United States Patent [19]

Roulette et al.

[11] **3,916,157**

[45] **Oct. 28, 1975**

[54] **SPECIMEN CARRIER**

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[22] Filed: **Aug. 16, 1972**

[21] Appl. No.: **281,071**

Related U.S. Application Data

[63] Continuation of Ser. No. 70,393, Sept. 8, 1970, abandoned.

[52] **U.S. Cl.** ..... **235/61.12 R;** 23/259; 73/53; 235/61.12 M; 235/11 R

[51] **Int. Cl.²** **G06K 19/04;** B01L 9/06; G06K 13/00

[58] **Field of Search** ... 73/53; 235/61.11 R, 61.11 E, 235/61.11 B, 61.12 R, 61.12 N, 61.12 M, 61.9 R, 61.7 R; 23/253, 259, 250; 356/36; 200/46; 194/9 R, 100 R, DIG. 11; 88/14

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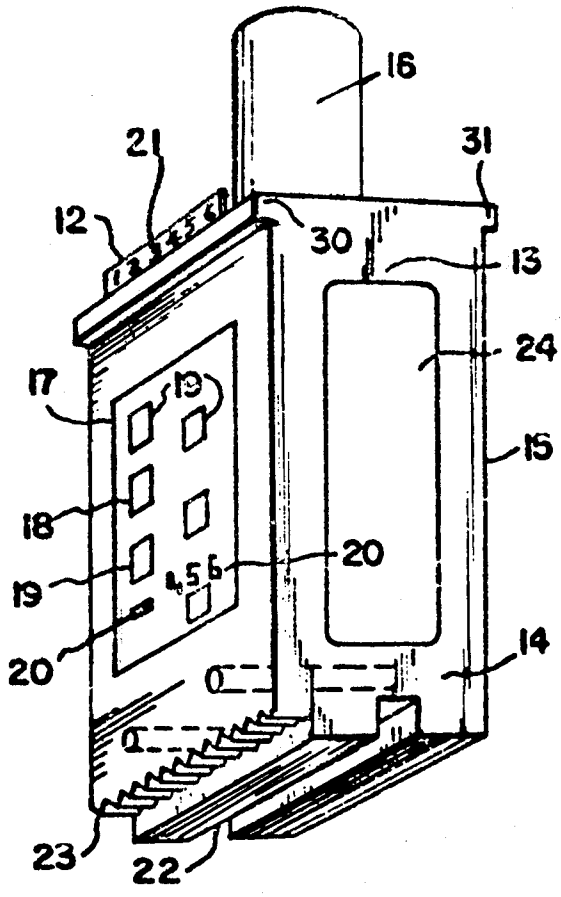
[57] **ABSTRACT**

The specification describes a carrier for test tubes or other containers that will keep the specimen together with its identification from the time the specimen is taken until the final results are obtained. The carrier is adapted to be handled automatically in conjunction with an analytic instrument and to provide for readout of identification and results from the analytic instrument.

