turned out to be highly flexible with regard to non-paste-like coating masses, such as adhesive liquids. Generally, a high flexibility regarding the viscosity of the adhesive liquids turned out to be applicable. Thus, all commercially available adhesive liquids turned out to be applicable, such as liquids having viscosities from 20 mPas to 10000 mPas.

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Further, the surface properties of the continuous adhesive strips turned out to be adjustable to the respective requirements. Thus, as outlined above, hydrophilic surfaces of the continuous adhesive strips turned out to be feasible, either by using adhesive-surfactant-mixtures or adhesives having a surfactant additive, and/or by using an additional step of applying surfactants to a surface of the adhesive test strip. These properties were specifically tested with acrylic liquid adhesives, such as acrylic liquid adhesives provided by Cytec Surface Specialties SA/NV, Brussels, Belgium, specifically of the Ucecryl type. In a pure format, these acrylic adhesives typically provide hydrophobic surface properties. However, by using surfactant additives and/or by applying one or more surfactants to the surface of the continuous adhesive strips, such as by using printing techniques, the surface properties could be modified, such as in order to perform a hydrophilic surface, all over the area of the continuous adhesive strip and/or over a part of the surface area of the continuous adhesive strip. As an example, Ucecryl® acrylic liquid adhesive is a polymer dispersion based on acrylic acid, having a pH of 3.5 to 5.5 and a solid content of 53.5 % to 56.5 %, and a viscosity of up to 350 mPas. As outlined above, preferably, the liquid adhesive preferably may comprise one or more liquid adhesives selected from the group consisting of: an Ucecryl® adhesive, as e.g. available by Cytec Surface Specialties SA/NV, Brussels, Belgium such as the Ucecryl® adhesives described in US 2009 0263652 A1. Additionally or alter-

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natively, one or more of the following liquid adhesives on the basis of an acrylate dispersion may be used: a helmitin® liquid adhesive, such as helmitin 35038; a swift®tak adhesive, such as swift®tak 2050; a technicoll® adhesive, such as technicoll® 9220 and/or technicoll® 921; a Dispercoll® adhesive, as available by Bayer MaterialScience AG, 5 Leverkusen, Germany, such as Dispercoll® U 56. Other liquid adhesives and/or combinations of the listed liquid adhesives and/or other liquid adhesives are feasible. All adhesives are available by Ruderer Klebetechnik GmbH, Zorneding, Germany.

Thus, summarizing, by using a direct application of the at least one liquid adhesive and by 10 using a slot coating process, the manufacturing turned out to be simplified in various ways and, still, turned out to provide a higher precision as compared to traditional manufacturing techniques.

The test elements provided by the method according to the present invention turned out to 15 be easily distinguishable from test elements manufactured by traditional techniques, such as by using lamination techniques and by using one-sided or double-sided adhesive tapes. Thus, generally, by conventional lamination techniques, continuous adhesive tapes having a width of less than 5 mm are hardly producible. Further, due to typical cutting processes used in adhesive laminates, traditional test elements typically provide a frayed or scraggy 20 border. Contrarily, when using the slot coating process, as proposed by the present invention, a sharp, well-defined borderline of the continuous adhesive strip was obtained. Further, in laminate setups using a double-sided or one-sided adhesive layer, typically, one or more substrate layers of the adhesive laminate may be detected. Similarly, the complex 25 layer setup of typical laminates, providing one or more adhesive layers and, typically, one or more substrate layers, in many applications tends to a mismatch with the continuous substrate tape, thereby leading to a waviness of the surface or even to a delamination of the setup. Thus, by using the direct slot coating process, as proposed in the present invention, an increased stability and a simplified and more stable layer setup may be provided.

30 Summarizing the findings of the present invention, the following embodiments are preferred:

Embodiment 1: A method for producing a test element for detecting at least one analyte in 35 a body fluid, the test element having at least one test chemical adapted to perform at least one detection reaction in the presence of the analyte, the method comprising the following steps:

a) a transport step, wherein a continuous substrate tape is provided, the continuous substrate tape being transported in a transport direction parallel to a direction of extension of the continuous substrate tape;

5 b) an adhesive application step, wherein at least one continuous adhesive strip is applied to the continuous substrate tape, by using a liquid adhesive and a slot coating process, the continuous adhesive strip being oriented parallel to the transport direction;

c) a cover element application step, wherein at least one cover element is applied to the continuous adhesive strip, thereby securing the cover element to the continuous substrate tape; and

10 d) an individualization step, wherein the continuous substrate tape is individualized into single test elements.

Embodiment 2: The method according to the preceding embodiment, further comprising the step of applying the test chemical to at least one of the continuous substrate tape and 15 the cover element.

Embodiment 3: The method according to one of the preceding embodiments, wherein the continuous adhesive strip has a width perpendicular to the transport direction of less than 5 mm.

20 Embodiment 4: The method according to the preceding embodiment, wherein the continuous adhesive strip has a width perpendicular to the transport direction of less than 4 mm.

Embodiment 5: The method according to one of the two preceding embodiments, wherein 25 the continuous adhesive strip has a width perpendicular to the transport direction of less than 3 mm.

Embodiment 6: The method according to one of the preceding embodiments, wherein the continuous adhesive strip has a width perpendicular to the transport direction of at least 1 30 mm and less than 5 mm.

Embodiment 7: The method according to one of the preceding embodiments, wherein the continuous adhesive strip has a width perpendicular to the transport direction of 0.5 mm to 40.0 mm, preferably a width of 1.0 mm to 5 mm, more preferably a width of 1.0 mm to 3.0 35 mm, preferably 2.0 mm.

