US 20090095623A1

(19) **United States**

(12) **Patent Application Publication**

Boiteau et al.

(10) **Pub. No.: US 2009/0095623 A1**

(43) **Pub. Date: Apr. 16, 2009**

(54) **IDENTIFICATION METHOD FOR ELECTROCHEMICAL TEST STRIPS**

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(21) Appl. No.: **12/248,195**

(22) Filed: **Oct. 9, 2008**

Related U.S. Application Data

(60) Provisional application No. 60/978,978, filed on Oct. 10, 2007.

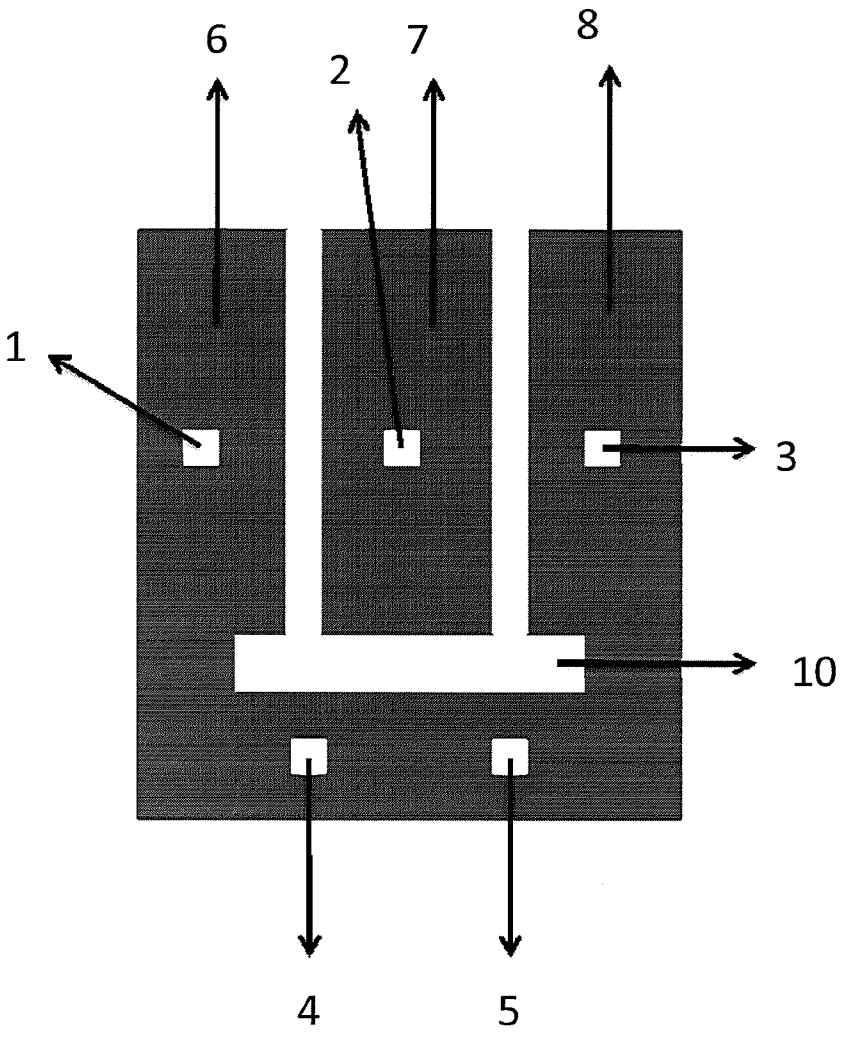
Publication Classification

(51) **Int. Cl.**
G01N 27/26 (2006.01)
B29C 67/00 (2006.01)

(52) **U.S. Cl.** **204/403.01**; 264/400

(57) **ABSTRACT**

The present invention provides a method and apparatus for creating test strips that may be identified based on differences in electrical conduction or resistance between contact point on the test strip. This is achieved by creating a base test strip with contact points that may be connected to other contact points by an electrical connection. These base test strips may be modified to create a difference in electrical conductivity between contact points, or a contact point may be eliminated. This modification can be used to distinguish different types of test strips based on electrical signature. Additionally, the base test strip may be created such that multiple modifications are possible to distinguish numerous characteristics of test strips.



