

Test tape cassette and analytical test tape therefor

Description

The invention concerns an analytical test tape in particular for use in a test tape cassette having a carrier tape that can be wound onto a spool and a plurality of test
5 elements that are distributed on the carrier tape in the tape longitudinal direction and have a spreading fabric for applying body fluid and an underlying reagent layer for detecting an analyte in the body fluid, wherein the spreading fabric is formed from fabric threads that are crossed in a grid shape. The invention additionally concerns a test tape cassette for insertion into a hand-held device, in particular for
10 blood sugar tests, comprising a cassette housing for storing tape spools, an analytical test tape that can be wound forwards by means of the tape spools, a plurality of analytical test elements stored on the test tape which have a spreading fabric for applying body fluid and an underlying reagent layer for detecting an analyte in the body fluid, wherein the cassette housing has an application tip that
15 deflects the test tape in order to provide the test elements.

In a test tape cassette of this type known from EP-A 1 878 379 the tape guide has a flat support frame on a measuring head which stretches a test element in a flat manner at the site of measurement. In this process the test tape is bent, starting from deflecting bevels, over the sides of the frame that run perpendicular to the tape
20 direction in order to achieve a freely stretched flat position. The label-like test elements or test fields used for the measurement have a central chemical carrier the side edges of which are engaged behind by the spreading fabric. A possible disadvantage of this has turned out to be that under the prevailing strains on the test tape structure on the flat support frame a gap may form between the spreading net
25 and the chemical carrier as illustrated in the drawing in fig. 9. In this case the gap dimensions are largest in the centre and decrease towards the sides which can

generate different capillary forces and ultimately result in undesired distributions (that may have a preferred direction) of the measuring medium.

In particular it was found that such a gap formation amplifies the tendency for "dewetting" i.e. a migration of the blood sample from the wetted fabric meshes and
5 increases the sensitivity towards contaminants (e.g. glucose) present on the skin of the user. The latter effect can be due to the fact that capillary blood collected by a skin puncture forms a drop of blood at the puncture site in which contaminants are initially concentrated in the boundary area that is in contact with the skin. The
10 "native" blood is then firstly distributed into the boundary areas of the chemical carrier due to the gap formation in the spreading fabric while the contaminated blood that flows in afterwards then reaches the central measuring spot which can impair the measuring performance.

Based on this the object of the invention is to optimize the test tape systems and the disposable test means used therein that are known in the prior art and to ensure a
15 further improved reliability and accuracy of the measurement.

The combination of features stated in the independent patent claims is proposed to achieve this object. Advantageous embodiments and further developments of the invention are derived from the dependent claims.

According to a preferred aspect of the invention, an analytical test tape is provided
20 especially for use in a test tape cassette in which the bending stiffness of the spreading fabric is modified by irregular changes in the property of the fabric threads in certain sections or locally. This allows the direction-dependent strains in the area of the application tip to be accordingly compensated for and taken into consideration in order to avoid gap formation. This can be optimized by adapting
25 the bending stiffness of the spreading fabric in order to reduce the gap between the

spreading fabric and the reagent layer of a test field provided for the application of body fluid.

An advantageous option for such a non-isotropic, area-by-area fabric modification is for the fabric threads to have reduced thread cross-sections in places preferably
5 by means of laser ablation or etching or mechanical removal of material.

Alternatively or in addition it is also possible that the fabric threads have a non-uniform design due to different thread materials, thread sizes, coatings or filament structures in order to modify the bending stiffness.

The bending stiffness can also be specifically adapted by locally varying the fabric
10 geometry of the spreading fabric for example by detaching individual fabric threads.

According to a further preferred embodiment the spreading fabric is wider than the reagent layer and is supported flat on the test tape by means of spacers in the area of its protruding side edges. This allows undesired gap formation associated with
15 fabric bending to be further suppressed.

In order to find a good compromise between an adequate minimum thickness for sample distribution and the radius of the wound up and used test tape, it is advantageous when the spreading fabric has a thickness of less than 150, preferably less than 110 μm .