Embodiment 8: The method according to one of the preceding embodiments, wherein at least two continuous adhesive strips are applied to the continuous substrate tape.

Embodiment 9: The method according to one of the preceding embodiments, wherein the

5 slot coating process comprises a slot die coating process.

Embodiment 10: The method according to one of the preceding embodiments, wherein the

slot coating process is adapted to apply a pressure of more than 1 bar to the liquid adhesive.

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Embodiment 11: The method according to one of the preceding embodiments, wherein the slot coating process is adapted to apply a pressure of 1 - 2 bar to the liquid adhesive.

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Embodiment 12: The method according to one of the preceding embodiments, wherein the liquid adhesive is supplied to a die of a die slot coater via a tubing system and at least one pump.

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Embodiment 13: The method according to one of the preceding embodiments, wherein, in the slot coating process, at least one slot die is used having a width perpendicular to the transport direction of less than 5 mm, preferably a width of less than 4 mm, and more preferably a width of less than 3 mm.

Embodiment 14: The method according to one of the three preceding embodiments, wherein the width is at least 1 mm.

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Embodiment 15: The method according to the preceding embodiment, wherein the width is 1-3 mm, preferably 2 mm.

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Embodiment 16: The method according to one of the preceding embodiments, wherein the continuous substrate tape is a flexible tape.

Embodiment 17: The method according to one of the preceding embodiments, wherein the continuous substrate tape comprises a plastic tape.

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Embodiment 18: The method according to one of the preceding embodiments, wherein the continuous substrate tape has a thickness of 10 µm to 1 mm, more preferably a thickness of 20 µm to 50 µm, and most preferably a thickness of 30 µm.

Embodiment 19: The method according to one of the preceding embodiments, wherein the continuous substrate tape is provided by using at least one supply reel.

5 Embodiment 20: The method according to one of the preceding embodiments, wherein the cover element comprises at least one functional element.

Embodiment 21: The method according to one of the preceding embodiments, wherein the cover element comprises at least one element selected from the group consisting of: a 10 spreading element; a capillary element; an electrode; a cover foil; a reagent foil comprising the at least one test chemical; a membrane for separating at least two components of the sample of the body fluid.

Embodiment 22: The method according to one of the preceding embodiments, wherein the 15 cover element is a continuous cover element being continuous in the direction of the extension of the substrate tape.

Embodiment 23: The method according to one of the preceding embodiments, wherein the cover element is provided by using at least one supply reel.

20 Embodiment 24: The method according to one of the preceding embodiments, wherein the at least one test chemical comprises at least one optical test chemical, wherein the optical test chemical is adapted to perform an optical detection reaction in the presence of the analyte, wherein at least one optically detectable property of at least one of the optical test 25 chemical and the body fluid changes due to the optical detection reaction.

Embodiment 25: The method according to one of the preceding embodiments, wherein the at least one test chemical comprises at least one electrochemical test chemical, wherein the electrochemical test chemical is adapted to perform at least one electrochemical detection 30 reaction in the presence of the analyte, wherein at least one electrically detectable property of at least one of the electrochemical test chemical and the body fluid changes due to the electrochemical detection reaction.

Embodiment 26: The method according to the preceding embodiment, wherein the method 35 further comprises the method step of applying at least one electrode to at least one of the continuous substrate tape and the cover element, wherein the electrochemical test chemical is applied to the electrode.

Embodiment 27: The method according to one of the preceding embodiments, wherein at least method steps b) and c) are performed in a continuous process.

5 Embodiment 28: The method according to the preceding embodiment, wherein no intermediate product is spooled onto a reel.

Embodiment 29: The method according to one of the two preceding embodiments, wherein the continuous process comprises a reel process.

10 Embodiment 30: The method according to one of the preceding embodiments, wherein the liquid adhesive has a viscosity of 20 mPas to 10000 mPas.

15 Embodiment 31: The method according to one of the preceding embodiments, wherein the liquid adhesive has a viscosity of more than 100 mPas.

20 Embodiment 32: The method according to one of the preceding embodiments, wherein the continuous adhesive strip has a thickness of 2 μm to 150 μm , preferably of 10 μm to 100 μm , more preferably of 5 μm to 50 μm , and most preferably of 10 μm to 20 μm , such as 15 μm .

25 Embodiment 33: The method according to one of the preceding embodiments, further comprising at least one drying step, wherein the continuous adhesive strip is at least partially dried in the drying step.

30 Embodiment 34: The method according to the preceding embodiment, wherein the drying step comprises at least one of: a heating of the adhesive strip; an exposure of the adhesive strip to hot gas; an exposure of the adhesive strip to electromagnetic radiation, preferably electromagnetic radiation in the ultraviolet spectral range.

35 Embodiment 35: The method according to one of the two preceding embodiments, wherein the drying step implies a drying by using at least one heating channel and/or at least one heating plate.

35 Embodiment 36: The method according to one of the preceding embodiments, wherein the cover element is pressed onto the continuous adhesive strip.

Embodiment 37: The method according to one of the preceding embodiments, wherein the liquid adhesive is an acrylic liquid adhesive.

Embodiment 38: The method according to one of the preceding embodiments, wherein the

5 liquid adhesive is a water-based liquid adhesive, preferably a water-borne emulsion.

Embodiment 39: The method according to one of the preceding embodiments, wherein the liquid adhesive comprises at least one surface-active additive, preferably at least one surfactant and, more preferably, at least one hydrophilic surfactant.

