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Taylor et al.

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[54] **METHOD FOR ORGANIZED ASSAY AND BENDABLE TEST TUBE RACK THEREFOR**

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[52] **U.S. Cl.** .....**23/230 R,** 23/253 R, 23/259, 141/378, 211/74

[51] **Int. Cl.**.....**A47b 73/00,** B011 9/00, G01n 33/16

[58] **Field of Search** .23/230 R, 253 R, 259; 141/378, 141/369; 291/72, 74, 77

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[57] **ABSTRACT**

Apparatus and method for systematic organization of samples. Flexible gangs of sample holders are used permitting organization in either a linear or a curved arrangement and transfer from one to the other arrangement without changing the juxtaposition and organization of individual samples. Identity strips are associated with each sample holder to provide for both computerized and non-computerized identification of the sample, recording information concerning intended treatments, assays, determinations, or data obtained therefrom.

9 Claims, 5 Drawing Figures

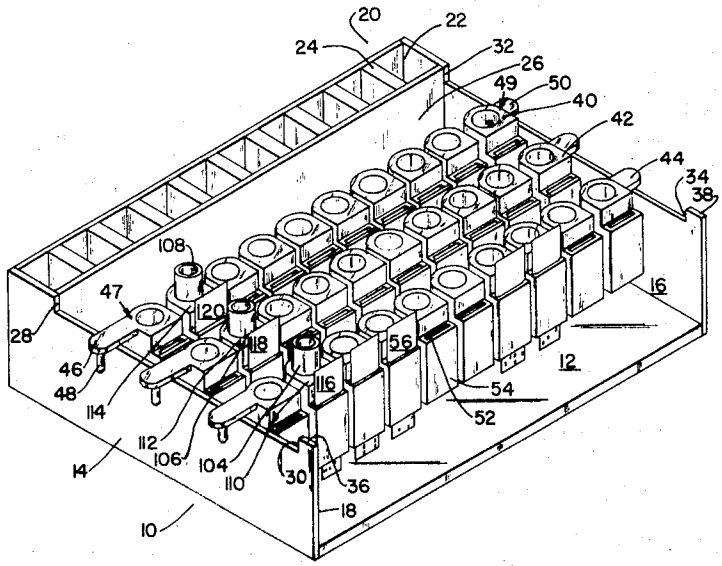


FIG_1

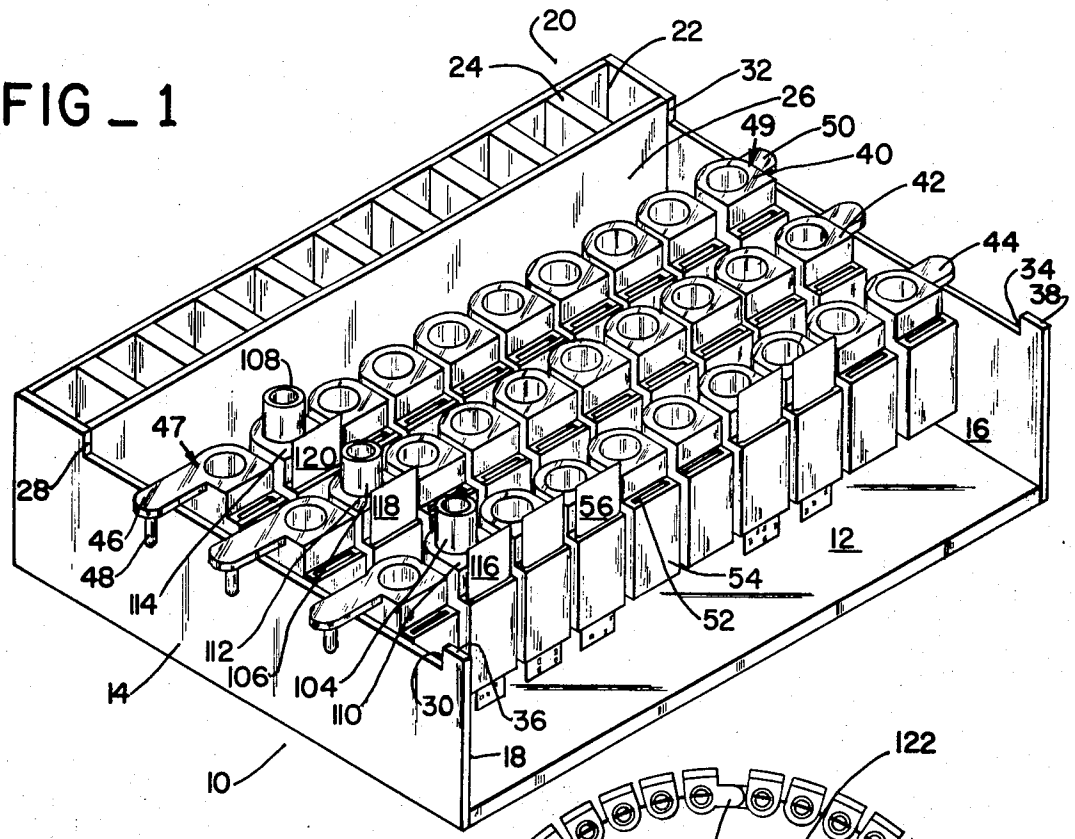
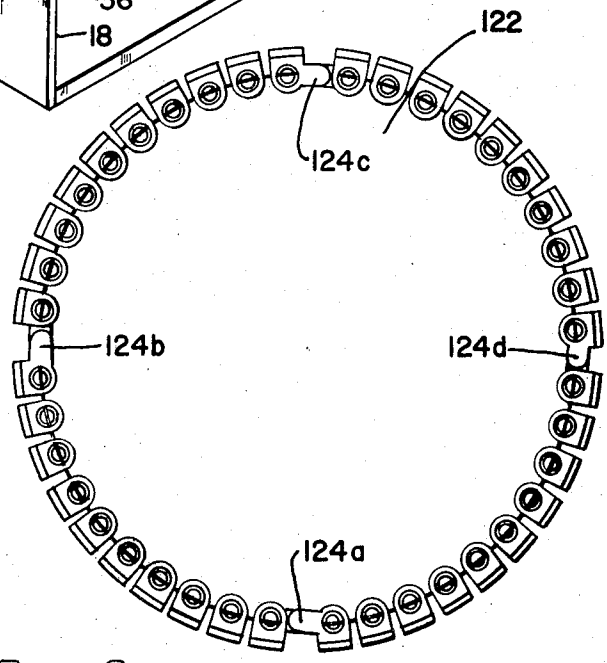


FIG_2



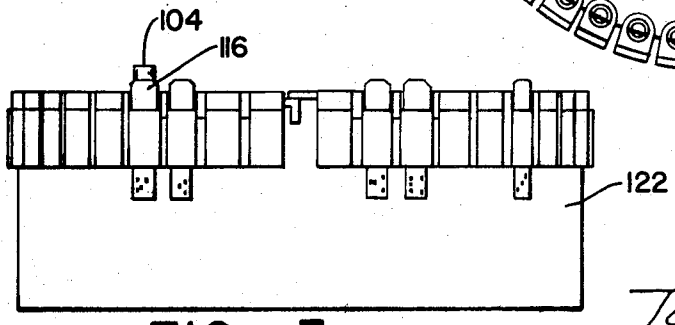


FIG_3

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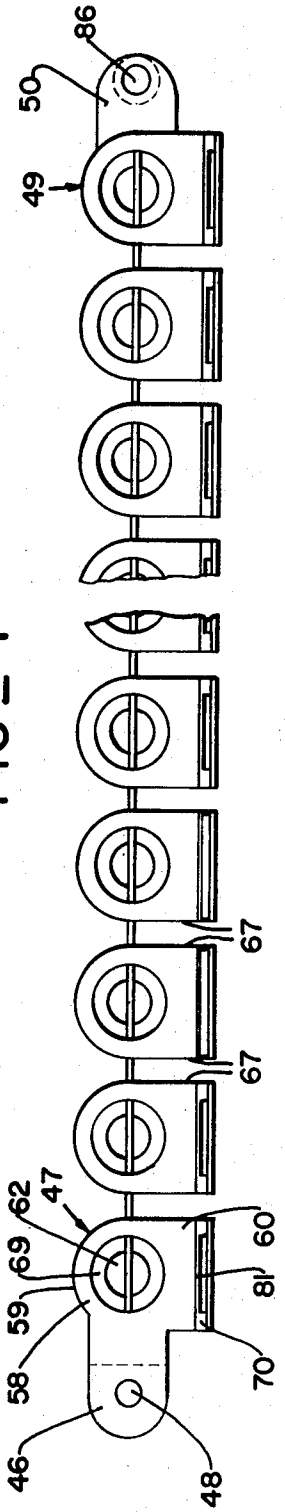


