

03 FEB 2000

TITLE OF THE INVENTION

SPECIMEN COLLECTION TIP

BACKGROUND OF THE INVENTION

The present invention generally relates to a
5 collection device for collecting a sample of liquid.
More particularly, the present invention pertains to
sample collection tip for collecting a blood sample
that is to be analyzed for purposes of measuring the
amount of a specific component in the blood sample,
10 such as the blood sugar level in the blood sample.

A blood sugar measuring device for measuring the
blood sugar content in an individual's blood is known.
This blood sugar measuring device effects the
measurement of the blood sugar level by supplying blood
15 (specimen material) to a test paper that assumes
a color proportional to the amount of sugar present
in the blood. The device then optically measures
the degree of the coloration of the test paper, and
quantifies the blood sugar content based on the results
20 of the optical measurement.

The end of this blood sugar measuring device is
adapted to receive a tip. The device performs the
measurement with the tip received on the end of the
device. An example of a blood sugar measuring device
25 of this type is illustrated in FIG. 11. FIG. 11 is
a longitudinal cross-section illustrating an automatic
blood sugar measuring device 200 provided with a tip

end 201 that receives a tip 10. The tip 10 is composed of a hollow portion 11 in the shape of a blind tube resembling a cup, a test paper 14 that is set on the inner surface of the hollow portion at the bottom
5 part of the hollow portion 11, and a slender tube 15 extending away from the hollow portion 11. The hollow portion 11 includes a skirt part 12 provided with a flange at the end opposite the tube 15.

When the tip 10 is brought into close proximity to
10 a specimen (blood) so that the specimen contacts the leading end of the tube 15 while the tip 10 is received on the tip part 201 of the blood measuring device 200 (with a gap 202 being provided), the specimen material flows into the tube 15 by virtue of capillary action
15 and is transported downwardly towards the test paper 14. The specimen is supplied to the test paper 14 in the region of the central part of the test paper 14 and is then spread radially outwardly on the test paper 14. The test paper 14 carries a reagent which reacts with
20 the blood sugar in the blood so that the test paper 14 undergoes a color change. A photometer (not shown) that includes an emitting element and a receiving element is installed in the vicinity of the tip part 201 of the blood-sugar measuring device 200. This
25 photometer optically measures the intensity of the color change assumed by the test paper 14.

This known tip 10 illustrated in FIG. 11, by

virtue of its particular configuration and construction,
is susceptible of certain improvements. The tip 10
is designed as a one-time use disposable component.
Thus, a new unused tip is required each time a new
5 measurement is necessary. When the patient elects to
carry one or more tips on his/her person for ready use,
one or more tips 10 are stored in a case specially
designed for easy transportation. In this case,
because the hollow portion 11 is shaped like a cup
10 possessing the skirt part 12, the entire height of the
tip 10 is constituted by the sum of the length (i.e.,
height) of the skirt part 12, the thickness of the
bottom wall of the hollow portion 11, and the length
(i.e., height) of the tube 15. Thus, the overall
15 height of the tip 10 is relatively large and so the
specially designed case used for storing the tip(s) 10
must also be relatively large in size. This tends to
make the storage and carrying of the tip(s) somewhat
inconvenient. Also, the relatively large size of the
20 tip 10 can be inconvenient when the tip 10 is to be
discarded after use.

Further, as noted above, the hollow portion 11 is
shaped to possess the skirt part 12. When the tip is
to be manufactured by injection molding, this construc-
25 tion can adversely affect the tip's formability and the
overall yield.

In light of the foregoing, a need exists for a

specimen collection tip which can be relatively easily fabricated with relatively high yield, is well suited to being reliably attached to the end of the measuring device while also being relatively easily removed, and
5 is capable of being conveniently stored and carried.

BRIEF SUMMARY OF THE INVENTION

According to one aspect of the invention,
a specimen collection tip for collecting a liquid specimen to be analyzed to determine the presence
10 or amount of a component in the specimen includes a generally planar base portion, a longitudinally extending tube extending away from the base portion, and a test paper. The tube includes an inflow path along which the specimen is adapted to flow and the
15 test paper is set on the base portion in communication with the inflow path for receiving specimen flowing through the inflow path. The test paper carries a reagent which reacts with the component in the specimen to produce a measurable color change indicative of the
20 presence or amount of the component in the sample.

According to another aspect of the invention,
a specimen collection tip for collecting a liquid specimen to be analyzed to determine the presence or amount of a component in the specimen includes a main
25 body in which is formed an inflow path along which the specimen is adapted to flow and a test paper fixed in position on the base portion in communication with the

inflow path for receiving specimen flowing through the
inflow path. The test paper carries a reagent which
reacts with the component in the specimen to produce
a measurable color change indicative of the presence
5 or amount of the component in the sample. A plurality
of spaced apart mounting projections are provided
on the main body for engaging a leading end part of
a measuring device that is adapted to detect the
measurable color change to mount the specimen
10 collection tip on the leading end part of the
measuring device.

A further aspect of the invention involves
a specimen collection tip for collecting a liquid
specimen to be analyzed to determine the presence
15 or amount of a component in the specimen. The tip
includes a main body in which is formed an inflow path
along which the specimen is adapted to flow and a test
paper fixed in position on the main body to receive the
specimen flowing through the inflow path. The test
20 paper carries a reagent which reacts with the component
in the specimen to produce a measurable color change.
At least one mounting projection extends from the main
body for mounting the specimen collection tip at a
forward end of a measuring device, with the mounting
25 projection being spaced inwardly from an adjoining
portion of the outer periphery of the main body so that
the adjoining portion of the outer periphery of the

main body extends outwardly beyond the at least one mounting projection for contacting the forward end of the measuring device when the specimen collection tip is mounted at the forward end of the measuring device.