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Embodiment 40: The method according to one of the preceding embodiments, wherein the method further comprises at least one step of applying at least one surfactant to a surface of the continuous adhesive strip, preferably at least one hydrophilic surfactant.

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Embodiment 41: The method according to one of the preceding embodiments, wherein the slot coating process implies the use of a die being separated from a surface of the continuous substrate tape by 20 µm to 1.0 mm, preferably by 30 µm to 90 µm.

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Embodiment 42: The method according to one of the preceding embodiments, further comprising the step of applying at least one continuous liner to the continuous adhesive strip, wherein the continuous liner is removed before applying the at least one cover element to the continuous adhesive strip.

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Embodiment 43: The method according to one of the preceding embodiments, wherein the continuous substrate tape is transported in the transport direction at a transport speed of 1 m/min to 150 m/min, preferably of 10 m/min to 100 m/min, more preferably of 20 m/min to 80 m/min, and most preferably of about 40 m/min.

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Embodiment 44: The method according to one of the preceding embodiments, wherein the adhesive application step is performed during a continuous transportation of the continuous substrate tape, preferably at a constant speed.

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Embodiment 45: The method according to one of the preceding embodiments, wherein the individualization step comprises a cutting of the continuous substrate tape in a cutting direction perpendicular to the transport direction.

Embodiment 46: A production device for producing a test element for detecting at least one analyte in a body fluid, the test element having at least one test chemical adapted to perform at least one detection reaction in the presence of the analyte, the production device comprising:

- 5 I. a tape transport device, the tape transport device being adapted for providing a continuous substrate tape, the tape transport device being adapted to transport the continuous substrate tape in a transport direction parallel to a direction of extension of the continuous substrate tape;
- 10 II. an adhesive application device, the adhesive application device being adapted for applying at least one continuous adhesive strip to the continuous substrate tape, by using a liquid adhesive and a slot coating process, the continuous adhesive strip being oriented parallel to the transport direction;
- 15 III. a cover element application device, the cover element application device being adapted for applying at least one cover element to the continuous adhesive strip, thereby securing the cover element to the continuous substrate tape; and
- IV. an individualization device, the individualization device being adapted for individualizing the continuous substrate tape into single test elements.

Embodiment 47: The production device according to the preceding embodiment, wherein the production device is adapted to perform the method according to one of the preceding embodiments referring to a method.

Embodiment 48: The production device according to one of the preceding embodiments referring to a production device, wherein the production device is adapted to perform a reel process, wherein at least the continuous substrate tape is supplied by at least one supply reel.

Embodiment 49: The production device according to one of the preceding embodiments referring to a production device, further comprising at least one test chemical application device, wherein the test chemical application device is adapted to apply the at least one test chemical to at least one of the continuous substrate tape and the cover element.

Embodiment 50: The production device according to one of the preceding embodiments referring to a production device, wherein the adhesive application device comprises at least one die slot coater.

Embodiment 51: The production device according to one of the preceding embodiments referring to a production device, wherein the adhesive application device is adapted to apply at least two continuous adhesive strips to the continuous substrate tape.

5 Embodiment 52: The production device according to one of the preceding embodiments referring to a production device, wherein the adhesive application device comprises at least one pressurizing device adapted to apply a pressure of more than 1 bar to the liquid adhesive.

10 Embodiment 53: The production device according to one of the preceding embodiments referring to a production device, wherein the adhesive application device comprises a tubing system and at least one pump for supplying the liquid adhesive.

15 Embodiment 54: The production device according to one of the preceding embodiments referring to a production device, wherein the adhesive application device comprises at least one slot die.

20 Embodiment 55: The production device according to the preceding embodiment, wherein the slot die has a width perpendicular to the transport direction of less than 5 mm, preferably of less than 4 mm, and more preferably a width of less than 3 mm.

Embodiment 56: The production device according to one of the two preceding embodiments, wherein the slot die has a width of at least 1 mm.

25 Embodiment 57: The production device according to one of the three preceding embodiments, wherein the slot die has a width of 1-3 mm, preferably 2 mm.

30 Embodiment 58: The production device according to one of the preceding embodiments referring to a production device, wherein the cover element application device comprises at least one supply reel.

35 Embodiment 59: The production device according to one of the preceding embodiments referring to a production device, further comprising at least one electrode application device, wherein the electrode application device is adapted to apply at least one metal electrode or electrode material to at least one of the continuous substrate tape and the cover element.

Embodiment 60: The production device according to one of the preceding embodiments referring to a production device, wherein the production device further comprises at least one surfactant application device, wherein the surfactant application device is adapted to apply at least one surfactant to a surface of the continuous adhesive strip.

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Embodiment 61: The production device according to one of the preceding embodiments referring to a production device, wherein the tape transport device is adapted to transport the continuous substrate tape at a transport speed of 1 m/min to 150 m/min, preferably of 10 m/min to 100 m/min, more preferably of 20 m/min to 80 m/min, and most preferably of 10 10 about 40 m/min.

Embodiment 62: A test element for detecting at least one analyte in a body fluid, the test element having at least one substrate and at least one cover element mounted to the substrate via at least one adhesive strip, the test element further having at least one test chemical adapted to perform at least one detection reaction in the presence of the analyte, wherein the test element is producible by the method according to one of the preceding embodiments referring to a method.

Embodiment 63: The test element according to the preceding embodiment, wherein the test 20 element further comprises at least one capillary element.

Embodiment 64: The test element according to one of the two preceding embodiments, wherein the test element is a test strip.