19 Claims, 5 Drawing Figures



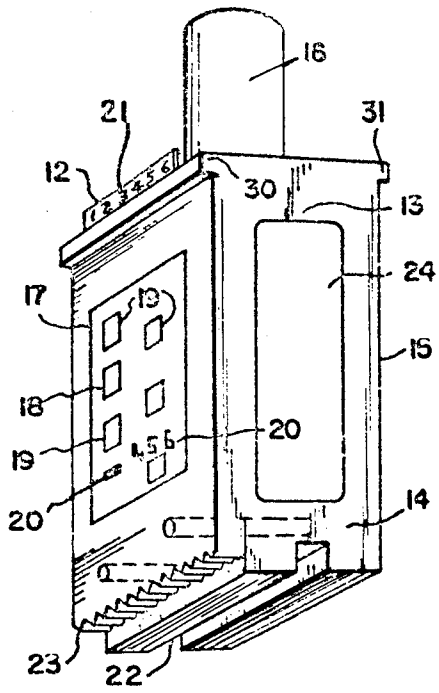


FIG. 1

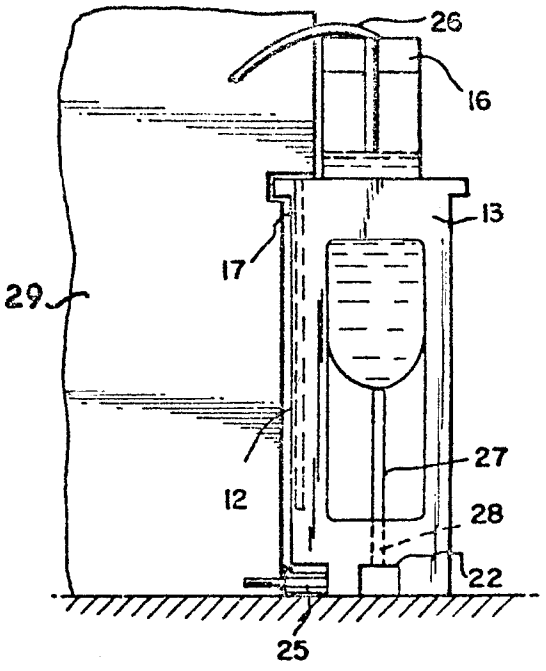


FIG. 2

DATE	100061	LAB	TEST	COLL. TIME-DATE
PATIENT NAME	☐ STAT ☐ PRE-OP	TEST NAME		
ROOM # BED ADM.	☐ TODAY ☐ ROUT.	SOURCE		100061
	PHYS. ORD. TEST	DIAGNOSIS		
SOCIAL SEC. NO. AGE	NURSE COLLECTED	COMMENTS		