20 A further aspect of the invention is based on the idea of designing the tape guide geometry and the test field structure in such a manner that gap formation between the spreading fabric and chemical carrier is substantially minimized under operating conditions. Accordingly it is proposed according to a this aspect of the invention that the application tip has a guide path which extends longitudinally to the test tape

(or in the direction of tape travel) in an arch shape and is uncurved crosswise thereto for supporting the test tape in a kink-free manner, and that the apex area of the guide path delimits a central opening as a measuring window for an optical measurement on the test elements. The arch-shaped longitudinal curvature of the guide path or running surface enables the bending stiffness of the test elements and in particular of the spreading fabric to be taken into account by means of an evenly supporting mechanical underbody thus avoiding sharp tape bends and hence gap formation. In order to avoid displacements in the multilayer structure, the tape curvature is only in one dimension, whereas an uncurved support is achieved in the tape transverse direction. At the same time the arched shape of the guide path can also ensure a targeted sample pick-up of even very small amounts of sample at the apex and, due to the measuring window positioned there in the form of a clear opening, also enables a reduction of the required test field area.

Another improvement in this regard can be achieved by means of the fact that the arc-shaped guide path has a fixed radius of curvature preferably in the range of 3 to 5 mm, and that the guide path has a longitudinal extension in the direction of tape transport in the range of 5 to 8 mm. In this connection it is advantageous when the longitudinal extension of the guide path is the same or less than the length of the test elements which is preferably in the range of 5 to 15 mm.

The operating conditions and in particular the tape pulling force should be adapted such that the test tape under tension is supported in a planar fashion on the guide path so that the spreading fabric lies essentially gap-free on the reagent layer.

In order to avoid gap formation under the unglued central area of the spreading fabric, it is advantageous when the reagent layer viewed in the tape transverse direction is narrower than the test tape and wider than the measuring window.

For an optimized optical detection of measured values from the rear side, it is advantageous when a housing wall of the application tip forming the guide path is bevelled on the rear side towards the measuring window.

5 In order to achieve usage and manufacturing advantages it is advantageous when the application tip is moulded in one piece preferably as an injection moulded part on the cassette housing and projects from the hand-held device in the operating state in order to punctually apply body fluid.

The invention is further elucidated in the following on the basis of the embodiment examples shown schematically in the drawing.

- 10 Fig. 1 shows a hand-held device for blood sugar tests comprising a test tape cassette inserted as a consumable in a partially broken side-view;
- Fig. 2 shows a section of a test tape of the test tape cassette with an analytical test element in a perspective view;
- Fig. 3 shows a housing member of the test tape cassette in a perspective view;
- 15 Fig. 4 shows an application tip of the test tape cassette in a top-view, in a longitudinal section and in cross-section;
- Fig. 5 and 6 show a section along the line 5 - 5 and 6 - 6 in fig. 4;
- Fig. 7 shows a spreading fabric for an analytical test element with weakened spots in a partial top-view;
- 20 Fig. 8 shows a further embodiment of a modified spreading fabric;

Fig. 9 shows a test field on an application tip according to the prior art in a cutaway perspective view.

The blood sugar measuring system 10 shown in fig. 1 enables glucose determinations to be carried out locally on blood samples collected by a skin
5 puncture especially for insulin-dependent patients. For this purpose the hand-held device 12 can be held and used in the hand of a subject as a mobile laboratory. In order to substantially simplify the handling, a test tape cassette 14 can be inserted into a cassette slot 16 of the device 12 as an analytical consumable for storing a plurality of individual tests, whereby in the operating state (with the protective cap
10 removed) an application tip 18 projects freely from the device 12 so that a test tape 20 can be deflected in this position in order to apply a drop of blood on the upper side to carry out a photometric analysis on the rear side. It is also possible to analyse other body fluids, for example tissue fluid.