25 Embodiment 65: A use of a slot coating process, preferably a slot die coating process, for applying at least one adhesive strip to a test element for detecting at least one analyte in a body fluid.

Short description of the Figures

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Further optional features and embodiments of the invention will be disclosed in more detail in the subsequent description of preferred embodiments, preferably in conjunction with the dependent claims. Therein, the respective optional features may be realized in an isolated fashion as well as in any arbitrary feasible combination, as the skilled person will realize.

35 The scope of the invention is not restricted by the preferred embodiments. The embodiments are schematically depicted in the Figures. Therein, identical reference numbers in these Figures refer to identical or functionally comparable elements.

In the Figures:

Figure 1 shows an exemplary embodiment of a production device for producing a test element for detecting at least one analyte in a body fluid, in a side view;

Figure 2 shows a simplified setup of a potential embodiment of an adhesive application device and a test chemical application device which may be used in the production device of Figure 1, in a partial perspective view; and

Figures 3 shows an embodiment of a test element producible by the method according to the present invention in a cross-sectional view.

Detailed description of the embodiments

In Figure 1, in a schematic side view, an embodiment of a production device 110 for producing a plurality of test elements 112 is depicted in a side view. The test elements 112 are adapted for detecting at least one analyte in a body fluid and each have at least one test chemical adapted to perform at least one detection reaction in the presence of the analyte.

Embodiments of the test element 112 will be disclosed in further detail below.

The production device, in this embodiment, is adapted to perform a method according to the present invention and, preferably, is adapted to perform a continuous in-line application process. The production device 110, for this purpose, provides a supply reel 114 for providing a continuous substrate tape 116. The supply reel 114 is part of a tape transport device 118 which may further comprise additional elements, such as one or more drives 120 and/or one or more rollers 122 and/or transport wheels. The transport device 118 is adapted to transport the continuous substrate tape 116 in a transport direction 124, which may be a continuous and steady transport direction 124 and/or which may comprise one or more turns or changes of the transport direction 124.

The production device 110 further comprises at least one adhesive application device 126 for applying one or more liquid adhesives 128 to the continuous substrate tape 116, thereby generating one or more continuous adhesive strips being oriented parallel to the transport direction 124, which is also a direction 130 of an extension of the continuous substrate tape 116. Thus, preferably, the continuous adhesive strip or continuous adhesive strips preferably are parallel to lateral edges of the continuous substrate tape 116. Preferably, at the loca-

tion of the adhesive application device 126, the transport direction 124 is a horizontal direction. However, other embodiments are feasible, such as non-vertical directions and/or even an application on the surface of an application wheel.

5 The production device 110 further comprises at least one cover element application device 132. The cover element application device 132 may be adapted to provide at least one cover element 134, preferably a continuous cover element 134, to the at least one continuous adhesive strip, which is not depicted in Figure 1 and which will be explained in further detail with respect to Figure 2 below. The cover element application device 132 may provide one or more supply reels 136 and/or one or more optional drives, which are not depicted. Further, additional elements may be provided, such as rollers 122. Preferably, the cover element 134 is or comprises a coated or non-coated continuous foil tape.

10 15 The production device 110 further comprises at least one individualization device 138. As depicted in Figure 1, the individualization device 138 may comprise one or more cutting devices, preferably for cutting the continuous substrate tape 116, with the at least one continuous adhesive strip and the cover element 134 disposed thereon, in a cutting direction perpendicular to the transport direction 124.

20 The production device 110 may comprise one or more additional devices. Thus, as depicted in Figure 1, at least one test chemical application device 140 may be provided, for providing one or more test chemicals 142 to the continuous test substrate 116, preferably in the form of one or more continuous test chemical strips, such as one or more test chemical strips being oriented parallel to the transport direction 124.

25 The at least one optional test chemical application device, which may be adapted to apply the test chemical to the continuous substrate tape 116 and/or to the cover element 134, may be located in various ways. Thus, as depicted in Figure 1, the test chemical application device 140 may be positioned upstream the at least one adhesive application device 126, 30 with regard to the transport direction 124. Additionally or alternatively, the at least one test chemical application device 140 may be located downstream the at least one adhesive application device 126 and/or may be located at the same position, with regard to the transport direction 124, as the adhesive application device 126.

35 Further, the production device 110 may optionally comprise one or more surfactant application devices 144. Thus, as an example, the at least one optional surfactant application device 144 may be located downstream the at least one adhesive application device 126

and may be adapted to apply at least one surfactant to a surface of the continuous adhesive strip. Thus, the at least one surfactant application device 144 may comprise one or more print heads and/or nozzles, such as one or more piezo print heads, for applying the surfactant.

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In Figure 2, a partial perspective view of the production device 110 is shown. In this embodiment, a perspective top view onto the continuous substrate tape 116 is shown. As can be seen in this top view, one or more electrodes 146 may be deposited on a surface of the continuous substrate tape 116, each electrode 146 being contacted via at least one contact pad 148 and appropriate leads 150. Further, virtual cutting lines 152 are shown, which indicate a separation between neighboring test elements 112 after the cutting step performed by the individualization device 138. After individualization along the virtual cutting lines 152, the continuous substrate tape 116 is divided into substrates 153. Similarly, the continuous adhesive strip 154 is divided into adhesive strips 155. The continuous test chemical strip 156 may be divided into individual test fields 157.