FIG. 3

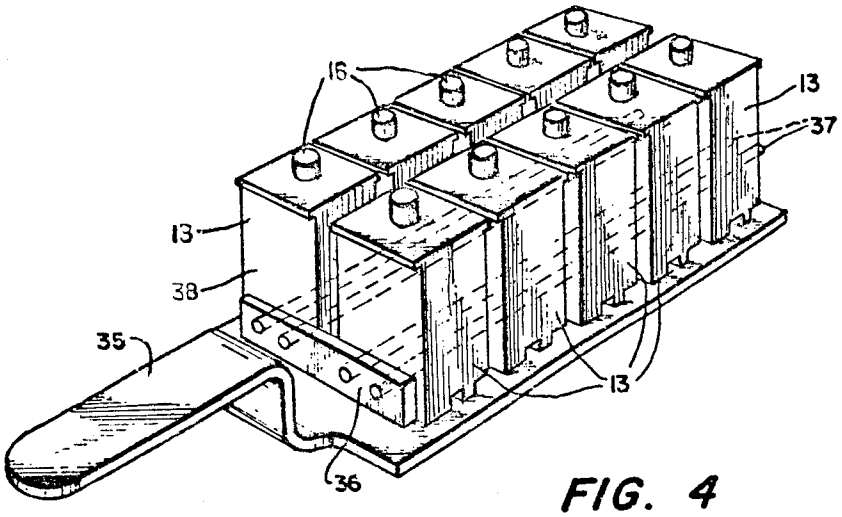

16
13
37
13
38
35
13
36

FIG. 4

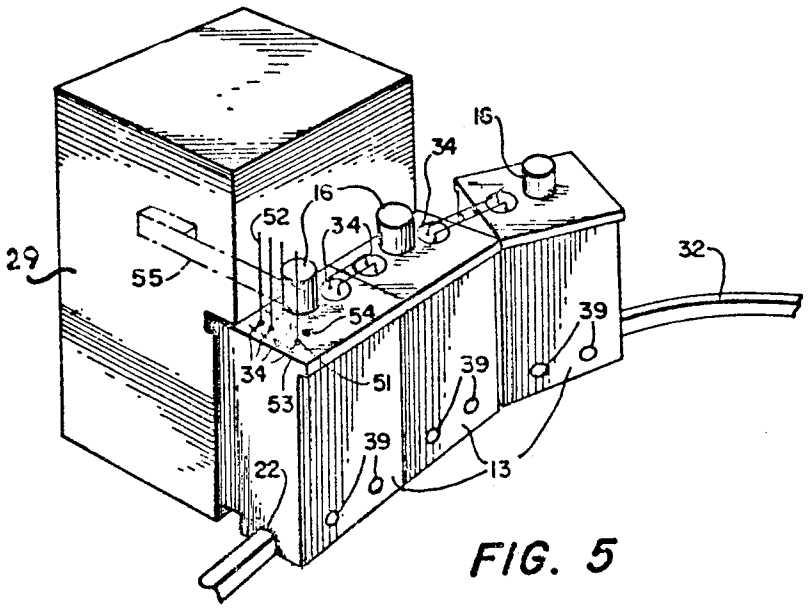

16
34
16
52
34
29
55
32
54
39
34
53
51
39
39
22
13

FIG. 5

SPECIMEN CARRIER

This is a continuation of application Ser. No. 70,393, filed Sept. 8, 1970, now abandoned. su

HISTORY OF THE PROBLEM

The identification of specimens analyzed in clinical laboratories has for many years been one of the most time consuming and potentially dangerous operations in the laboratory. An error in the identification of a sample could easily result in either the wrong medication being applied to a patient, or no medication when medication is needed. Given the power and potency of today's modern drugs, the hazard of error is enormous.

A typical system used throughout most of the clinical laboratories in the country involves the following steps. First the sample is drawn and a requisition slip for the sample source identification is attached to the test tube with a rubber band. Upon arrival in the clinical laboratory, the requisition slip is detached from the sample tube, and a lab control number is attached to the tube and written on the requistion slip. For many of the tests, the sample tube is then placed in a centrifuge and spun, and then decanted by any one of several means into other test tubes. At this point the numbered label from the original bulk sample is transferred to the decanted sample or in some instances multiple lab control numbers are applied to the various tubes. At this point in the analysis, the analyzing procedure begins, and the test tube is either fed into a large automatic clinical analyzer, or it is manually given some chemical processing such as the adding of chemical reagents, shaking, heating, dialyzing, etc. In addition, certain portions of the bulk sample may be subejcted to detector tests using instruments such as a colorimeter, a spectrophotometer, a fluorometer, a flame photometer, a pH meter, cell counters, or a variety of manual techniques. After the various tests have been completed, the lab technician records the results and the lab control number on a worksheet in the laboratory. The data from the worksheet is then transcribed back to the initial requisition form and the results sent back to the nursing station or doctor who requested the analysis. A charge for this service is then initiated by detaching one part of the requisition, entering the fee and forwarding to the business office.

Several designs presently utilized in the prior art attach a machine readable card to the specimen, using a rubber band. The card is unprotected and easily damaged in manipulations and then must be specially placed in the instrument in some fashion. For the few analytical instruments so configured, the specimen must be transferred to special containers that fit the specimen handling hardware and the identity cards must be separately handled. One prominent commercial analyzer for example, requires that when the specimen is transferred, the identification label must be separately transferred introducing a handling step which further multiplies the hazard of error.

The analytical instruments on the market today generally do not provide for discrete specimen identification or any machine reading of the specimen identification. In many automated instruments the sequence of results is used to assign the analyzed value to specimen. This rigidity necessary in maintaining a fixed sequence which may not be altered once the order of specimens is listed on the roster, compromises the ability to make changes necessitated by the arrival of specimens requiring high priority handling. Further, the hazard created by the assumption of a fixed sequence properly recorded, and the time lost in manually recording this sequence renders this a most unsatisfactory method.

As can be seen from the above description, there are many places for error in which the wrong number could be entered or the wrong results recorded between the patient and the final results.

The new automatic analytical instruments that have appeared in recent years have been a great boon to the technician insofar as the actual test is concerned. However, most of the efforts in this field have involved the performance and logging of tests in the usual fashion plus the addition job of card punching so that the results could be recorded in the computer memory. Clearly, these programs preserve all of the existing sources of error created by transcription and transposition mistakes. They have also added a new dimension requiring additional manpower and creating new hazards without any of the benefits of process control.

In addition to the possibly catastrophic effects resulting from a transposition error, the technician time in logging, calculating, recording, charging, and transcribing has grown to be especially significant. The clinical laboratory for one large metropolitan hospital logs several million test results in one year after examination of more than 250,000 specimens. Although many of the tests are performed on partially automated machines, the mathematical extrapolations, the recording and transcription of the numbers, were done by hand. Automation has emphasized analytical instrument design, which has reduced the technician's time in the actual performance of tests. While this has reduced the ratio of time spent on calculations and analysis, it has increased the portion of time spent on clerical duties as opposed to the technical work. At this time all of the testing, calculating, recording, and reporting is done by hand. The new automatic clinical analyzers have generated sufficient volume and variety that the workload can no longer be handled manually.