FIG_4

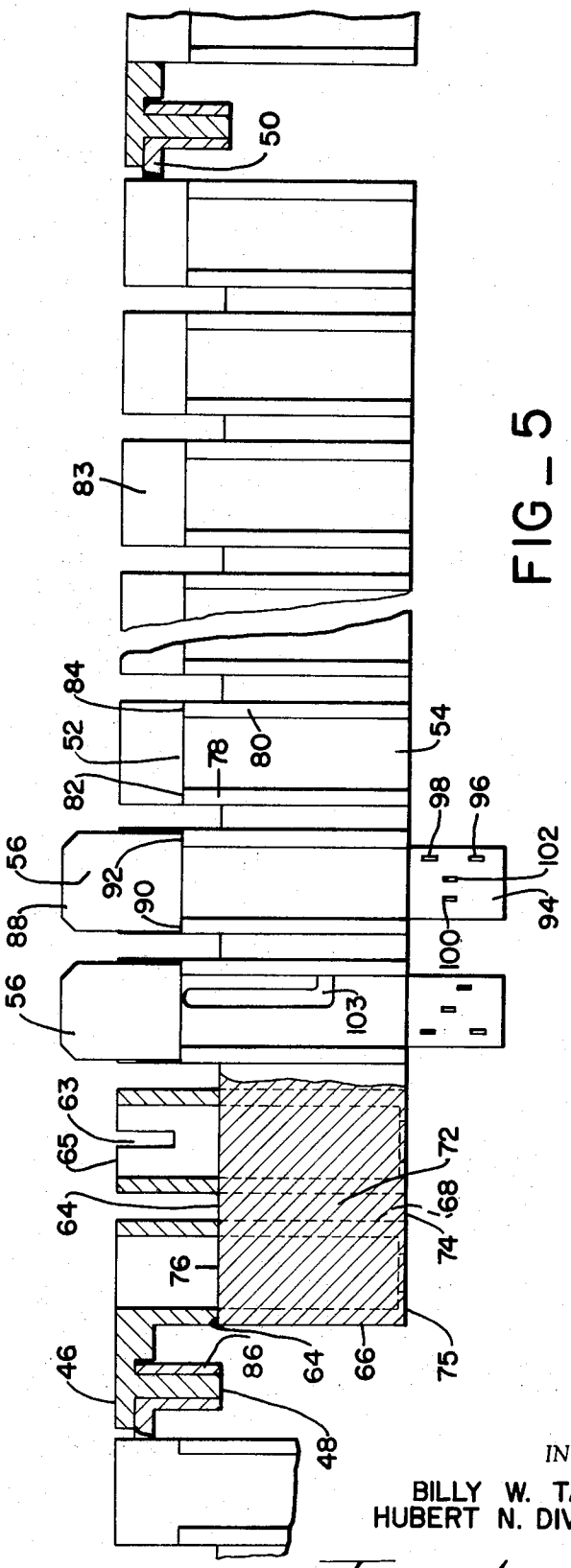


FIG_5

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METHOD FOR ORGANIZED ASSAY AND BENDABLE TEST TUBE RACK THEREFOR

BACKGROUND OF THE INVENTION

1. Field of the Invention

In clinical assaying, it has become extremely common to have a large number of different samples, e.g., blood, which must be distributed for a significant number of tests, each test requiring specific reagents or characterizations related to that test. In view of the importance of the results, it is essential that each one of the samples be quickly and efficiently related to a specific source. Where samples have to be moved about and the order of the samples is continually being changed, errors in marking and recording, or switching of samples, become extremely difficult to police.