Further, in Figure 2, an optional embodiment of the adhesive application device 126 and/or the test chemical application device 140 is shown. Thus, in this specific embodiment, a combined application device is used which provides two adhesive application devices 126 and one test chemical application device 140. The adhesive application devices 126 provide a slot coater, preferably a die slot coater, adapted to apply one or more than one continuous adhesive strips 154 to the continuous substrate tape 116. In this specific embodiment, as an example, two parallel continuous adhesive strips 154 are provided, one of them on the left hand side being located outside the electrodes 146, and the other one, on the right hand side, being located in the area of the leads 150. The continuous adhesive strips 154 may have the same width perpendicular to the transport direction 124 and/or may have a different width. Other embodiments, such as other locations of the continuous adhesive strips 154, are feasible.

30 Further, the combined application device comprises the at least one test chemical application device 140. This test chemical application device 140 may also comprise one or more slot coaters and is adapted for applying at least one test chemical 142 to the continuous substrate tape 116. As an example, in this embodiment or other embodiments of the present invention, a continuous test chemical strip 156 may be generated, which, preferably, is oriented parallel to the transport direction 124. As an example, the test chemical application device 140 may also be or comprise at least one slot coater, preferably a die slot coat-

er. However, additionally or alternatively, other techniques may be used for depositing the at least one test chemical 142, such as non-continuous techniques.

As depicted in the exemplary embodiment of Figure 2, preferably, the at least one test chemical 142 is applied to at least one of the electrodes 146, such as to one working electrode. Preferably, one or more of the electrodes 146 remain free of the test chemical 142. Further, preferably, the contact pads 148 remain free both of the liquid adhesive 128 and the test chemical 142, in order to provide a sufficient electrical contact.

For providing the liquid adhesive 128 to the adhesive application device 126, one or more tanks 158 may be provided, in conjunction with an appropriate tubing system 160 and/or with at least one pump 162. Similarly, for providing the test chemical 142, preferably in a liquid form and/or as a paste, a tank 164 may be provided, in conjunction with a tubing system 166 and/or at least one pump 168.

The production device 110 may comprise one or more additional elements. Thus, as schematically depicted in Figure 1, the production device 110 optionally may comprise one or more drying devices 170, such as one or more heating plates and/or one or more electromagnetic radiation sources. Further, additionally or alternatively, the production device 110 may comprise one or more pressurizing devices 172, such as one or more pressurizing devices 172 adapted to press the cover element 134 onto the continuous adhesive strip 154 and/or onto the continuous substrate tape 116. Thus, the at least one pressurizing device 172, as depicted in Figure 1, may comprise one or more nibs or roller gaps between two rollers 122. Other embodiments are feasible.

In Figure 3, an exemplary embodiment of a test element 112 is depicted which is producible by the method according to the present invention and/or by using the production device 110 according to the present invention. The test element 112 is depicted in a cross-sectional view, such as in a direction of view parallel to the direction of extension 130 of the continuous substrate tape 116 in Figure 2.

The test element 112 comprises one or more substrates 153, which, as outlined above, may be cut from a continuous substrate tape 116 (see e.g. Figure 2 above). To the substrate 153, one or more adhesive strips 155 are applied, which are generated by the adhesive application step, as outlined above. Further, one or more cover elements 134 are applied to the adhesive strips 155, which may be generated by the above-mentioned adhesive application step, followed by the individualization step, in which one or more continuous adhesive

strips 154, e.g. as shown in Figure 2 above, may be cut into the adhesive strips 155. Further, the test element 112 may optionally comprise one or more test fields 157, which each may comprise one or more test chemicals and/or other types of reagents and which may be generated by a slot coating process and/or by any other suitable process, such as at least 5 one printing process.

The substrate 153 may comprise a plastic foil 224, covered by a conductive layer 226 facing in an upward direction. The at least one conductive layer 226 may be patterned in an arbitrary fashion. The at least one conductive layer 226 provides one or more contact pads 10 148. On top of the conductive layer 226, a test field 157 having one or more test chemicals 142 is applied. On both sides of the test field 157, adhesive strips 155 are provided, which, in this case, preferably have electrically insulating properties.

On top of the adhesive strips 155, one or more cover elements 134 are applied, which, in 15 this embodiment, may comprise a plurality of elements. Thus, on top of the adhesive strips 155, firstly, a membrane 228 is applied, which covers the test field 157 and which is adapted to separate particulate components from the sample of the body fluid, such as in order to separate red blood cells from a sample of whole blood penetrating the membrane 228. On top of the membrane 228, a cover foil 230 may be provided, which, on its side 20 facing the membrane 228, comprises an adhesive layer 232. As an example, an adhesive tape may be used for the cover foil 230.

The cover foil 230 comprises a through-hole 234 which allows for an application of a sample of the body fluid onto the membrane 228. By the membrane 228, particulate components 25 are separated from the sample, whereas the remainder of the sample may penetrate the membrane 228 and reach the test field 157, where a test reaction may take place.

The method and the production device according to the present invention generally may be used for manufacturing optical test elements, electrochemical test elements, such as in Figure 3, or hybrid test elements, i.e. test elements comprising both means for optical measurements and for electrochemical measurements.