5 BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING

Additional features and characteristics of the present invention will become more apparent from the following detailed description considered with reference to the accompanying drawing figures in which
10 like elements are designated by like reference numerals and wherein:

FIG. 1 is a longitudinal cross-sectional view of the specimen collection tip according to a first embodiment of the present invention;

15 FIG. 2 is a bottom view of the specimen collection tip shown in FIG. 1;

FIG. 3 is a bottom view of the specimen collection tip shown in FIG. 1 illustrating the features of the tip without the test paper;

20 FIG. 4 is a perspective view of the collecting portion of the specimen collection tip shown in FIG. 1 illustrating the specimen inlet side part;

FIG. 5 is a perspective view of the specimen outlet side part of the collecting portion of the specimen collection tip shown in FIG. 1;
25

FIG. 6 is a longitudinal cross-sectional view of the specimen collection tip mounted on the tip

receiving part of the measuring device;

FIG. 7 is a longitudinal cross-sectional view of the specimen collection tip according to a second embodiment of the present invention;

5 FIG. 8 is a bottom view of the specimen collection tip shown in FIG. 7;

FIG. 9 is a bottom view of the specimen collection tip shown in FIG. 7 illustrating the features of the tip without the test paper;

10 FIG. 10 is a side view of a patient's finger and the specimen collection tip of the present invention illustrating the use of the tip for collecting a specimen of blood;

15 FIG. 11 is a longitudinal cross-sectional view of the end portion of a measuring device on which is mounted the collection tip of known construction; and

FIG. 12 is a longitudinal cross-sectional view of the specimen collection tip of the present invention accommodated in a container.

20 DETAILED DESCRIPTION OF THE INVENTION

As illustrated in FIG. 6, the specimen collection tip 1 of the present invention is adapted to be mounted on the tip receiving part 101 of a measuring device which in this described version forms an analyte
25 measuring device 100. As shown in FIGS. 1 to 6, the specimen collection tip 1 is composed of a base portion 2, a slender tube 3 extending away from the upper face

of the base portion, a plurality of mounting claws or mounting projections 4 extending away from the lower face of the base portion 2 in a direction opposite the slender tube 3, and a test paper 5 that is set on the lower face of the base portion 2.

The base portion 2 possesses an overall flat disc shape having a circular outer configuration, although it is to be recognized that the base portion may be other than circular in shape. For example, the base portion 2 can possess other polygonal shapes.

The thickness of the base portion 2 is not limited to any specific dimension, although it has been found that a thickness in the approximate range of 0.3 mm - 3.0 mm, preferably in the approximate range of 0.7 mm - 1.5 mm is quite useful. If the thickness of the base portion 2 significantly exceeds 3.0 mm, the size of the tip may be needlessly large. On the other hand, if the thickness of the base portion 2 is significantly less than 0.3 mm, the strength of the tip may be undesirably affected.

The outside diameter of the base portion 2 is preferably about equal to or smaller than the outside diameter of the leading end of the tip receiving part 101 of the measuring device. In the illustrated embodiment, the outside diameter of the base portion 2 is slightly smaller than the outside diameter of the leading end of the tip receiving part 101 of the

measuring device. By virtue of this arrangement, accidental separation of the tip 1 from the tip receiving part 101 can be prevented even when the tip of an individual's finger happens to touch the outer edge part of the base portion 2 because the outer edge part of the base portion does not extend outwardly beyond the confines of the outer surface of the tip receiving part 101 of the measuring device 100 as shown in FIG. 6.

The lower face of the base portion 2 is provided with a pedestal part 21 on which is supported and fixed the test paper 5. The outer periphery of the test paper 5 forms a fixing part 51 of the test paper that is fixed or secured to the pedestal part 21. The test paper 5 can be secured or fixed to the pedestal part 21 of the base portion 2 by a variety of methods such as, for example, fusion or adhesion with an adhesive agent.

The outer periphery of the base portion 2 than is located radially outwardly of the pedestal part 21 is provided with a flange part 22. The thickness of this flange part 22 is less than the thickness of the pedestal part 21 so that the lower face 23 of the flange part 22 is recessed relative to the pedestal part 21. The lower face 23 of the flange part 22 is formed as a flat planar surface.

When the specimen collecting tip 1 is mounted on the tip receiving part 101 of the analyte measuring

device 100 as shown in FIG. 6, the lower face 23 of the flange part 22 collides with or contacts the leading end face of the tip inserting part 101 and fixes the position of the tip 1 in the vertical direction with respect to the tip inserting part 101 of the analyte measuring device 100. Thus, the base portion 2 of the specimen collection tip 1 functions to position the tip 1 relative to the tip inserting part 101.

The slender tube 3 that extends away from the base portion 2 forms a capillary tube that is adapted to initially receive and draw in the specimen (e.g., blood) during use of the tip. The slender tube 3 includes a specimen inflow path 31 that extends in a direction substantially perpendicular to the test paper 5. The leading end of the specimen inflow path 31 forms a specimen inlet 32 and the opposite end of the specimen inflow path 31 forms a specimen outlet 33.

The specimen inflow path 31 is adapted to receive and draw in specimen to the test paper 5 by capillary action. It has been found that the specimen inflow path 31 is well suited to draw-in blood under capillary action when the inside diameter (average) of the specimen inflow path 31 is in the approximate range of 0.2 mm - 2.0 mm, preferably in the approximate range of 0.3 mm - 1.0 mm. If the inside diameter of the specimen inflow path 31 is unduly large, the transfer of the blood specimen by capillary action may be

adversely affected and rendered more difficult. On the other hand, if the inside diameter of the specimen inflow path 31 is unduly small, the speed at which the blood specimen is supplied to the test paper 5 may be adversely affected (i.e., may be needlessly slowed) and the supply of the blood specimen in a sufficient amount to the test paper 5 may take an excessively long time.

The inner diameter (i.e., lateral cross-section) of the specimen inflow path 31 is illustrated as being generally constant along its entire length. However, it is to be understood that the inner diameter of the specimen inflow path 31 may vary along the longitudinal extent of the specimen inflow path 31.