There is, therefore, a need for systematizing and organizing the removal of samples from a source, the combination of the various aliquots with different reagents, and the recording and organizing of the results. The apparatus and method should be compatible with the different pieces of equipment used for sample determination employed today. Furthermore, it must be simple, easily understood, and safe to handle and use.

2. Description of the Prior Art

Various pieces of equipment are available for clinical laboratories, with a variety of sample holders, labeling techniques, circular reagent dispensers and analyzers. Discussions of laboratory techniques and equipment may be found in Benson, et al., Multiple Laboratory Screening, Academic Press, 1969 and Brittin, et al., Automation and Data Processing in the Clinical Laboratory, Thomas, Springfield, Ill., 1970.

SUMMARY OF THE INVENTION

Apparatus and method are provided for organizing systematic sampling and assay, by employing a flexible rack having a plurality of sample container holders, so as to be suitable for use both in a straight or arched structure. Each sample holder containing a sample is associated with a particular marking device, which may be color/coded, punched, tabbed, numbered, or given other indicia.

The rack can be assembled end-to-end and side-by-side forming a systematic group for assigning different samples to each container holder in the linear direction (column) and different aliquots in the side direction (row). The rack is also supplied with both sample and aliquot identification.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a rack holder having a plurality of racks;

FIG. 2 is a circular rack holder, the individual racks in tandem bending with the circumference;

FIG. 3 is a side view of a rack holder with individual designation strips, as situated on a circular rack holder;

FIG. 4 is a top view of the rack holder;

FIG. 5 is a side view of the rack holder with specific strip designations.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

In a clinical laboratory, one or more samples are brought in for a series of the same or different tests.

Frequently, depending on the results of the tests, further tests may be carried out, with additional samples being drawn from the original sample. It is important during these tests that all of the aliquots withdrawn from the original sample be easily and readily associated with the original sample and that the results obtained be easily recorded and identifiable with a particular sample.

In the present invention, a single or series of racks are used which have a plurality of sample container holders (referred to as sample holders) or receptacles joined in a flexible manner to permit association with both rectangular or circular rack holders. A variety of rack holders are possible which permit the linear extension of the rack and allow for objects depending from the individual sample holders, e.g., identity markers. One such rack holder is indicated in FIG. 1. The rectangular rack holder is a box having three sides, being open on one side for convenient access. Samples of blood, urine or other biological fluid are brought into the laboratory and can be placed one at a time in a fixed ordered relationship. Each sample has some code designation.

The rack holder has a series of compartments which may be used for holding samples, identification tabs or both, so that portions taken from the original sample, will be associated with a specific order originally established in the rack holder. Perpendicular to and extending from the terminal portion of the fixed series of cells or compartments are two sides upon which the ends of the racks rest. The series of racks are supported by these sides and the individual sample holder in each rack conforms with and is aligned with each of the compartments in the fixed line. Therefore, one can have any number of racks from 1 to n and there is an individual sample holder in each rack which is aligned with the fixed cell.

Special designation slips are provided which fit into a housing provided on the sample holders in the racks. Therefore, with each sample, a color or other simple code designation may be used to indicate from which of the samples material has been taken and introduced into the sample holders in the racks. Other designations may also be provided on the identification slips, such as the test to be carried out, reagents to be added or other information which is considered pertinent during the determinations. Furthermore, the slips may be marked with the results, so that at the end of all the determinations, the slips may be removed and the results recorded.

After aliquots have been withdrawn from the original sample and introduced into the sample vials, cups or other containers in the sample holders of the racks, the racks may now be moved to any site in accordance with the scheduled tests. The identification marker stays with the individual sample, and provides ready identification of the sample and what is to be done with the sample. The racks may be mounted linearly or on a turntable for automated addition of reagents or reading of results. The racks have a pin at one end and pin holder at the other, so that they may be aligned in long rows and retain a predetermined distance between the samples and individual racks.

The identifying markers may extend beyond, both below and above, the sample holder. This permits

punching of the identifying marker with results which may be read on a computer. Therefore, by having automated reading of results, and automated punching to indicate the results, the possibility of error is minimized in relating the sample and result.