Fig. 2 shows a section of the test tape 20 guided in the test tape cassette 14. This
15 comprises a windable flexible transport tape 22 and a plurality of test elements 24 stored thereon for successive single use and spaced apart from one another in the tape longitudinal direction. For example the transport tape 22 consists of a 5 mm wide and 12 μm thick foil on which the test elements 24, each having a total height of about 200 μm , are mounted.

20 The multilayer test elements 24 which are label-like flat structures with a rectangular outline have a double-sided adhesive strip 26 glued onto the transport tape 22, a chemical carrier 28 mounted thereon and a spreading fabric 30 that spans the chemical carrier 28 on the upper side facing away from the transport tape 20 for a two-dimensional dispersion of a blood sample applied from above onto the
25 spreading fabric. Spacers 32 are provided on the sides next to the chemical carrier 28 in order to support the whole area of the spreading fabric 30 in a flat and step-free manner.

The chemical carrier 28 comprises a light-permeable carrier foil 34 and a reagent layer 36 mounted thereon which is built up in a known manner from an upper pigment layer with an underlying dry chemistry film.

5 The spacers 32 consist of a base strip 40 adhering to the upper adhesive layer 38 of the double-sided adhesive strip 26 and an adhesive layer 42 located thereon for laterally attaching the spreading fabric 30.

10 The spreading fabric 30 shown only schematically in fig. 2 and with the thickness not to scale, is formed by grid-like interlaced fabric threads 44, 46. These can be connected together as warp threads 44 and weft threads 46 in plane weave and have a non-uniform structure to locally modify the bending stiffness as elucidated in more detail below. The spreading fabric 30 which has a thickness of about 100 μm ensures a rapid uptake of the liquid sample onto the free upper side and a two-dimensional dispersion on the underlying reagent layer 36 due to its capillary interspaces.

15 The one-sided closure of the fabric openings by the adhesive material of the flanking adhesive layers 42 forms a type of honey comb structure above the spacers 32 which prevents blood flowing to the side edges of the test element 20. Thus, the liquid dispersion or spreading occurs in a targeted manner in the unglued central area of the fabric 30 above the reagent layer 36 where it is possible to dispense with
20 the hydrophobic edge strips of the prior art that are for example specifically applied as wax strips by means of thermal transfer printing, without disadvantages.

The dry chemistry film which in particular is based on enzymes of the reagent layer 36 responds to an analyte (glucose) by a colour change so that a reflection-photometric detection can take place through the transparent foil composite 22, 26,
25 34 from the rear side of the test tape 20.

Fig. 3 shows the cassette housing 50 of the test tape cassette 12 with the housing cover removed. The housing 50 encloses a supply chamber 50 for the sealed storage of a supply spool 54 for unused test tape. A rotating driven take-up spool 58 for winding used test tape is mounted on a housing flange 56. Thus, the test tape 20 is pulled over a uniform tape guide formed by the cassette housing 50 from the supply spool 54, deflected over the application tip 18 and disposed of on the take-up spool 58 wherein a passage seal 60 on the supply chamber 50 ensures that tape tension is maintained.

Hence, the test fields 24 can be successively brought into use on the application tip 18 by winding the transport tape 22 forwards in order to apply a small amount of sample in a targeted manner. As a result of the pulling force exerted in this process the multilayer tape structure is subjected to direction-dependent stretching or contractions especially in the area of narrow deflecting points.

In the case of the prior art as shown in fig. 9 for a known application tip 18' with a flat support frame 62, the bending stiffness of the spreading fabric 30' in the longitudinal and transverse tape direction can lead to a lifting or arching over the chemical carrier 28'. This effect is due, on the one hand, to bending at the narrow deflection points 64 and to tape arching in the transverse direction due to the lateral fabric bonding below the level of the chemical carrier 28'. This results in the formation of a gap 66 in the central area between the spreading fabric 30' and chemical carrier 28' that can impair blood transfer and thus the measurement result.