The total length of the specimen inflow path 31 may be in the approximate range of 1.0 mm - 10.0 mm, preferably in the approximate range of 2.0 mm - 5.0 mm. If the length of the specimen inflow path 31 is excessively large, the transfer of the blood specimen by capillary action may take an unduly long time. On the other hand, if the length of the specimen inflow path 31 is unduly small, the blood specimen may possibly adhere to the outer face of the bottom part of the base portion 2 in the state shown in FIG. 10.

A groove 34 forming a first groove that communicates with the specimen inflow path 31 is formed on the leading end face of the slender tube 3. In the illustrated embodiment, the groove 34 is a straight

groove extending across the entire diameter of the slender tube 3 as shown in FIG. 4 so that the opposite ends of the groove 34 open to the outer periphery of the slender tube 3.

5 The provision of the groove 34 is advantageous in that it facilitates a smooth and reliable supply of the blood specimen to the test paper 5. This is because the groove 34 helps ensure that the specimen inflow path 31 remains open and is not blocked so that an
10 inlet path for the blood specimen is secured even when the leading end face of the slender tube 3 is brought into contact with the surface of an individual's finger tip during the collection of blood. The groove 34 thus advantageously ensures that a part of the surface at
15 the leading end face of the slender tube 3 does not directly contact the skin when the leading end face of the slender tube 3 is brought into contact with an individual's skin during use, thus providing an access path to the specimen inflow path 31 for the blood
20 specimen.

 The depth P_1 of the groove can be set depending upon various conditions including the condition of the skin of the individual. While this depth of the groove 34 can vary, it has been found useful that the depth P_1
25 be generally greater than 0.1 mm, preferably within the approximate range of 0.2 mm - 1.8 mm. If the depth P_1 of the groove 34 is unduly small, the passage of the

blood specimen into the groove 34 may possibly be insufficient such as when the condition of the individuals' skin results in a relatively large adhesive force of the blood to the individual's skin.

5 The shape, layout, etc. of the groove 34, and the number of grooves, is not limited to the embodiment shown in the drawing figures. A different shape, number and layout of grooves is possible, consistent with the objective that a part of the surface at the
10 leading end face of the slender tube 3 does not contact the skin when the leading end face of the slender tube 3 is brought into contact with an individual's skin during use. For example, a plurality of radially oriented grooves 34 (e.g., in a cruciform pattern)
15 positioned around the specimen inlet 32 of the specimen inflow path 31 is one possibility as is a pattern of grooves 34 laid out in a parallel manner.

 A projecting part 35 is formed adjacent the end of the slender tube 3 forming the specimen outlet 33.
20 This projecting part 35 slightly protrudes from the lower face of the base portion 2 as seen in, for example, FIG. 1. Also, as shown in FIG. 5, this projecting part 35 is provided with a plurality of grooves 36 that form second grooves. These grooves
25 36 communicate with the specimen inflow path 31 and are formed on the end face of the projecting part 35 that faces away from the specimen inlet 32. In the

illustrated embodiment, the grooves 36 together define a cruciform shape. In addition to opening into the specimen inflow path 31, the ends of the grooves 36 open to the outer periphery of the projecting part 35.

5 The grooves 36 formed in the projecting part 35 are quite advantageous in facilitating the flow of the blood specimen onto the test paper 5. Blood specimen flowing through the specimen inflow path 31 and reaching the specimen outlet 33 expands outwardly from
10 the specimen outlet 33 via the grooves 36 and is thus readily supplied to and spread out onto the test paper 5. Thus, a relatively quick and uniform spreading of the blood specimen to the test paper 5 is facilitated to thereby contribute to accurate measurement results.

15 The depth P_2 of the grooves 36 is not restricted to any particular dimension, although it has been found useful if the grooves possess a depth of at least 0.01 mm, preferably within the approximate range of 0.05 mm - 0.5 mm. If the depth P_2 of the grooves 36
20 is excessively small, the grooves may not be able to adequately function in the intended manner.

 Also, in a manner similar to that described above, the shape, layout, number, etc. of the grooves 36 is not limited to the embodiment shown in the drawing
25 figures. A different shape, number and layout of grooves is possible, consistent with achievement of the intended function of the grooves. For example,

a pattern of grooves 36 laid out in parallel may be employed.

5 A seen with reference to FIG. 1, the securement of the test paper 5 to the base portion 2 produces a gap 6 between the test paper 5 and the base portion 2 of the tip 1. This gap 6 is obtained by virtue of the recess that exists in the lower surface of the base portion 2 at a location inwardly of the pedestal part 21. That is, the raised pedestal part 21 to which the test paper 10 5 is secured results in the portion of the lower face of the base portion 2 located inwardly of the pedestal part 21 being recessed relative to the pedestal part 21. The gap 6 is thus formed and results in the portion of the tests paper 5 located inwardly of the peripheral 15 fixing part 51 being spaced from the lower face of the base portion 2.

This gap 6 between the test paper 5 and the lower surface of the base portion 2 aids in and promotes the spread of blood on the test paper 5. The blood flowing 20 out of the specimen outlet 33 of the specimen inflow path 31 expands radially outwardly through the gap 6 by capillary action and so the spread of the blood specimen on the test paper 5 can be effected relatively quickly and uniformly.

25 The depth of the gap 6 forming the spacing distance between the test paper 5 and the lower face of the base portion 2 is not limited to any particular

dimension. However, the depth of the gap 6 should preferably be greater than 0.02 mm (average value), preferably within the approximate range of 0.04 mm - 0.4 mm. Within these general parameters, the gap 6 is able to effectively function in the intended manner. The depth of the gap 6 may be constant along substantially the majority of the radial extent of the gap or may vary (for example, gradually decreasing) from the central part toward the outer periphery of the test paper 5.