For a more detailed description of the method as well as the apparatus, turn now to a consideration of FIG. **1**. A box **10** is provided which conveniently has a floor **12** and two side walls **14** and **16**, perpendicular to the floor **12**. The box is open at one end **18** and closed at the other end **20**. At the closed end is provided a series of square compartments indicated by the exemplary compartment **22**. The compartments are divided and spaced evenly by walls, only one wall being given a number designation **24**. The remaining side of the individual compartment is enclosed by a wall **26**.

The dimensions of the individual compartments may be varied widely depending on their function. If the compartments are to be used as vial holders, the dimensions will be determined by the size of the vial. If the cells are primarily to hold the identifying markers, the depth and other dimensions will conform to the markers. The dimensions can be varied quite widely to fit any particular container, vial, or marker; most commonly, the container will not be larger than about a 50 cc test tube and the markers will be from 2 to 4 inches long and ⅛ to ¾ inch wide, and may vary in dimension. Any number of compartments may be present, although conveniently, the number would usually vary from 8 to 20, more usually from about 10 to 16, so that the racks are of convenient size for manipulation and transfer.

While not indicated, various simple methods may be used for identification of the original sample. These identifying means may be associated with the compartment or fitted onto the container itself or both. The particular mode chosen will generally be one of convenience and be governed to some degree by the methods employed in assembling the samples.

Walls **14** and **16** are diminished in height for a portion of their distance from **28** to **30** and **32** to **34** respectively. Thus, stops **36** and **38** are provided at the ends of the wall to prevent a rack from slipping off and to limit the number of racks.

As indicated previously, a compartment **22** can be used for the identification tabs. That is, in each row, tabs will be associated with a particular row and have some identifying mark specific to that row. Therefore, any samples in that row will always be identified with that row by its identifying marker.

When an assay or other determination is to be carried out, the racks are set up in the box **10**. Any number of racks may be employed, depending on the number of repetitive determinations on samples; that is, how many samples are to be associated with a row or particular identification. The dimensions of the box **10** are such so as to insure substantial alignment of each sample holder (therefore, each sample) in a row, perpendicular to the fixed compartment.

In FIG. **1**, extending across the box are a plurality of sample holder racks **40**, **42** and **44**. The racks are merely illustrative; there could only be one, or there could be many more, depending on the particular capacity of the storage box **10**. Extending over one wall **14** is an arm **46** (affixed to the terminal sample holder **47**) having a pin **48**. Affixed to the sample holder **49** at the other end of the rack **40** and extending across the opposite wall **16**, is an arm **50**, having a pin housing **86**. The racks can be aligned in tandem by having the pin **48** of one rack housed in the pin housing **86** of another rack.

The pin and pin housing are used for alignment, both in the lower position and for fitting the racks on a turntable. One or more boxes **10** may be set, side-by-side, and the pin **48** of the rack **40** set into the pin housing **86** of the adjacent rack, so that a continuous row of racks is obtained. Usually, each row will be intended for sample aliquots, which are either derived from the same initial sample, or more usually, will be used in the same test procedure.

The rack **40** is supported by arms **46** and **50** lying on the walls **14** and **16**. The other racks have similar arms and are similarly supported. Each of the sample holders lines up with a fixed cell so that there is a line of sample holders in a specific row. Affixed to each sample holder in the row is a marker housing **52** having a window **54**. An identifying marker(s) **56** is held in the housing **52** to identify the sample, if present. In organizing the samples, one can provide long rows of sample holders for a particular test and columns of sample holders (the aligned sample holders in adjacent racks) associated with a particular sample. Depending on the tests to be carried out on the sample aliquots of the sample would be placed in the appropriate containers. Each row of racks would be for a particular test, so that some rows would be skipped, when the particular assay was not required for the sample. Therefore, in distributing the sample, the operator would go down a column introducing aliquots only in rows concerned with the assays which were requested for the sample.

For more detailed consideration of the sample holder rack, turn now to a consideration of FIGS. **4** and **5**. The sample holder **58** (all the sample holders being equivalent, only one will be considered) can have a hemispherical or arcuate portion **59** which extends and joins to a rectangular portion **60** providing two side walls **67** to be substantially rectangular. A tubular opening or channel **62** extends through the entire length of the sample holder. A notch **63** can be provided in the rim **65** to permit nesting of cups of varying diameters. Adjacent the bottom end of the tubular portion is a circularly constricted shoulder portion **69**, extending about ¼ to ½ inch up the tubular opening **62**. The shoulder provides insurance against a vial slipping through the sample holder, and provides added strength.