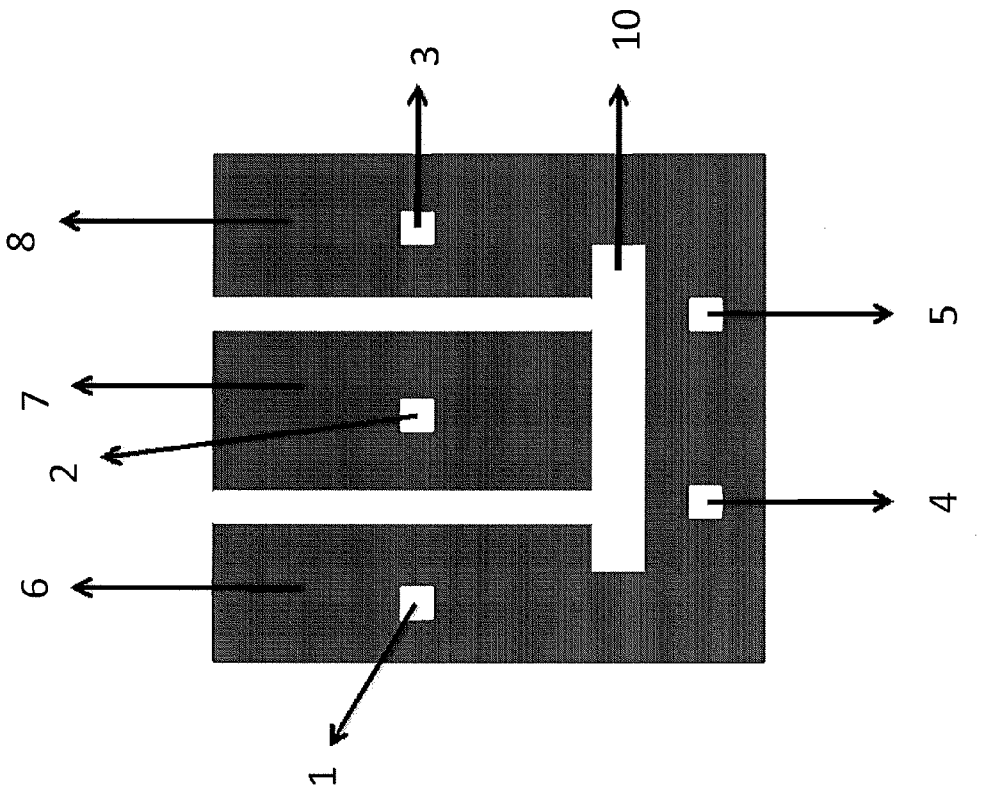


Fig 1

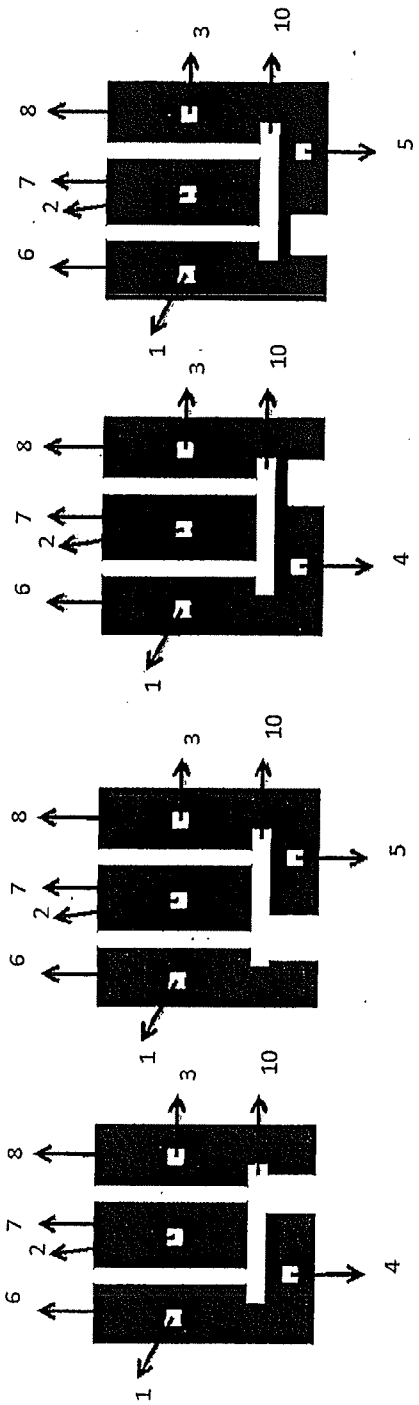


Fig 2

Fig 3

Fig 4

Fig 5

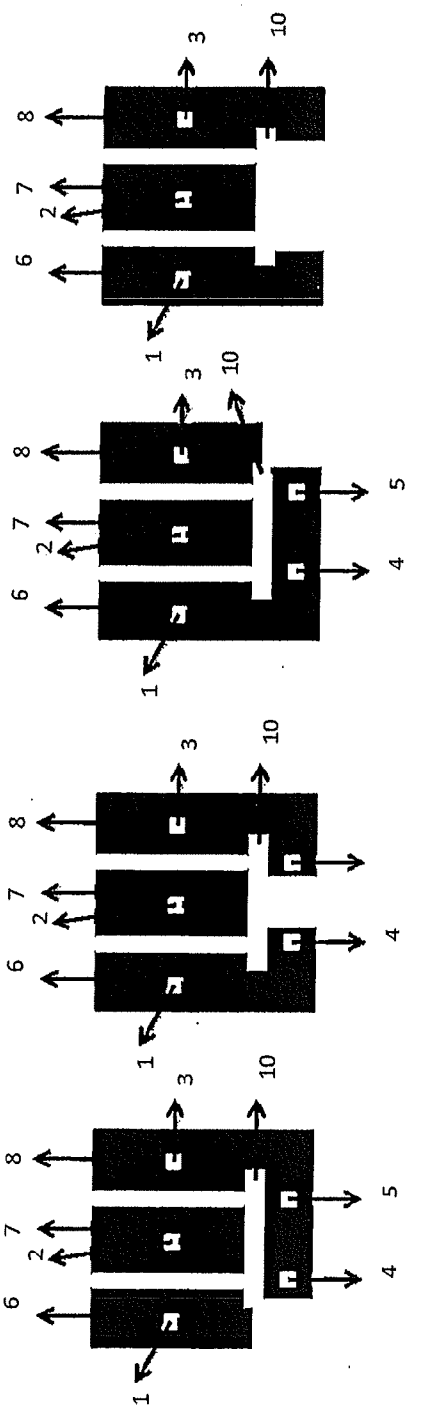


Fig 6

Fig 7

Fig 8

Fig 9

Fig 10A

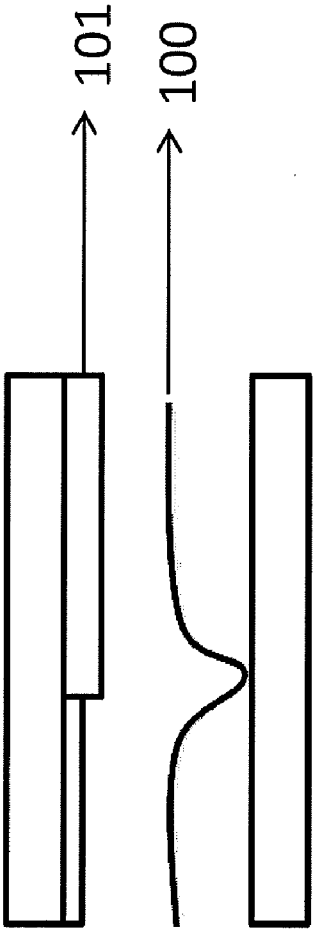
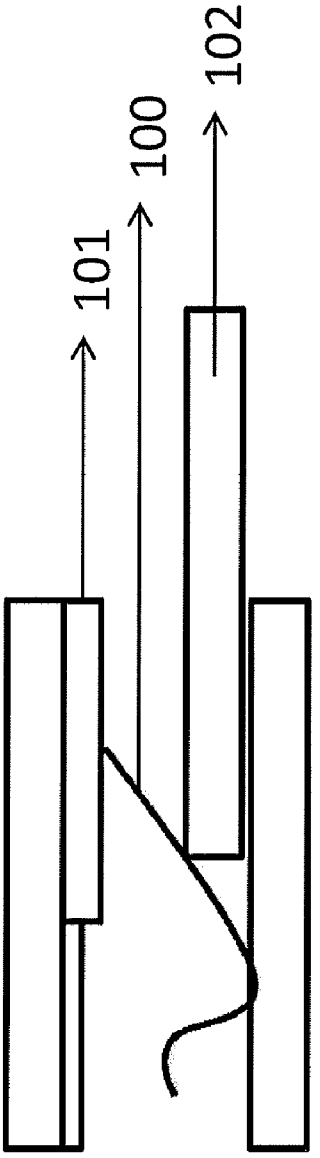


Fig 10B



IDENTIFICATION METHOD FOR ELECTROCHEMICAL TEST STRIPS

BACKGROUND OF THE INVENTION

[0001] This application relates to a method for identification of electrochemical test strips to distinguish one type or one lot of test strips from another using a meter such as that which is used with the test strip to assess the amount of an analyte, such as glucose, in a sample.

[0002] Small-volume, single-use disposable test strips are in common use in application such as the self-measurement of blood glucose levels by diabetics. These test strips contain electrodes and reagents, and in use are associated with a meter that provides the circuitry to analyze a sample placed in the meter. In order to maintain appropriate quality control and comply with different regulatory standards, strips made for sales in different geographical regions may be made in a different and distinguishable manner.

SUMMARY OF THE INVENTION