The outer periphery of the gap 6 possesses an increased depth as seen in FIG. 1 to define a specimen reservoir 61. This reservoir 61 may possess an annular shape communicating with the gap 6 and may be produced by forming an annular recess in the lower surface of the base portion at a position just inward of the pedestal part 21. The blood which has expanded radially outwardly through the gap 6 is retained in the specimen reservoir 61 and is prevented from moving further outward toward the outer periphery of the test paper 5 that is fixed to the base portion 2 by adhesion or fusion (i.e., the fixing part 51 of the test paper 5). Also, in the event an excessive amount of the specimen is supplied through the specimen inflow path 31 to the gap 6, the leakage of excess specimen through the phenomenon of wetting can be precluded. Thus, contamination of the leading end of the tip inserting

part 101 of the analyte measuring device 100 due to the adhesion of the specimen (e.g., blood) can be prevented.

The mounting claws or projections 4 are provided on the lower face of the base portion 2. In the illustrated embodiment, three mounting projections 4 are provided and are spaced apart at equal intervals from one another along the circumferential extent of the base portion (i.e., at 120 intervals). The mounting projections 4 are adapted to be elastically deformed in the radial direction of the base portion 2. As seen in FIG. 1 for example, the mounting claws 4 are positioned radially inwardly of the maximum outside diameter of the base portion 2 of the tip at a position adjacent the outer periphery of the test paper 5. More specifically, the mounting projections 4 are disposed at the outer periphery of the pedestal part 21 of the base portion 2 at the boundary with the flange part 22 of the base portion that engages the end face of the tip receiving part 101 of the measuring device.

The outwardly facing surface of each mounting claw 4 includes a radially outwardly directed protuberance 41. In the illustrated version, the protuberances 41 are each defined by tapered sides that meet at a point. As seen with reference to FIG. 6, when the tip 1 is mounted on the tip receiving part 101 of the measuring device 100, the mounting claws 4 fit into an annular recess 102 formed in the tip inserting part 101.

The protuberance 41 on each mounting projections 4 engages a ridge 103 formed on the tip receiving part 101 of the measuring device 100. The ridge 103 is formed by a part of the inner wall of the recess 102 that protrudes radially inwardly toward the center. The mounting claws 4 are urged by virtue of their own elastic force to expand radially outwardly, with the protuberances 41 being pressed by this elastic force against the radially inwardly directed ridge 103. This elastic force urging the mounting claws 4 and the protuberances 41 outwardly helps maintain a reliable and effective engagement between the protuberances 104 and the ridge 103 so that the tip 1 is maintained in position on the end of the tip receiving part 101 of the measuring device 100.

Because the mounting claws 4 are positioned inside the outer periphery of the base portion 2 as described above, the mounting projections 4 remain contained within the tip receiving part 101 and are not exposed through the outer peripheral part of the tip receiving part 101. Thus, in the event the tip receiving part 101 collides with something, the tip 1 is inhibited from being removed or separated from the tip receiving part 101. Further, the mounting of the tip 1 within the recess 102 in the tip receiving part 101 of the measuring device 100 can be maintained in a rather stable manner by virtue of the disposition of the

mounting claws 4 at equal angular intervals and the engagement of the protuberances 41 of the mounting claws 4 with the tip receiving part 101.

5 In accordance with the present invention, the slender tube 3 and the base portion 2 together define a main body that is generally a solid main body. This main body is provided with a through hole (i.e., the specimen inflow path 31) that functions as a capillary tube for drawing in a specimen and directing the
10 specimen towards the test paper 5. The test paper 5 is set on the main body so as to communicate with the specimen inflow path 31 and receive the specimen. The main body is also provided with the mounting claws or projections 4 that allow the collection tip
15 to be inserted into the tip receiving part 101 of the measuring device 100.

The base portion 2, the slender tube 3, and the mounting claws 4 constructed as described above are preferably formed of a resinous material. Examples of
20 suitable resinous materials include acrylic resin, polystyrene, polyethylene, polypropylene, hard polyvinyl chloride, polycarbonate, polymethyl methacrylate, ABS resin, polyester, polyphenylene sulfide (PPS), polyamide, polyimide, polyacetal, and
25 various resinous materials such as polymer alloys and polymer blends containing one or more of the resins mentioned above. Among resinous materials such as

those mentioned above, resinous materials like acrylic resins which have a high degree of hydrophilicity or which have undergone a treatment for imparting hydrophilicity have proven to be particularly suitable for the purpose of permitting quick introduction and spread of a specimen.

The treatment for imparting hydrophilicity can be accomplished, for example, by treatments such as physical activation as plasma treatment, glow discharge, corona discharge, and ultraviolet light irradiation and by incorporation (application) of surfactant, water-soluble silicon, hydroxypropyl cellulose, polyethylene glycol, and polypropylene glycol.

The overall shape of the test paper 5 that is secured to the base portion may be circular in shape, but is not limited to such a configuration. Other possibilities include, among other shapes, elliptically shaped test paper and test paper having a polygonal shape.

When the test paper 5 is circular in shape, the outside diameter of the test paper 5 can be on the order of approximately 2 mm - 12 mm, preferably in the approximate range of 3 mm - 8 mm. Of course, the size of the test paper 5 will also depend on the size of the base portion 2, including the dimension of the pedestal part 21 to which the test paper 5 is secured.

The thickness of the test paper 5 may vary,

although it has been found that test paper having a thickness in the approximate range of 0.02 mm - 1.0 mm, preferably in the approximate range of 0.05 mm - 0.4 mm is useful.

5 The test paper 5 is provided with a centrally located and axially extending convex portion or protuberance 531 that extends out of the plane of the test paper 5. As seen in FIGS. 1 and 6, the protuberance 531 extends or protrudes towards the
10 path 31. Although the height or axial extent of the protuberance 531 is not restricted to any specific dimension, the protuberance 531 is preferably dimensioned so that it extends or protrudes into the path 31, thereby being located in the specimen
15 outlet 33. The height of the protuberance 531 can thus be on the order of about 0.02 mm - 1.0 mm, preferably about 0.05 mm - 0.4 mm.

 The shape and outer dimension of the protuberance 531 is preferably the same as or smaller than the
20 internal diameter of the path 31 at the specimen outlet 33. The shape, dimensions and other characteristics of the protuberance 531 are not limited by the foregoing, and are preferably appropriately selected depending upon, for example, the cross-sectional shape and
25 dimensions of the path 31.