List of reference numbers

- 110 production device
- 112 test element
- 114 supply reel
- 116 continuous substrate tape
- 118 tape transport device
- 120 drive
- 122 roller
- 124 transport direction
- 126 adhesive application device
- 128 liquid adhesive
- 130 direction of extension
- 132 cover element application device
- 134 cover element
- 136 supply reel
- 138 individualization device
- 140 test chemical application device
- 142 test chemical
- 144 surfactant application device
- 146 electrode
- 148 contact pad
- 150 lead
- 152 virtual cutting line
- 153 substrate
- 154 continuous adhesive strip
- 155 adhesive strip
- 156 continuous test chemical strip
- 157 test field
- 158 tank
- 160 tubing system
- 162 pump
- 164 tank
- 166 tubing system
- 168 pump
- 170 drying device
- 172 pressurizing device

- 41 -

224 plastic foil
226 conductive layer
228 membrane
230 cover foil
232 adhesive layer
234 through-hole

Claims

1. A method for producing a test element (112) for detecting at least one analyte in a body fluid, the test element (112) having at least one test chemical (142) adapted to perform at least one detection reaction in the presence of the analyte, the method comprising the following steps:
 - a) a transport step, wherein a continuous substrate tape (116) is provided, the continuous substrate tape (116) being transported in a transport direction (124) parallel to a direction of extension (130) of the continuous substrate tape (116);
 - b) an adhesive application step, wherein at least one continuous adhesive strip (154) is applied to the continuous substrate tape (116), by using a liquid adhesive (128) and a slot coating process, the continuous adhesive strip (154) being oriented parallel to the transport direction (124);
 - c) a cover element application step, wherein at least one cover element (134) is applied to the continuous adhesive strip (154), thereby securing the cover element (134) to the continuous substrate tape (116); and
 - d) an individualization step, wherein the continuous substrate tape (116) is individualized into single test elements (112).
2. The method according to the preceding claim, further comprising the step of applying the test chemical (142) to at least one of the continuous substrate tape (116) and the cover element (134).
3. The method according to one of the preceding claims, wherein the continuous adhesive strip (154) has a width perpendicular to the transport direction (124) of less than 5 mm.
4. The method according to one of the preceding claims, wherein at least two continuous adhesive strips (154) are applied to the continuous substrate tape (116).
5. The method according to one of the preceding claims, wherein the continuous substrate tape (116) is a flexible tape.
6. The method according to one of the preceding claims, wherein the continuous substrate tape (116) comprises a plastic tape.

7. The method according to one of the preceding claims, wherein the cover element (134) is a continuous cover element (134) being continuous in the direction of the extension (130) of the substrate tape.

5

8. The method according to one of the preceding claims, wherein the liquid adhesive (128) has a viscosity of 20 mPas to 10000 mPas.

9. The method according to one of the preceding claims, further comprising at least one drying step, wherein the continuous adhesive strip (154) is at least partially dried in the drying step.

10. The method according to one of the preceding claims, wherein the cover element (134) is pressed onto the continuous adhesive strip (154).

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11. The method according to one of the preceding claims, wherein the method further comprises at least one step of applying at least one surfactant to a surface of the continuous adhesive strip (154), preferably at least one hydrophilic surfactant.

20 12. A production device for producing a test element (112) for detecting at least one analyte in a body fluid, the test element (112) having at least one test chemical (142) adapted to perform at least one detection reaction in the presence of the analyte, the production device comprising:

25 I. a tape transport device, the tape transport device being adapted for providing a continuous substrate tape (116), the tape transport device being adapted to transport the continuous substrate tape (116) in a transport direction (124) parallel to a direction of extension (130) of the continuous substrate tape (116);

II. an adhesive application device, the adhesive application device being adapted for applying at least one continuous adhesive strip (154) to the continuous substrate tape (116), by using a liquid adhesive (128) and a slot coating process, the continuous adhesive strip (154) being oriented parallel to the transport direction (124);

30 III. a cover element application device (132), the cover element application device (132) being adapted for applying at least one cover element (134) to the continu-

ous adhesive strip (154), thereby securing the cover element to the continuous substrate tape (116); and

IV. an individualization device (138), the individualization device (138) being adapted for individualizing the continuous substrate tape (116) into single test elements (112).

5. 13. The production device according to the preceding claim, further comprising at least one test chemical application device (140), wherein the test chemical application device (140) is adapted to apply the at least one test chemical (142) to at least one of the continuous substrate tape (116) and the cover element (134).

14. A test element (112) for detecting at least one analyte in a body fluid, the test element (112) having at least one substrate (153) and at least one cover element (134) mounted to the substrate (153) via at least one adhesive strip (155), the test element (112) further having at least one test chemical (142) adapted to perform at least one detection reaction in the presence of the analyte, wherein the test element (112) is producible by the method according to one of the preceding method claims.

15. A use of a slot coating process for applying at least one adhesive strip (155) to a test element (112) for detecting at least one analyte in a body fluid.