[0003] The present invention provides a method of making a plurality of test strips where the test strips are part of either a base test strip group or one or more modified test strip groups. The modified test strip groups are distinguishable from the base group. According to the method, a base test strips are created where the base test strips have a region of electrically conductive material and a plurality of accessible contact points connected to one another by said electrically conductive material. These contact points interact with an analyte test meter, such as a blood glucose test meter.

[0004] Some of the base test strips are modified by physical removal of electrically conductive material or complete removal of at least one contact point to create a group of modified test strips. The test strips within the modified test strip group are distinguishable from the base test strip due to a difference in electrical conductivity/resistance between the contact points. Additional groups of modified test strips may be created by removal of electrically conductive material or complete removal of at least one contact point from some of the base test strips, to a different extent, such that the additional modified test strip group is distinguishable from the base test strip and the first modified test strip group.

[0005] The test strips may be assigned to groups based on meeting or not meeting a specification. To do this, representatives of a lot of base test strips are tested to determine whether the lot meets a specification. The lot of test strips is then assigned to a group based on meeting the specification and the test strips assigned to a modified test strip group are modified to indicate the group.

[0006] This method creates a family of test strips including a base test strip group and at least one modified test strip group. The base test strips have a region of electrically conductive material and a plurality of accessible contact points connected to one another by said electrically conductive material. The modified test strip are base test strips modified by physical removal of electrically conductive material or at least one contact point. The modified test strip is distinguishable from the base test strip due to a difference in electrical conductivity/resistance between the contact points. Additional modified test strip groups may also be created where a portion of the base test strip is modified by removal of electrically conductive material or at least one contact point and the additional modified test strip group is distinguishable from both the base test strip and the first modified test strip group. Test strips within the family may be assigned to a group based on whether representative samples of a base test strip lot meet a specification.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. **1** illustrates an embodiment of a base test strip of the invention.