 The protuberance 531 imparts advantageous characteristics to the test paper 5 from the standpoint

of facilitating the supply of the liquid sample to the test paper 5. That is, by virtue of the protuberance 531, liquid specimen in the path 31 first contacts the test paper 5 at the protuberance 531 which preferably
5 extends into the specimen outlet 33 which means that the liquid specimen is rapidly supplied to the test paper 5.

The test paper 5 is also provided with an axially extending annular convex portion or protuberance 532
10 which protrudes in the same direction as the protuberance 531. This annular protuberance 532 is positioned radially outwardly of the centrally located protuberance 531, and is disposed adjacent the outer circumference of the test paper 5. The end portion of
15 the protuberance 532 is positioned in the specimen reservoir 61 as seen in FIGS. 1 and 6.

The annular protuberance 532 is adapted to restrict the outward spreading of the liquid specimen on the test paper 5. Consequently, excess liquid
20 specimen is prevented from flowing out beyond the annular protuberance 532 towards the outer periphery of the test paper.

The outer diameter of the annular protuberance 532 is not restricted to any particular value, although it
25 is preferred that the outer diameter of the annular protuberance 532 be 60% - 95% of the outside diameter of the test paper 5, and preferably 70% - 90% of the

outside diameter of the test paper 5.

It is preferred that the width of the annular protuberance 532 be on the order of about 0.03 mm - 1.0 mm, preferably in the range of about 0.05 mm - 0.5 mm. The height of the annular protuberance 532 can be about 0.02 mm - 1.0 mm, preferably in the range of about 0.05 mm - 0.4 mm.

The shape and dimensions (e.g., diameter, width, height and the like) of the annular protuberance 532 can be appropriately selected depending on the shape and other characteristics of the main body.

The hemispherical protuberance 531 and the annular protuberance 532 can be formed by embossing (e.g., by pressing the bottom end of the test paper 5 through use of a punch) or cutting out.

The test paper 5 used with the specimen collection tip and measuring device of the present invention may be produced by depositing (e.g., impregnating) a reagent (coloring reagent) on a porous sheet. Examples of materials forming the porous sheet include non-woven fabric, woven fabric, stretched sheet, membrane filter, and filter paper. Examples of the raw material used for producing the porous sheet include polyesters, polyamides, polyolefins, polysulfones, celluloses, silicates, and fluorine type resins. More specifically polyethylene terephthalate, polybutylene terephthalate, polyether sulfone, nitrocellulose, cellulose, glass,

and polytetrafluoroethylene (Teflon) may be used.

Preferably, the porous sheet is impregnated with an aqueous solution of a reagent. For the sake of expediting the absorption and expansion of the specimen, the porous sheet is preferably formed of a raw material possessing hydrophilicity or subjected to a treatment for imparting hydrophilicity. The methods available for the treatment aimed at imparting hydrophilicity are the same as those cited above.

Examples of the reagents to be deposited on the test paper 5 for measuring blood sugar include glucose oxidase (GOD), peroxidase (POD), and a coloring agent (coloring reagent) such as, for example, 4-aminoantipyrine or N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine. Depending on the kind of analyte subjected to the measurement, reagents such as, for example, ascorbic acid oxidase, alcohol oxidase, and cholesterol oxidase which react with blood components and the same coloring agents (coloring reagents) as mentioned above may be used. Optionally, the reagent may additionally incorporate buffering agents such as a phosphate buffer solution. Of course, the kind and composition of the reagent is not limited to those mentioned above.

As described above, the outer peripheral part of the test paper 5 forms a fixing part 51 that is fixed to the pedestal part 21 of the tip proper 2 through,

for example, fusion or adhesion with an adhesive agent.

As seen with reference to FIG. 2, the test paper 5 is fixed to the pedestal part 21 at a plurality of intermittently spaced apart fixing points 52 along the

5 outer peripheral part of the test paper 5. These fixing points 52, which are preferably disposed at equal intervals, result in spaces between the test paper 5 and the pedestal part 21, with each of the spaces being located between adjacent pairs of the

10 fixing points 52. This construction permits ventilation to be established between the adjacent fixing points 52. As the specimen (e.g., blood) flows out of the specimen outlet 33 and is spread onto the test paper 5, the air entrapped in the gap 6 and the
15 specimen reservoir 61 is efficiently discharged through the spaces between the fixing points 52. As a result, the spread of the specimen is expedited or facilitated.

It is also possible to fix the central part of the test paper 5 to the lower face of the projecting part
20 35 by way of, for example, fusion or adhesion with an adhesive agent. The test paper 5 can thus be supported on and fixed to the base portion 2 of the tip more stably. Further, obstruction of the uniform expansion of the specimen (e.g., blood) by the deformation
25 (bending, warping, undulation, etc.) of the test paper 5 can be precluded.

In the embodiment of the present invention

described above, the base portion 2, the slender tube 3,
and the mounting claws 4 are formed integrally in one
piece as a unitary tip. However, it is also possible
to form these portions separately or of different raw
5 materials and then join the portions together.

The tip 1 according to the present invention may
be accommodated in a container 8 constructed in the
manner illustrated in FIG. 12. The inside diameter of
the container 8 and the outside diameter of the tip 1
10 are preferably dimensioned relative to each other so
that the tip may not fall down under its weight even in
the absence of a closing seal 81.

FIGS. 7 to 9 illustrate a specimen collection
tip according to a second embodiment of the present
15 invention. Some of the features associated with this
tip according to the second embodiment are similar to
those described above in connection with the first
embodiment and a description of those features will
not be repeated here. The features of the second
20 embodiment of the tip differing from those associated
with the first embodiment will be described below.