1/3

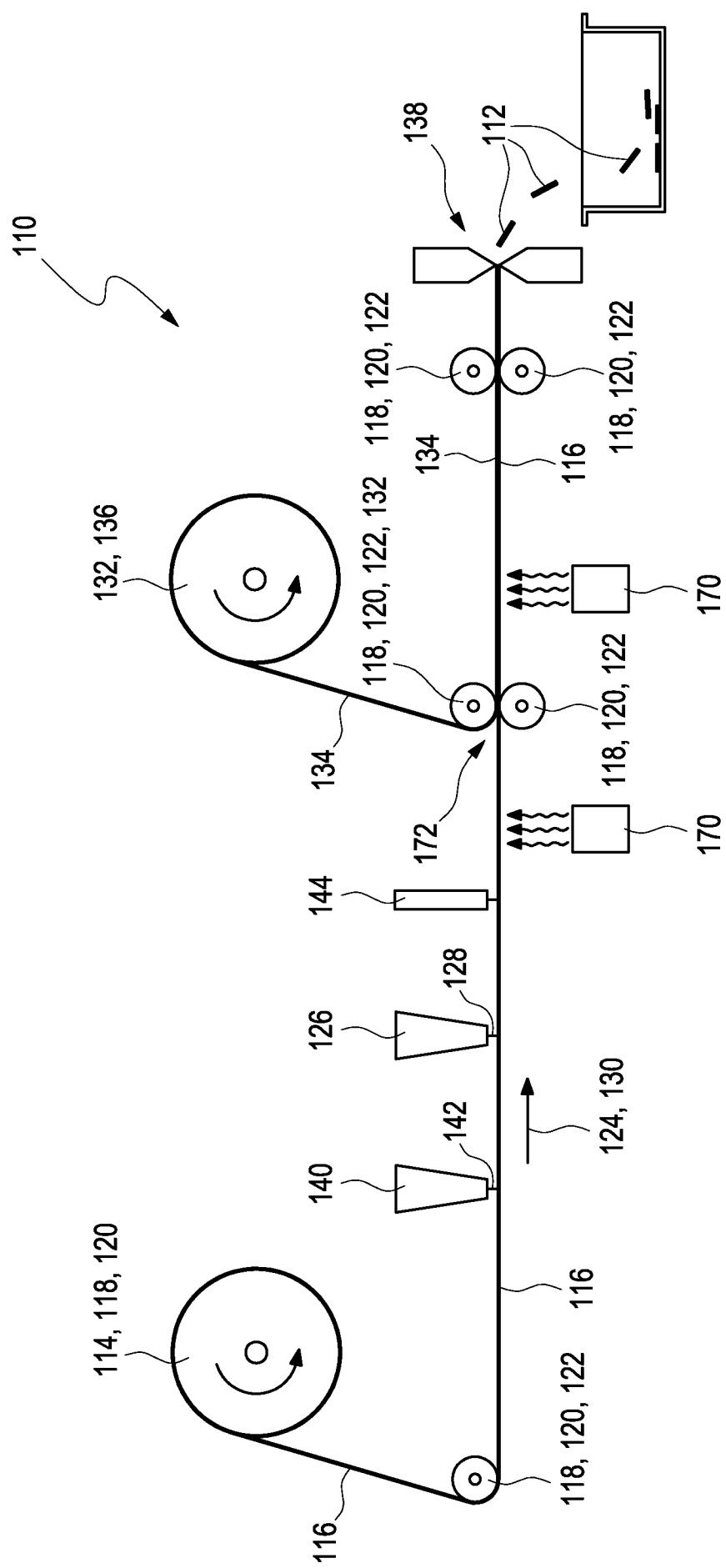


Fig. 1

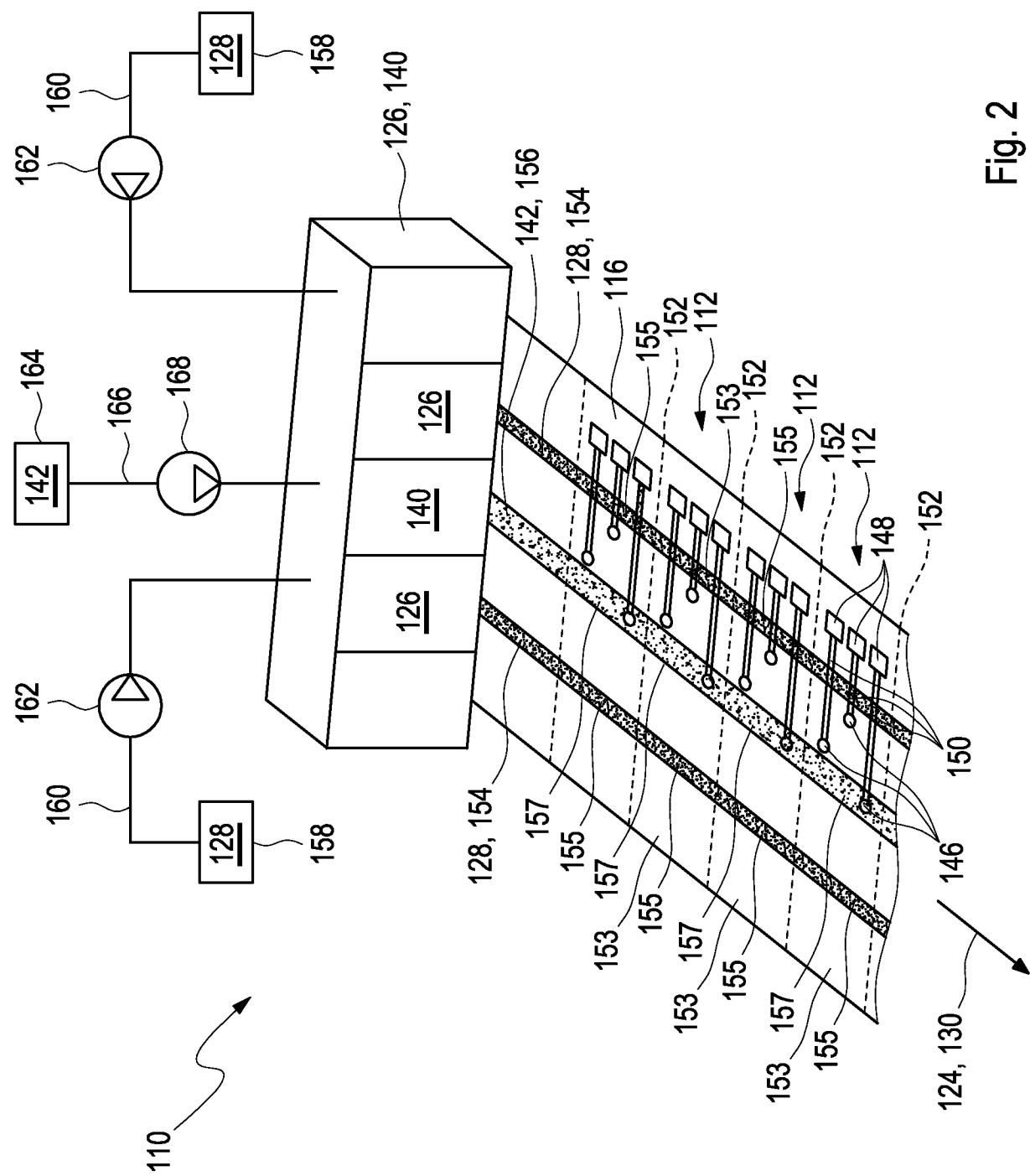


Fig. 2

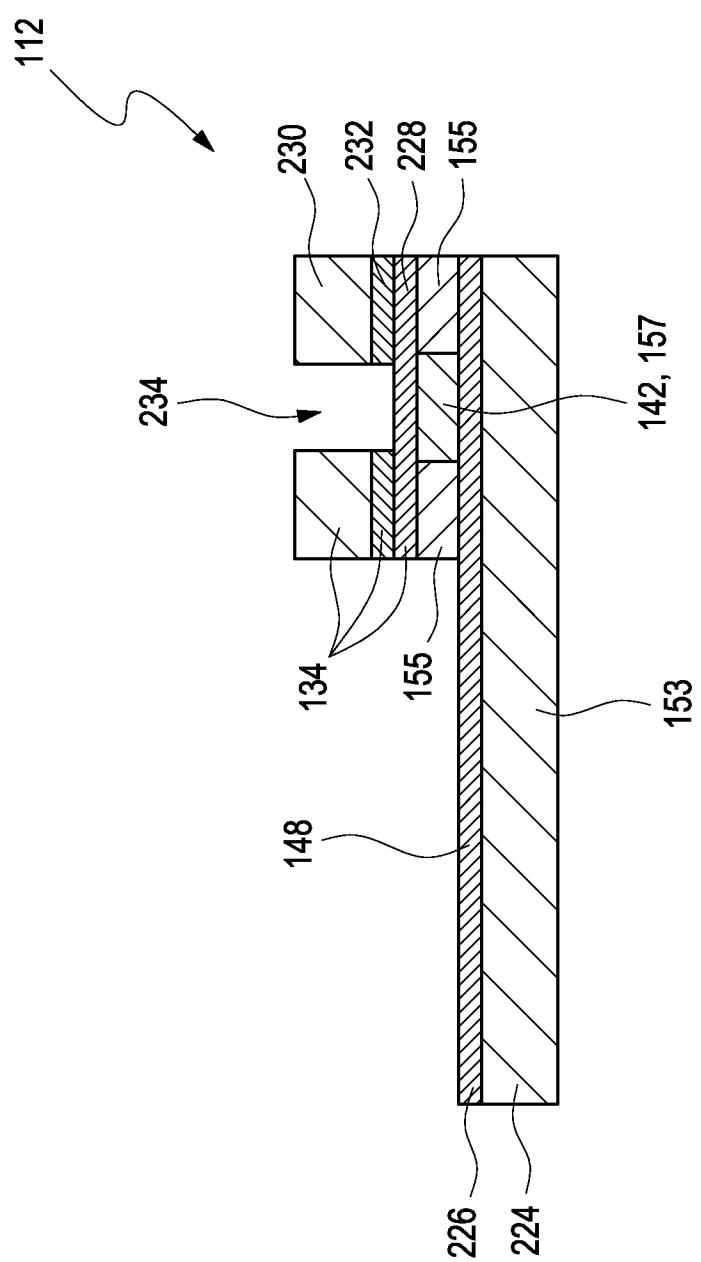


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/061983

A. CLASSIFICATION OF SUBJECT MATTER
INV. G01N27/327
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G01N B01L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 291 650 A1 (ARKRAY INC [JP]) 12 March 2003 (2003-03-12) cited in the application paragraphs [0051] - [0055]; figures 8,9 -----	14,15
Y	US 2008/164142 A1 (ALVAREZ-ICAZA MANUEL [GB] ET AL) 10 July 2008 (2008-07-10) cited in the application figure 4 -----	1-13
Y	US 2008/164142 A1 (ALVAREZ-ICAZA MANUEL [GB] ET AL) 10 July 2008 (2008-07-10) cited in the application figure 4 -----	1-13
X	EP 0 297 389 A2 (BOEHRINGER MANNHEIM GMBH [DE]) 4 January 1989 (1989-01-04) cited in the application column 5, lines 20-36; figure 3 sentences 34-46; figure 5 ----- -/-	1-15

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
1 July 2014	09/07/2014
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Wilhelms-Shalganov, J

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/061983

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 612 554 A1 (LIFESCAN INC [US]) 4 January 2006 (2006-01-04) cited in the application paragraph [0028]; figure 1 -----	14,15
A	US 2004/251132 A1 (LEACH CHRISTOPHER PHILIP [GB] ET AL) 16 December 2004 (2004-12-16) paragraph [0046]; figures 1A, 1B -----	1-15
A	US 2012/263879 A1 (WILSEY CHRISTOPHER D [US] ET AL) 18 October 2012 (2012-10-18) abstract; figures 1,4 -----	1-15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2014/061983

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