In order to avoid the gap formation described above, the application tip 18 is provided according to figs. 4 to 6 with an outwardly convex guide path 68 for the test tape 20 extending in an arched shape in the tape longitudinal direction or tape transport direction. The apex area of the guide path 68 delimits on all sides a central opening 70 as a measuring window for an optical measurement of the test elements 24 from the rear side.

In order to feed the test tape 20 into and away from the application tip 18, guide bevels 72 which enclose an acute angle adjoin the ends of the guide path 68. Side boundaries 74 are also provided in this area which secure the test tape 20 against lateral displacement while the guide path 68 remains free from such side
5 boundaries.

As shown best in fig. 5 the arc-shaped guide path 68 has a predetermined, defined radius of curvature which is expediently in the range of 3 to 5 mm. Correspondingly the guide path 68 can have a longitudinal extension in the tape transport direction in the range of 5 to 8 mm. In this connection it is expedient when the test elements 24
10 are adapted to the longitudinal extension of the guide path 68. It is particularly advantageous to shorten the test elements 24 to a length that is as short as possible in order to avoid tensile and shearing stresses caused by deflecting points.

As can be clearly seen in fig. 6, the guide path 68 is uncurved or linear when viewed in the tape transverse direction so that the spreading fabric 30 is only bent in
15 one dimension in the tape longitudinal direction and in doing so lies essentially gap-free on the reagent layer 36. The reagent layer 36 is advantageously wider than the measuring window 70 so that the measuring spot in every case lies on the reagent layer 36. The housing wall 76 of the application tip 18 formed on the front side as a guide path 68 is bevelled on its rear side 78 towards the measuring window 70 for
20 the beam path of the photometric measuring optics.

The bending stiffness of the spreading fabric 30 is appropriately modified in some areas or locally as a further measure for avoiding or reducing gap formation between the spreading fabric 30 and the reagent layer 36.

In general the bending stiffness of a fabric sample can be determined by the
25 cantilever method. In this method the bending behaviour under its own weight is

determined by measuring a bending length at which the fabric sample is bent downwards under its own weight by a defined angle.

For example a high bending stiffness in the tape transverse direction can be provided in order to ensure a required flatness of the spreading fabric. However, a
5 low bending stiffness in the tape longitudinal direction may also be necessary in order to be able to deflect the spreading fabric without undesired arching or a delamination of other parts of the overall test element structure occurring.

An isotropic fabric with uniform weft and warp threads can, depending on the thread thickness and fabric thickness, only have one uniformly high or low bending
10 stiffness in relation to the desired test element architecture.

In order to obtain a sufficiently thick spreading fabric for the test function with areas of high bending stiffness and at the same time with areas of low bending stiffness, there are the following methods of modifying the bending stiffness in certain areas or locally:

- 15 - the use of threads of different thicknesses in appropriate areas of the fabric;
- detaching individual threads in certain areas;
- an additional coating in certain areas;
- dilution or local weakening of one or more threads;
- 20 - the use of different thread materials;
- the use of different thread qualities (e.g. multifilament threads).

Fig. 7 shows an embodiment example of a spreading fabric 30 in which only one of the thread systems 44, 46 (for example the weft threads 46) has reduced thread cross-sections at certain positions. This can be generated by providing the fabric
25 threads 46 in the prefabricated fabric 30 with weakened spots 80 by means of laser ablation. Etching methods or a mechanical removal of material for example by

means of a wafer saw are also conceivable in order to introduce local weakened spots to reduce the bending stiffness.

Fig. 8 illustrates a further embodiment example in which the bending stiffness of the spreading fabric 30 is modified by different thread thicknesses in the area of its
5 two thread systems. In this case the warp threads 44 have a lower thread thickness and consequently a lower bending stiffness than the thicker weft threads 46. It is also possible to locally vary the fabric geometry of the spreading fabric 30 for example by detaching individual fabric threads.