The tip 1 according to the second embodiment
includes a base portion 2 that is composed of two parts
2a, 2b. A first one of the parts 2a includes the
25 flange part 22, the lower face 23 and the three
mounting claws 4 that function in the same manner as
described above. The second part 2b of the base

portion includes the slender tube 3 that forms
a capillary tube similar to that described above.
The opposite ends of the slender tube 3 are similar in
construction to those of the first embodiment described
5 above in that the forward most end of the slender tube
is provided with the groove 34 while the opposite end
is provided with the projecting part 35 possessing
several grooves 36.

The second part 2b of the base portion is fitted
10 within the first part 2a of the base portion in the
manner shown in FIG. 7, with the second part 26 having
an upstanding outer peripheral wall that receives the
first part 2a. An annular recess 24 is formed on the
inner wall surface of the outer peripheral wall of
15 the first part 2a. This annular recess 24 receives
a radially outwardly facing annular protuberance 25
formed on the outer periphery of the second part 2b.
The engagement between the protuberance 25 and the
recess 24 causes the first part 2a and the second part
20 2b of the base portion to be coupled integrally
together to form the base portion 2 of the tip 1.

The lower face of the second part 2b is provided
with a recess defining the specimen reservoir 61.
Located radially outwardly of the specimen reservoir
25 61 on the second part 2b of the base portion 2 are
a plurality of spaced apart hemispherical projections
26 which form spacers for supporting the test paper 5.

These projections 26 are circumferentially spaced apart on the lower face of the second part 2b of the base portion 2.

5 When the second part 2b of the base portion is fitted into the first part 2a of the base portion, the gap 61 similar to the one described above exists between the lower face of the second part 2b and the test paper 5. The annular recess forming the specimen reservoir 61 communicates with the gap 6 and has
10 a depth greater than the depth of the gap 6. The functions associated with the gap 6 and the specimen reservoir 61 are the same as those described above in connection with the first embodiment.

The first part 2a of the base portion 2 is
15 provided with a plurality of fan-type or arcuate shaped nipping pieces 27. The illustrated embodiment of the tip includes three nipping pieces 27, and each of the nipping pieces 27 is located between adjacent pairs of the mounting claws 4. The three nipping pieces 27 are
20 spaced apart at an equal angular interval of 120 in the illustrated embodiment.

When the first part 2a and the second part 2b are in a coupled state as illustrated in FIG. 7, the test paper 5 is supported and fixed on the base portion by
25 virtue of the outer peripheral part (i.e., the fixing part 51) of the test paper 5 being nipped between the projections 26 on the second part 2b and the nipping

pieces 27 on the first part 2a. As shown in FIG. 7,
the first part 2a of the base portion includes a
generally centrally located opening through which the
test paper 5 is exposed. As a result, when the blood
specimen is absorbed on the test paper 5, the color
change in the test paper can be sensed by the analyte
measuring device 100.

In this version, because the projections 26 are
intermittently formed in a spaced apart manner along
the peripheral or circumferential direction of the
second part 2b, the fixing points at which the test
paper 5 is nipped are similarly distributed in
an intermittent spaced apart manner. As a result,
the spaces between the adjacent fixing points allow
ventilation of air. Thus, as the specimen (e.g.,
blood) flows out of the specimen outlet 33 and spreads
out onto the test paper 5, air in the gap 6 and the
specimen reservoir 61 is efficiently discharged and so
the outward spread of the specimen is not hindered but
rather is facilitated.

The tip 1 according to the second embodiment of
the present invention is advantageous in facilitating
the fixation of the test paper 5 on the tip proper 2
because the test paper 5 is adapted to be fixed by
being nipped between the first and second parts 2a, 2b
forming the base portion.

The specimen collection tips 1 described above are

adapted to be inserted into the tip receiving part 10 of the analyte measuring device (device for measuring a component in blood) 100. Now, the analyte measuring device 100 will be described briefly.

5 The analyte measuring device 100 includes the previously mentioned tip receiving part 101. The tip receiving part 101 is preferably cylindrical in shape and allows the tip 1 to be removably inserted in the leading end of the tip receiving part 101.

10 The tip receiving part 101 of the measuring device 100 includes the annular recess 102. This recess 102 opens into the leading end of the tip receiving part 101. The inner wall surface bounding the recess 102 possesses a radially inwardly directed annular ridge
15 103 having tapering surfaces as seen in FIG. 6.

 The tip receiving part 101 is provided with a photometric part (not shown) that includes an emission element (light-emitting diode) and a reception element (photodiode). The emission element is adapted to
20 generate a pulsed light at a prescribed time interval.

 The analyte measuring device 100 also includes a control unit formed of a microcomputer. This control unit has a built-in operation part for computing the target component in blood (such as, for example, sugar)
25 based on the signal from the photometric part.

 In use, the specimen collection tip 1 is inserted into the tip receiving part 101, and the specimen flows

to the test paper 5 in the tip 1 and is spread across the test paper 5, as will be described below, before the measurement is started. When the emission element is lit up, the light emitted from the emission element impinges on the test paper 5 in the tip 1 and produces a reflected light. The intensity of this reflected light corresponds to the intensity of the color assumed by the test paper 5. The color assumed by the test paper 5 is based on the amount (concentration) of the target component in the specimen and so the intensity of the reflected light corresponds to the amount or concentration of the target component in the specimen. The reflected light is received by the reception element and is subjected to photoelectric conversion. The reception element issues an analog signal corresponding to the amount of received light. This analog signal is converted into a digital signal and is sent to the control unit where it is subjected to required treatments such as arithmetic operations and corrections to quantify the amount of the target component in the specimen (i.e., to determine the numerical value of the blood sugar level).

Quite advantageously, the tip receiving part 101 is not contaminated by adhesion of blood because the test paper 5 does not contact the tip receiving part 101 of the measuring device while the specimen collection tip is inserted in the tip receiving

part 101.

Further, while the tip is received in the tip receiving part 101 of the measuring device, the lower face 23 of the flange part 22 contacts the leading end
5 of the tip receiving part 101 to fix the position of the slender tube 3 of the tip 1 with respect to the longitudinal direction.