[0008] FIGS. **2-9** illustrate embodiments of a modified test strip of the invention.

[0009] FIG. **10**A illustrates a strip port connector.

[0010] FIG. **10**B illustrates a strip port connector with a strip inserted.

DETAILED DESCRIPTION OF THE INVENTION

[0011] The present application provides a new approach to the preparation of strips that are part of identifiable groups. These groups may be based on different geographical regions, they may be used to differentiate manufacturers (for example where one brand uses multiple manufacturing sources) or they may be used to differentiate the time of manufacture, thus becoming a type of hard-coded expiration date. In addition, the approach of the invention can be used to distinguish a strip designed for one type of analyte (such as glucose) from another type of analyte (such as cholesterol) such that a multi-function meter will perform the correct analysis with information provided from the strip, not the user.

[0012] A further benefit of the present invention is that the encoding for identification of the strips can be applied after a quality control check has been run such that strips can be directed into groups as a final step in manufacturing, rather than requiring a separate manufacturing process for each group of strips. Thus, in one example, strips that meet very high quality control standards can be identified in the method of the invention for use with a meter that does not require a calibration code (a no-code meter), while strips manufactured in the same initial process that do not meet the rigid standards for uniformity but are otherwise acceptable can be identified for use in meters that require a calibration code for the particular lot of the test strips. This eliminates wastage, thus controlling the costs of the strips. Uniformity of test strips within a lot is an example of a "specification" on which assignment to groups can be based.

[0013] Once the strips have been assigned to a group, the strips are packaged and may be labeled to indicate the characteristics of the group. For example, the group may be labeled to indicate type of analyte, type of meter, whether a calibration code is necessary, and/or geographic region.

[0014] The invention operates by using notches or holes cut into defined locations in a test strip to interrupt initially formed electrical connections. FIG. **1** shows a connection end of a test strip prior to the formation of notches. In the illustrated embodiment, there are 5 points on the strip (labeled **1-5**) where electrical contact can be made via 5 pins from the strip port connector (SPC, not shown). In actual practice there can be more contact points, or fewer contact points than the five shown here. In preferred embodiments, the contact points are arranged in two or more groups, each at a different depth from the end of the test strip. The exact alignment of these rows as a single line is not required, although it may make it easier to design the contacts in the SPC. In common usage, the contact points **1**, **2** and **3** also serve as the electrical connectors

to for example to working and counter electrodes and a fill detection electrode. The numerals **6**, **7** and **8** in the figure refer to the leads from such structures which may or may not be electrically isolated from one another. For example, leads **6** and **8** can both be in contact with a common electrode or one leg can be in contact with the sample space and an active measurement electrode (working or counter) and the other may simply be a conductive region that is not involved in measurement. Lead **7** is then in contact with the other of the measurement electrodes. The specific arrangement of the leads is not critical to the present invention.

[0015] In the figures of this application, the contact points are shown as white squares for clarity. The contact points do not have to be separate structures, however, and are generally just locations on the conductive surface of the test strip that are accessible to probes on the SPC.

[0016] The strip as depicted in FIG. **1** also includes a region of insulating material **10** which separates leads **6**, **7** and **8** from each other, and which partially separate the two rows of contact points. This region is suitably an underlying insulating substrate where the conductive material is not disposed.

[0017] The presence and/or absence of electrical continuity between electrical contact points on the strip is be probed by the meter to ensure uniqueness of the strip. Pairs of points and/or combinations of pairs of points can be used to arrive at strip designs that are unique with respect to the electrical features.