While virtually all of the automatic clinical analyzers have provided with them a specific carrier for the bulk sample, it is still necessary to decant portions of the original bulk sample from the original test tube into the machine's specimen carrier before the analysis is begun.

The current state of laboratory development is really mechanization rather than automation as it is so often called. In order to achieve the benefits of computers in the clinical laboratory, absolute accurate specimen identification is essential. For safety, efficiency and reliability, such identification must be applied at the time of collection and accompany the specimen through all manipulations to the analytical station. The carrier for the specimen's identification must allow visual identification and routing. The carrier must be adaptable to the variety of specimen containers used and be stable under refrigeration, incubation, autoclaving, and centrifugation.

OBJECTS OF INVENTION

It is an object of my invention to provide a method and means for identification of the bulk sample from the time the specimen is taken until after all of the analyzing steps are completed, and the report generated.

It is another object of my invention to permit discrete specimen identification providing machine as well as visual readable capability.

It is another object of my invention to provide a carrier with identification that can accompany the specimen through freezing, refrigeration, autoclaving, and centrifugation.

It is another object of my invention to provide a self-supporting carrier for a standard test tube or other container which may be utilized in the manual analysis of the specimen, or in an automatic clinical analyzer.

It is another object of my invention to provide a carrier adaptable to various common types of test tubes and other specimen containers.

It is another object of my invention to provide a carrier which will permit the formation of an endless chain of specimen carriers for use is an automatic clinical analyzer.

It is another object of my invention to provide a carrier which will permit the automatic elevation of the specimen container to permit the automatic sipping of a discrete specimen during automatic clinical analysis.

It is another object of my invention to provide an identification for a carrier which may be read visually, as well as mechanically, by means of optical scanning, magnetic readout, or a punch card station.

It is another object of my invention to provide a carrier which is dynamically and statically balanced about the three major axes for use in centrifugation.

It is another object of my invention to provide a test tube carrier with identification which will allow the automatic computer printout of test results, patient history, and billing when used in conjunction with an automatic clinical analyzer.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an isometric view of my specimen carrier with a standard test tube inserted therein.

FIG. **2** is a side view of my specimen carrier illustrating the elevation of a standard test tube for the automatic sipping by an automatic clinical analyzer.

FIG. **3** is a plan view of the requisition form and punch card identification utilized in my invention.

FIG. **4** is an isometric view of my specimen carrier when utilized in the manual analysis of laboratory specimens.

FIG. **5** is an isometric view of an endless train of specimen carriers utilized in an automatic clinical analyzer.

DETAILED DESCRIPTION OF THE INVENTION

In the present invention, when a doctor requests that a certain test be performed, a therapist or technician will draw the sample into a test tube or other standard container and place the test tube in the specimen carrier. At the same time the requistion form illustrated in FIG. **3** may be filled out by the nurse drawing the sample, or generated by a computer requisitioning program. The tear tab portion **12** is then detached from the requisition form and slipped into the specimen carrier in a manner which will be later described. This tear tab carries with it a visual and machine readable identification number that will serve not only as the requisition number, but also the lab and control number as the sample is analyzed. The carrier, together with its specimen and identification, is then sent to the clinical laboratory where it is normally centrifuged. After the centrifugation, the carrier is then inserted into a self-propelled train for sampling by an automatic analytical instrument or other analyzing machinery, or it may be transferred from lab bench to lab bench for manual analysis. Since the carrier is selfsupporting, it provides a support stand and base for the test tube during analysis. If the analysis is done by an automatic clinical analyzer, the machine readable identification provides a computer input for each and every sample. In this manner the computer is able to provide a report of the analysis to the physician as well as to correlate the results of a previous test on the same sample with the result that is now being transmitted from a specific analysis. Thus the number of utilized not only in a multiple analysis operation wherein the results of a previous step are correlated, but it is also useful in the subsequent analysis of a different bulk sample taken from the same patient. It is also used in determining the proper routing of the report.