The holding ability (i.e., the fitting strength) of the tip 1 relative to the tip receiving part 101
10 while the tip is inserted in the tip receiving part 101 is always generally constant because this holding ability is substantially exclusively dependent upon the elastic force of the mounting projections or claws 4.

The specimen collection tip 1 is accurately
15 positioned on the tip receiving part 101 with respect to the lateral direction (i.e., in the direction defined by the plane in which the test paper lies) and is not susceptible to being shifted or moved in this direction because the mounting claws 4 are anchored
20 with elastic pressure in the region of the radially inwardly directed ridge 103. Thus, measurement errors due to positional deviations can be diminished, thereby increasing the measurement accuracy.

From the above description, it can be seen that
25 the specimen collection tip of the present invention is designed to efficiently collect a specimen of blood, for example, and is adapted to interface with the

analyte measuring device in a way that allows the specimen collected on the collection tip to be analyzed. The specimen collection tip 1 constitutes the male portion of the interface with the measuring device 100 and is adapted to be fitted into the recess 102 (female portion) in the leading end of the tip receiving part 101 of the measuring device 100. While the leading end of the tip receiving part 101 of the measuring device 100 is covered by the base portion 2 of the collection tip 1, the upstanding outer peripheral side of the tip receiving part 101 remains exposed. Nevertheless, by virtue of the construction of the specimen collection tip 1, the exposed upstanding outer peripheral side of the tip receiving part 101 is not susceptible to being contaminated.

FIG. 10 illustrates the way in which the specimen collection tip 1 can be used to collect a specimen in the form of a blood sample. The collection of blood is initiated by piercing the individual's finger tip (or ear lobe) with a needle or a scalpel to cause blood 7 to flow out of the puncture in a small amount (e.g., in the approximate range of 2 l - 6 l) onto the skin.

Meanwhile, the specimen collection tip 1 is inserted in the manner described above into the tip receiving part 101 of the analyte measuring device 100. This can be achieved by bringing the tip receiving part

101 of the measuring device 100 into engagement with the specimen collection tip 1, possibly while the tip is accommodated in the container 8 shown in FIG. 12 (after the covering seal 81 has been removed. Then, the leading end surface of the slender tube 3 is brought close to or in contact with the individual's skin. The blood 7 on the finger tip is able to flow through the groove 34 to the specimen inlet 32 and, by virtue of capillary action, flows along the specimen inflow path 32 in the direction of the test paper 5 where it reaches the specimen outlet 33. The blood 7 on the finger tip is not excessively dispersed or lost on the skin because it is efficiently drawn into the specimen inflow path 32 through the lateral surface opening of the groove 34 that opens to the outer periphery of the slender tube 3.

As the blood reaches the specimen outlet 33, part of the blood contacts the central part of the test paper 5 and is absorbed by the test paper 5. At the same, part of the blood advances through the grooves 36 in the protuberance 35 and reaches the gap 6. The blood flowing into the gap 6 is absorbed and spread by the test paper 5 that is opposed to the gap 6, and is gradually spread radially outwardly toward the outer periphery of the test paper 5. As the blood is absorbed and spread outwardly, the specimen inflow path 31 generates suction force anew and induces

a continuous supply of blood to the test paper 5.

Even when the amount of the blood 7 on the finger tip is comparatively small, therefore, this blood 7 can be supplied without any waste to the test paper 5.

5 Conversely, even when the amount of the blood 7 on the finger tip is relatively large and excessive blood is supplied to the test paper 5, the possibility of the blood leaking out of the test paper 5 and adhering to and contaminating the lower face 23 of the tip 1, the
10 surface of the tip receiving part 101, the photometric part, or the peripheral parts of the measuring device is precluded because the excess blood is retained in the specimen reservoir 61. This excess blood is thus
15 prevented from flowing out of the reservoir toward the outer periphery. Thus, the blood in the current specimen being measured has no adverse affect on subsequent measurement cycles with different specimens. Also, the used tip 1 can be safely discarded without causing any infection.

20 As the blood is supplied to and spread onto the test paper 5, the target component (such as, for example, sugar) in the blood reacts with the reagent carried on the test paper 5 and the reaction produces a color change in the test paper corresponding to the
25 amount or concentration of the target component in the blood sample.

The amount of the target component in the blood

(the numerical value of blood sugar) can be determined by optically measuring the intensity of the color change assumed by the test paper 5 through the use of the blood component measuring device 1 as described above.

By virtue of the specimen collection tip 1 of the present invention, the blood 7 can be quickly and reliably supplied to and spread across the test paper 5 in a rather simple manner. As a result, a reduction in measurement errors can be realized and the accuracy of the measurement improved.

After the measurement is completed, a pin 104 built in the tip receiving part 101 as shown in FIG. 6 is moved towards the leading end of the tip receiving part 101 of the measuring device so that the leading end of the pin 104 contacts and pushes against the flange part 22 of the tip 1 to thereby remove the used specimen collection tip 1 from the tip receiving part 101. By covering the tip 1 with the empty container 8 and then removing the tip from the tip receiving part 101, the possibility of the used tip being touched by an individual is avoided. Further, the possibility of the blood causing contamination through touch is diminished because the used tip can be discarded as accommodated in the container.

The test paper 5 used in the specimen collection tip of the present invention is not limited to a single

layer construction as illustrated in the drawing figures, but may be constructed by superposing a plurality of layers on one another. The component layers of such a multi-layer construction may possess
5 different functions. For example, in a two-layer construction, one of the two layers may function to permit the passage of red blood cells while the other layer functions to carry the reagent.

The description set forth above is designed to
10 facilitate an understanding of the present invention in the context of using blood as the specimen. However, the present invention is not limited to the use of blood as the specimen. The specimen materials which may be used effectively in this invention include, for
15 example, such specimens as urine, lymph, cerebrospinal fluid, bile, and saliva, diluted liquids thereof, and concentrated liquids thereof.

Examples of target components for measurement other than blood sugar level include inorganic ions of
20 protein, cholesterol, uric acid, creatinine, alcohol, and sodium and hemoglobin (occult blood).