If a continuous membrane is to be used to join the sample holders, at about ⅛ the way down the sample holder **58**, indicated at **64**, two slots or grooves **66** and **68** are introduced, extending the remaining length of the sample holder **58** and being present on opposite sides of the sample holder, determining a plane parallel to the flat side **70** of the sample holder. The slots are equidistant from the corner of the flat side **70**. Extending through the slots is a membrane or flexible plastic sheet **72** having its bottom edge **74** substantially aligned with the bottom of the sample holder **75**. The membrane extends through a series of sample holder slots, the sample holders being evenly spaced a few millimeters apart. The spacing is adjusted to fit into the auto-

mated equipment which is available in the laboratory, so as to provide the proper spacing for the timing or movement of the equipment during the addition or removal of reagents to or from the vials in the sample holders.

The membrane is dimensioned so as to provide a support for the number of sample holders to be on an individual rack. The membrane will be anywhere from 6 inches to 2 feet long, usually from 9 inches to 18 inches long (the transverse dimension). The width of the membrane will be determined by the slot size, the membrane normally extending the full length of the slot, preferably not extending beyond the base of the sample holder. In this way, the sample holders, which have a flat base, provide a relatively stable conformation, which can stand unsupported on a bench top. Usually the width (upward dimension) will be from ¾ of an inch to 2 inches, when dealing with sample holders for vials of from about 1.0 to 50 cc. capacity.

The thickness of the membrane can be varied widely, depending on the tensile and elastic properties of the material employed. Usually, the polymer will be at least 1/32 inch thick and not more than 8/32 inch thick, more usually from about 2/32 to 5/32 inch in thickness. The particular dimensions are primarily a matter of convenience, adapted to the size of the sample holders to be accommodated.

The membrane provides a stop **76** to prevent the via' from going to the bottom of the sample holder. By extending about one-half to two-thirds the length of the tubular opening **62**, to the stop **76**, the vial is held in a tubular section about one-half to one-third the length of the tubular opening **62**. The particular size will be fixed by the vials to be used, although one size, can accommodate a number of different vials of diminishing diameter, at or below the diameter of the tubular opening **62**. In addition, the membrane **72** provides a mounting support for a plurality of sample holders, which can be maintained in a fixed predetermined spatial relationship. The sample holders may be mounted on the membrane in a variety of ways, either fixedly or removably. For example, a plurality of notches may be introduced in one edge of the membrane, being spaced apart so that the sample holder fits down over the notch and is locked into position at a fixed distance from the next sample holder. Alternatively, the sample holder may be glued to the membrane so as to fixedly retain its position in relationship to the other sample holders. Various ways may be used in accordance with the particular needs in a laboratory.

Instead of mounting the complete holder on the membrane, the membrane may be bonded to the back side of the sample holders. No notches would be required for insertion of the membrane. Any bonding material could be used, or the entire rack could be molded as an integral piece. This mode would leave the channel open.

The membrane is characterized in having sufficient rigidity so as to maintain the sample holders in a substantially straight line and at a fixed distance. At the same time, it has sufficient flexibility to bend to provide a mild arc, so as to be adapted to a turntable, yet, when removed from the confines of the turntable, the membrane has sufficient resistance to deformation to return substantially to its original straight position. Various plastic sheets of material may be employed which have the necessary tensile properties. Illustrative plastics include polyethylene, polypropylene, polystyrene, etc.

Of course, other means can be employed which would fulfill the function of the flexible membrane. Flexible interconnectors could be bonded to the sides of the sample holders, such as spring steel, which have the necessary resilience and rigidity. The facets of the interconnecting means is the maintenance of the spatial relationship of the sample holders, sufficient resilience to permit arching, and sufficient rigidity to return substantially to a straight line when the restraint inducing the curving is removed.

Another embodiment is to prepare the rack in a single mold, where the plastic material employed provides the desired flexibility between the sample holder. In this embodiment, the web would not enter the container channel, so that the channel would be open for most, or all, of its length.