Claims

1. Analytical test tape, in particular for use in a test tape cassette (14) having a carrier tape that can be wound onto a spool and a plurality of test elements (24) that are distributed on the carrier tape in the tape longitudinal direction
5 and have a spreading fabric (30) for applying body fluid and an underlying reagent layer (36) for detecting an analyte in the body fluid, wherein the spreading fabric (30) is formed from fabric threads (44, 46) that are crossed in a grid shape, **characterized in that** the bending stiffness of the spreading fabric (30) is sectionally modified.
- 10 2. Analytical test tape according to claim 1, **characterized in that** the bending stiffness of the spreading fabric (30) is adapted in order to reduce the gap between the spreading fabric (30) and the reagent layer (36) of a test field (20) provided for the application of body fluid.
- 15 3. Analytical test tape according to claim 1 or 2, **characterized in that** the fabric threads (44, 46) in parts have reduced thread cross-sections preferably by laser ablation or etching or mechanical removal of material.
- 20 4. Analytical test tape according to one of the claims 1 to 3, **characterized in that** the fabric threads (44, 46) have a non-uniform design due to different thread materials, thread sizes, coatings or filament structures in order to modify the bending stiffness.
5. Analytical test tape according to one of the claims 1 to 4, **characterized in that** the fabric geometry of the spreading fabric (30) is locally varied for example by detaching individual fabric threads (44, 46).

6. Analytical test tape according to one of the claims 1 to 5, **characterized in that** the spreading fabric (30) is wider than the reagent layer (36) and is supported flat on the test tape (20) by means of spacers (32) in the area of its protruding side edges.
- 5 7. Analytical test tape according to one of the claims 1 to 6, **characterized in that** the spreading fabric (30) has a thickness of less than 150, preferably less than 110 μm .
8. Test tape cassette for insertion into a hand-held device (10), in particular for blood sugar tests, comprising a cassette housing (50) for storing tape spools
10 (54, 58), an analytical test tape (20) in particular according to one of the previous claims that can be wound forwards by means of the tape spools (54, 58), a plurality of analytical test elements (24) stored on the test tape (20) which have a spreading fabric (30) for applying body fluid and an underlying reagent layer (36) for detecting an analyte in the body fluid,
15 wherein the cassette housing (50) has an application tip (18) that deflects the test tape (20) in order to provide the test elements (24), **characterized in that** the application tip (18) has a guide path (68) which extends in an arch shape longitudinally to the test tape (20) and is uncurved at right angles thereto for supporting the test tape in a kink-free manner, and that the apex
20 area of the guide path (68) delimits a central opening as a measuring window (70) for an optical measurement on the test elements (24).
9. Test tape cassette according to claim 8, **characterized in that** the arc-shaped guide path (68) has a fixed radius of curvature preferably in the range of 3 to 5 mm.

10. Test tape cassette according to claim 8 or 9, **characterized in that** that the guide path (68) has a longitudinal extension in the direction of tape transport in the range of 5 to 8 mm.
- 5 11. Test tape cassette according to one of the claims 8 to 10, **characterized in that** the longitudinal extension of the guide path (68) is the same or less than the length of the test elements (24) which is preferably in the range of 5 to 15 mm.
- 10 12. Test tape cassette according to one of the claims 8 to 11, **characterized in that** the test tape (20) under tension is supported in a planar fashion on the guide path (68) such that the spreading fabric (30) lies essentially gap-free on the reagent layer (36).
13. Test tape cassette according to one of the claims 8 to 12, **characterized in that** the reagent layer (36) viewed in the tape transverse direction is narrower than the test tape (20) and wider than the measuring window (70).
- 15 14. Test tape cassette according to one of the claims 8 to 13, **characterized in that** a housing wall (76) of the application tip (18) forming the guide path (68) is bevelled on the rear side towards the measuring window (70).
- 20 15. Test tape cassette according to one of the claims 8 to 14, **characterized in that** the application tip (18) is moulded in one piece preferably as an injection moulded part on the cassette housing (50) and projects from the hand-held device (10) in the operating state in order to punctually apply body fluid.