The analyte measuring device fitted with the specimen collection tip of the present invention may be outfitted not only for optically measuring (color
25 measuring) the intensity of the color assumed by the test paper as a result of the reaction of the target component in the specimen with the reagent, quantifying

the result of the measurement, and displaying the numerical value, but also for electrically measuring the change in potential corresponding to the amount of the target component in the specimen material,
5 quantifying the result of measurement, and displaying the numerical value.

The principles, preferred embodiments and modes of operation of the present invention have been described in the foregoing specification. However, the invention
10 which is intended to be protected is not to be construed as limited to the particular embodiments described. Further, the embodiments described herein are to be regarded as illustrative rather than restrictive. Variations and changes may be made by
15 others, and equivalents employed, without departing from the spirit of the present invention. Accordingly, it is expressly intended that all such variations, changes and equivalents which fall within the spirit and scope of the invention be embraced thereby.



CLAIMS

1. A specimen collection tip for collecting a liquid specimen to be analyzed to determine the presence or amount of a component in the specimen comprising: a generally planar base portion, a longitudinally extending tube extending away from said base portion, said tube including an inflow path along which the specimen is adapted to flow, a test paper set on base portion in communication with the inflow path for receiving specimen flowing through the inflow path, said test paper carrying a reagent which reacts with the component in the specimen to produce a measurable color change indicative of the presence or amount of the component in the sample.
2. The specimen collection tip according to claim 1, wherein the reagent carried by the test paper is of a type which reacts with the component in the specimen to determine a concentration of the component in the specimen.
3. The specimen collection tip according to claim 1, including a plurality of spaced apart mounting projections extending away from the base portion in a direction opposite the direction in which the tube extends.
4. The specimen collection tip according to claim 3, wherein said base portion possesses an outer periphery, and said mounting projections being



positioned radially inwardly of said outer periphery of the base portion.

5 5. The specimen collection tip according to claim 1, wherein said base portion is comprised of two parts, said test paper being fixed between said two parts.

10 6. The specimen collection tip according to claim 1, wherein said inflow path for the specimen extends in a direction substantially perpendicular to said test paper.

15 7. A specimen collection tip for collecting a liquid specimen to be analyzed to determine the presence of a component in the specimen comprising: a main body in which is formed an inflow path along which the specimen is adapted to flow, a test paper fixed in position on the base portion in communication with the inflow path for receiving specimen flowing through the inflow path, said test paper carrying a reagent which reacts with the component in the specimen to produce
20 a measurable color change indicative of the presence of the component in the sample, a plurality of spaced apart mounting projections provided on the main body for engaging a leading end part of a measuring device that is adapted to detect said measurable color change.

25 8. The specimen collection tip according to claim 7, wherein the reagent carried by the test paper is of a type which reacts with the component in the



specimen to determine a concentration of the component in the specimen.

5 9. The specimen collection tip according to claim 7, wherein said mounting projections surround the test paper.

10 10. The specimen collection tip according to claim 7, wherein said mounting projections each have a radially outwardly facing surface provided with a protuberance that is adapted to engage a ridge formed on an inner wall surface of a recess formed in the leading end part of the measuring device.

15 11. The specimen collection tip according to claim 7, wherein said main body includes a base portion possessing an outer periphery and a capillary tube extending away from the base portion in a direction opposite said mounting projections, said mounting projections being positioned radially inwardly of said outer periphery of the base portion.

20 12. The specimen collection tip according to claim 11, wherein said base portion is comprised of a first part and a second part, said test paper being fixed between said first and second parts.

25 13. The specimen collection tip according to claim 7, wherein said main body includes a flange part radially outwardly beyond the mounting projections.

14. The specimen collection tip according to claim 7, wherein said inflow path for the specimen



extends in a direction substantially perpendicular to said test paper.

15 15. A specimen collection tip for collecting
a liquid specimen to be analyzed to determine the
presence of a component in the specimen comprising:
a main body in which is formed an inflow path along
which the specimen is adapted to flow, the main body
having an outer periphery, a test paper fixed in
position on the main body to receive the specimen
10 flowing through the inflow path, said test paper
carrying a reagent which reacts with the component in
the specimen to produce a measurable color change,
at least one mounting projection extending from the
main body for mounting the specimen collection tip at
15 a forward end of a measuring device, said at least
one mounting projection being spaced inwardly from
an adjoining portion of the outer periphery of the
main body so that the adjoining portion of the outer
periphery of the main body extends outwardly beyond the
20 at least one mounting projection for contacting the
forward end of the measuring device when the specimen
collection tip is mounted at the forward end of the
measuring device.

25 16. The specimen collection tip according to
claim 15, including a plurality of mounting projections
extending from the main body and spaced inwardly from
the adjoining portion of the outer periphery of the



main body.

17. The specimen collection tip according to claim 16, wherein said mounting projections surround the test paper.

5 18. The specimen collection tip according to claim 15, wherein said mounting projection has an outwardly facing peripheral surface provided with a protuberance that is adapted to engage a ridge formed on an inner wall surface of a recess formed in
10 the leading end part of the measuring device.

19. The specimen collection tip according to claim 15, wherein said main body includes oppositely facing first and second faces, said mounting projection extending away from the first face and said test paper
15 being fixed to said first face.

20. The specimen collection tip according to claim 15, wherein said main body includes first and second parts, said mounting projection extending from the first part and said test paper being fixed between
20 said first part and said second part.

21. The specimen collection tip according to claim 15, wherein said inflow path for the specimen extends in a direction substantially perpendicular to said test paper.

25 22. The specimen collection tip according to claim 15, wherein said main body includes a base portion defined by first and second parts, said inflow

path being defined by a capillary tube extending away from said second part of the base portion.

23. The specimen collection tip according to claim 22, wherein said mounting projection extends from
5 the first part of the base portion and said test paper is fixed between said first part and said second part.

24. A specimen collection tip, substantially as hereinbefore described with reference to the accompanying drawings.