Rigidly fixed to the flat wall **70** of the sample holder are two small extension walls **78** and **80**, extending outwardly from the wall and beginning at about 1/5 of the way down the back wall of the sample holder at positions **82** and **84** and extending to the bottom of the sample holder. The extension may be grooved to aid in holding the markers. The grooved extensions are sufficient to hold the identity marker **56**, but may be joined by a clear wall **54** to form a housing or enclosure **52** for holding the identity marker **56**. The clear wall can be any clear material, particularly Lucite or other clear plastic, and may be bonded or fastened to the extension walls **78** and **80** so as to provide the desired enclosure.

Preferably, the identity marker is displaced a short distance from wall **70** by stepped wall **81**. Conveniently, the stepped wall extends the full length of the housing **52** so that the positions of the identity marker **56** extending beyond the walls **78** and **80** of the enclosure do not lie flat against the sample holder wall **70**, the stepped wall providing a relieved portion **83**. This can be convenient or in some instances necessary for ease of removal of the identity markers **56** or for sensing of information printed on the marker, particularly on the portion above the enclosure **52**.

The identifying marker **56** has an expanded head **88** and shoulders **90** and **92** which rest on the extension wall top edges **82** and **84** respectively. The shoulders **90** and **92** of the marker head which rest on the edges **82** and **84**, prevent the marker from slipping through the housing **52**. Other means may be provided for holding the marker in place. The marker then extends down having a strip which fits between the extension walls **78** and **80** and extends below the bottom of the sample holder, providing a portion **94** for carrying information or actuating the various devices. For example, holes **96** and **98** can be cut in the marker **56**, which when the sample holder is in the proper position will actuate a device to add a particular reagent or take a particular reading. By appropriate mechanisms, the reading can then be recorded by introducing additional holes **100** and **102**, which can be read on a computer and provide the results in relationship to the particular sample.

The marker may have a channel **103** cut into one side, so as to flex against the extension wall **80** to provide enhanced retention of the marker **56** in the enclosure **52**. If desired, the marker need extend only a por-

tion of the distance down into the housing **54**, only the head **56** extending outside the housing **54**. A notch **103** may be used so as to provide a tight fit for the marker and retain the marker in the housing during the various manipulations.

Turning now to a consideration of a particular mode of operation. For illustrative purposes, only one sample will be considered, although it must be understood, that the same procedure could be repeated with a plurality of samples and in a wide diversity of ways. Let us assume that three different assays are to be carried out on the same sample. Three vials are provided **104**, **106** and **108**, situated in sample holders **110**, **112** and **114** respectively. The reagents appropriate for the determinations are present in the vials and markers **116**, **118** and **120** indicate the particular test that is to be carried out. As previously mentioned, this can be indicated by a color code, number code or other convenient designation, which can be read by an instrument. The appropriate amount of the sample to be assayed is introduced into the three vials **104**, **106** and **108**, and the appropriate code indication indicated on the markers **116**, **118** and **120** respectively, designating the particular sample.

For purposes of the present discussion, it will be assumed that the assay will be carried out on a turntable **122**. The racks **40**, **42** and **44** are removed from the box **10** and placed on the turntable in appropriate positions, forming a circle around the turntable. The racks are connected at positions **124** *a*, *b*, *c* and *d* by the pin and pin slots, so as to provide a continuous circle of samples with appropriate spacings between the samples. Above the turntable, not indicated in the drawing, are a plurality of reagent holders, feeding to a common syringe. Each one can be accommodated with its own valve mechanism, which is automatically operated. The turntable is automatically operated turning to provide an individual sample under the syringe according to a predetermined schedule. A side view of the turntable is indicated in FIG. **3**. When vial **104** approaches the position under the syringe, the marker **116** has the necessary information to indicate what additional reagents should be added to the vial. By appropriate mechanisms, the reagents are introduced into the vial **104** and agitated, either mechanically or manually, as convenient.

In many instances it may be desirable to mount only one rack on the turntable. Therefore, the table can be provided with various connectors or holders for holding the rack in place. Posts can be provided having an opening at the top to receive the female housing **86**. An adaptor can be provided for the pin **48** to provide a snug fit in the post opening. Alternatively or in addition, a series of spaced pins can be mounted on the turntable, onto which the sample holders could be mounted. Other mounts or flexible holders could be employed, as convenient.