[0018] FIGS. **2-9** show different notching patterns that can be used to define different strip identification groups. In FIG. **2**, the notch extends into the insulating region **10**, eliminates contact point **5** and disconnects **3** from every other point on the test strip. Thus, measurement of the connection (for example as a resistance measurement) between points **1** and **4** would show connection (low resistance) while that between **3** and **4** would show no connection (high/infinite resistance) comparable to that observed between point **2** and point **4**. Point **2** in this figure is always electrically isolated, and therefore measurements using point **2** can, if desired be used as a kind of control indicator of the no connection. Tests with a connector where point **3** was eliminated would show comparable yet distinguishable results. In FIG. **3**, the notch eliminates contact point **4** and disconnects **1** from every other point. Thus, this test strip would produce results parallel to but different from the results of the strip of FIG. **2**.

[0019] The notch can be long enough to extend into the insulating region **10** as shown in FIGS. **2** and **3** or it can extend only partially into the end of the strip as show in FIGS. **4** and **5**. In FIG. **4**, the notch eliminates contact point **5** but does not disconnect **3** from every other contact point. Rather, the resistance between **4** and **3** is dependent on the width of the conductive portion, and thus can be used as an indicator of the place and extent of notching. Similarly, in FIG. **5**, the notch eliminates contact point **4** but does not disconnect **1** from every other contact point. The resistance between **1** and **5** is dependent on the width of the conductive portion.

[0020] In FIG. **6**, the notch breaks the continuity between **1** and **5**. In FIG. **7**, the notch breaks the continuity between **4** and **5**. In FIG. **8**, the notch breaks the continuity between **3** and **5**. In FIG. **9**, the notch eliminates points **4** and **5**. In this configuration, one of the leads, for example lead **6**, does not make contact with the sample chamber, it just serves the back of the strip. Thus, electrical continuity is maintained between points **1** and **3**.

[0021] As noted above, alteration in the width of the conductive path is achieved by notching out portions of the strip as a physical removal of the entire thickness of the strip. Alternatively, this can be achieved by laser ablation to remove the conductive material between the contact points. Thus in a general sense the invention provides a postprocessing step in which conductive material is removed to modify the electrical continuity between selected ones of a plurality of contact points in order to provide for a multiplicity of possible group identifications.

[0022] The notching can be complete (100%) so as to completely sever the electrical connection such that no current can flow across (as shown in FIG. **2**), or it may be incomplete. The lower the width of the conductive path, the greater the resistance. The variable extent of notching (eg: 25%, 50%, 75%) will alter the resistance correspondingly. One example is shown in (FIG. **4**, **5**). Isolation of one conductive point can be achieved by ablating a ring around that contact point. In the case of an ablated ring around a contact point, the diameter of the ring can be used define the extent of notching so that a large diameter ring (overlapping both the insulating region and the end of the strip) will result in complete notching while smaller diameter rings can be used to produce different levels of resistance. Similar results can be achieved by cutting holes (rather than end notches) that surround one of the contact points. Indeed, a hole may be preferred to an end notch in cases of an incomplete cut where variable resistance is utilized, since alignment is not critical as long as the hole does not overlap with either the end of the strip or the insulating region **10**. These techniques provide examples of removal of electrically conductive material.

[0023] The use of variable resistance adds great versatility to the identification capabilities of the invention because the same structure, with a limited number of contact points, can produce many different and distinguishable configurations each of which can be assessed without any change in the design of the SPC.

[0024] The strips of the invention with conductive material removed to define identifiable groups can be used in combination with mechanical features on the strip and meter to prevent improper insertion (i.e. upside down) of the test strip. Features of this type are known in the art, for example from U.S. Pat. No. 5,526,120, which is incorporated herein by reference. In addition, the SPC can have a post in a position corresponding to a notch which will be received in the notch when an appropriate strip is inserted in the SPC and which will prevent insertion of a strip with a notch in an inappropriate position for the particular meter.