If a completely automated system is desired, and, for example, colorimetry is being used for analysis, the sample may at the same station, or at a different station, be read by a colorimeter. The result can then be indicated on the marker by any convenient means, such as punch holes, printed numbers, etc. When all of the assays have been carried out, the vials may be used for other purposes if convenient or be discarded and the identifying markers removed. Each identifying marker will now indicate the particular test carried out, the identity of the sample, and the results of the assay. By using computerized methods, all of these values will be read from the same marker and will be associated one with the other. Furthermore, the markers provide a permanent record of the results, which can be referred to as required.

The present system provides a versatile method for clinical determinations, insuring accuracy and efficiency. The sample holders conveniently maintain a vial in relationship to an identifying marker, which can be repeatedly marked as the sample is carried through the various procedures. The marker then maintains a permanent record of the history of the particular sample. Furthermore, the sample holders can be supported by a membrane so as to be maintained in a fixed ordered relationship. The samples in the sample holders can then be maintained in the same relationship while being carried from one procedure to the next. The samples can be used where they are aligned in a straight line relationship or in an arced relationship about a turntable. By using the rack, assay methods can be simply and efficiently organized in a repetitive manner to insure accuracy in recording results and relating the results to the particular sample. In addition, relatively unskilled people can be rapidly taught the method and be brought to a high degree of proficiency within a short period of time.

What is claimed is:

1. A method for carrying out assays on a plurality of samples, whereby the sample containers are originally aligned in straight rows and columns and then moved to a circular turntable, without requiring the transfer of samples individually which comprises: arranging a plurality of rows of flexibly connected sample container holders, so that the sample holders having the same position in each row form a substantially linear column, distributing samples into sample containers situated in said sample container holders; and transferring one or more of said rows to a circular turntable, arching the flexible connections to conform with the circular turntable.

2. A method according to claim **1**, wherein an identifying marker joined to each sample container holder having a sample, so as to provide identification of the sample during an assay.

3. A method for carrying out a systematic and organized assay to obtain accurate and reliable results and relate the results to a particular sample which comprises: arranging a plurality of racks, having a plurality of sample container holders flexibly interconnected so as to provide a series of parallel rows of sample container holders; connecting an identifying marker to at least each sample container holder into which a sample is to be introduced; introducing samples to be assayed into sample containers in said sample container holders in conformance with the identifying marker; moving the sample racks to either straight or curving dispensing devices in accordance with the information on the identifying markers; registering results obtained from the determinations of the samples identified by the identifying markers; and recording the results.

4. A method according to claim **3**, wherein the results are punch holed onto the identifying markers or

indicia printed on the identifying markers, so as to be capable of being read by a computer.

5. A sample container holder for use in a systematic organization of sample containers adapted for mounting on a flexible membrane comprising: a receptacle member having a first curved side, a second side opposite said first curved side, two side walls, oppositely situated joining said first and second side, and forming opposite corners where said side walls meet said second side, a flat base surface; a circular channel extending through said receptacle member downwardly, at least a portion of the way to said base; extending from said base upwardly through said receptacle member, slot means for mounting on a membrane, the slot means forming openings in each of said side walls which are equidistant from said corners; and an identifying marker holding means affixed to said second side.

6. A sample container holder according to claim 5, wherein said identifying marker holder means comprises: a relieved portion of said second side providing a stepped wall; and at other than said relieved portion, grooved side walls extending outwardly from said second side.

7. A sample container holder according to claim 5, wherein at least one of said sides of said receptacle member is notched at the top surface to provide a convenient cup holder.

8. A sample container holder rack for use in systematic assaying of samples whereby the sample containers are maintained in a stable arrangement during the assay, which comprises: a plurality of sample container holder means; interconnecting means for flexibly interconnecting said sample container holding means in a uniformly spaced relationship; sample identification means associated with said sample container holder means, and two terminal sample container holder means, having connecting means for connecting racks in tandem.

9. A sample container holder rack according to claim 8, wherein said interconnecting means is a flexible plastic web extending a portion of the length of said sample container holder means.

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