[0025] Where a notch is used that extends to the end of the strip, the presence or absence of a notch in a particular position can also be used to interact with a switch mechanism, which can be used to activate the meter if a correctly coded strip is inserted, or to set the operation of the meter depending on the type of strip (as indicated by the position of the notch) inserted. As depicted in FIG. **10**A, the strip port connector may contain a deflectable switch part **100** and a fixed switch contact **101**. When a strip **102** is inserted that is not notched in alignment with this switch, the deflectable switch portion **100** is deflected to make contact with the fixed switch contact **101** as show in FIG. **10**B. When the strip is notched in alignment with the switch, however, no deflection occurs.

1. A method of making a plurality of test strips wherein said test strips are part of a base test strip group or a modified test strip group distinguishable from the base group comprising

creating a plurality of base test strips, each with a region of electrically conductive material, and a plurality of accessible contact points connected to one another by said electrically conductive material; and

modifying a portion of the base test strips by physical removal of electrically conductive material or at least one contact point to create a first modified test strip group wherein the test strip within the modified test strip group is distinguishable from the base test strip due to a difference in electrical conductivity/resistance between the contact points.

2. The method of claim **1** further comprising the step of modifying an additional portion of the base test strips by removal of electrically conductive material or at least one contact point to create an additional modified test strip group distinguishable from the base test strip and the first modified test strip group.

3. The method of claim **2** further comprising

testing representative base test strips of a lot to determine whether the lot meets a specification;

assigning the strips of the lot to a group based on meeting the specification; and

modifying test strips assigned to a modified test strip group to indicate the group.

4. The method of claim **3** where the specification indicates that the test strip is of a suitable quality as to be used without calibration.

5. The method of claim **3** where said test strips are used to detect glucose.

6. The method of claim **1** further comprising

testing representative base test strips of a lot to determine whether the lot meets a specification;

assigning the strips of the lot to a group based on meeting the specification; and

modifying test strips assigned to a modified test strip group to indicate the group.

7. The method of claim **6** where said test strips are used to detect glucose.

8. The method of claim **1** where said test strips are used to detect glucose.

9. The method of claim **6** where the specification indicates that the test strip is of a suitable quality as to be used without calibration.

10. The method of claim **1** wherein the base test strips have contact points arranged in two or more groups, each at a different depth from an end of the test strip.

11. The method of claim **10** wherein

the base test strips have five contact points, arranged in two rows, with a first row having two contact points at a lesser depth from the end of the test strip and a second row with three contact points at a greater depth from the end of the test strip;

a region of insulating material separates one of the contact points in the second row from the other two contact points in the second row; and

said insulating material partially separates the first row and second row of contact points.

12. The family of test strips of claim **22** further comprising an additional modified test strip group where a portion of the base test strip is modified by removal of electrically conductive material or at least one contact point and the additional modified test strip group is distinguishable from the base test strip and the first modified test strip group.

13. The family of test strips of claim **12** wherein test strips in one of the base test strip group and the first modified group meet a specification and those in the other group do not meet the specification, wherein meeting the specification is determined by testing of representative samples from a lot.

14. The method of claim **13** where the specification indicates that the test strip is of a suitable quality as to be used without calibration.

15. The method of claim **13** where said test strips are used to detect glucose.

16. The family of test strips of claim **22** wherein test strips in one of the base test strip group and the first modified group meet a specification and those in the other group do not meet the specification, wherein meeting the specification is determined by testing of representative samples from a lot.

17. The method of claim **16** where the specification indicates that the test strip is of a suitable quality as to be used without calibration.

18. The method of claim **16** where said test strips are used to detect glucose.

19. The method of claim **22** where said test strips are used to detect glucose.

20. The family of test strips from claim **22** where test strips in each group are manufactured for a different geographic region.

21. The family of test strips from claim **22** where test strips in each group are manufactured for a different type of meter.

22. A family of test strips comprising a base test strip group and at least one modified test strip group where

said base test strip has a region of electrically conductive material, and a plurality of accessible contact points connected to one another by said electrically conductive material; and

a modified test strip group comprising a base test strip modified by physical removal of electrically conductive material or at least one contact point wherein the modified test strip is distinguishable from the base test strip due to a difference in electrical conductivity/resistance between the contact points.

* * * * *