The test results from the automatic clinical analyzer in conjunction with the specimen number are fed automatically into the computer memory for subsequent printout at the nurse's station together with the specimen identification.

Technician observations may also be entered relevant to the specimen and its examination. This information obtained by the technician is entered in conjunction with the instrument's analytical result and the specimen number through the "Laboratory Data Control Station."

This carrier is part of a larger system, the "Laboratory Data Control System," which includes a communications console, a reader for recognition of the card number, the card reader electronics, and a portion of the drive mechanism for driving the carrier past the card reader.

A manual keyboard is provided for the technician at certain stations for entering the results of any essentially morphologic tests such as hematology, urinalysis, or bacteriology. For these tests, the technician will enter into the computer memory system the results observed from the test, without the requirement of keying in the requisition number, since this will also be read from the specimen carrier.

Examples of analytic instruments which provide an analogue readout are colorimeters, flame photometers, fluorometers, spectrophotometers, densitometers, blood cell counters, chloridometers, pH meters, and fibrometers. An electronic analogue to digital conversion will occur automatically at the time of analysis with the direct electronic transfer to the computer in its memory bank. At the same time the result is identified as well as being logged so that the identification of the sample throughout the entire analysis operation is done automatically by machine to prevent the human errors in transposition.

After all of the analytical steps are completed, the computer is then able to provide an automatic printout of all tests and test results when queried about the identification number. Since the identification number was entered in the first requisition, and carried throughout all of the analyzing steps, the only chance for error in the identification of the sample would be computer error caused by completely random failure within the computer.

In addition to the immediate transfer of information electronically from the clinical laboratory to the nursing station where the results are printed out, the com-

puter also provides automatic billing for the lab analysis when the bill is prepared. In addition a physician will automatically be able to obtain a complete case record including all previous analyses by querying the computer using the patient's name. The availability of a single, type-written, printed compilation containing both daily test results and a complete record of all test results on that patient eliminates the frustration of leafing through pages of charts to find the pertinent past reports as is presently required.

The specimen carrier itself is molded from plastic, although it may be formed out of any suitable material and is illustrated in FIG. **1.** The specimen carrier **13** constitutes a stable base portion **14** and support means **15** extending upwardly from the base to support a test tube or other standard container **16.** This allows the specimen carrier to be self-supporting when placed on a flat horizontal surface to support the specimen carrier **16** in an upright position. identification means **17** are provided along the inner walls of the specimen carrier to allow the entry of the tear tab **12.** This tab is inserted in a pair of narrow slots **17** (FIG. **2**) and is visible through a large opening **18** which is provided in the front of the specimen carrier. The tear tab **12,** illustrated in FIG. **1** is provided with a plurality of punch apertures **19** or magnetically coated indicia **20.**

For the purposes of the invention, any suitable machine readable identification may be used. FIG. **1** illustrates a card which may be read by an optical scanner by scanning the numbers printed on tab **12** on the upper most portion **21.** It may also be read by an optical scanner which would scan the face of the tear tab and provide a reflected light reading that would provide an absent pulse where ever the light failed to strike the card due to the punch card openings **19.** The tear tab also provides for magnetic identification by means of magnetic indicia **20.** This indicia may be magnitized, unmagnitized, or magnetized in opposite polarities or may be a specific geometric arrangement of permeable material to enable a magnetic sensor to obtain a digital or analogue output. Additionally, the punchcard openings **19** would allow a machine reading by mechanical fingers, to provide a punchcard readout.

Base **14** defnes a guide rail opening **22** and transmissions means **23.** Transmission means **23** constitutes a rack gear which is moulded or mounted on the bottom of the carrier for an engagement with a corresponding transmission means in the "Laboratory Data Control Station." In this manner the carrier may be transported automatically past the station to acquire the requisition number and to start the next analysis.

Carrier **13** also defines a pair of openings **24** on either side or rear of the standard container **16** to enable an optically deformable beam to analyze the bulk sample by projecting the beam through the opening in the specimen carrier and the bulk sample.

The requisition form **11** has appropriate spaces for entry of the patient's name, the room and bed number, the outpatient address, the patient's social security number and age, the physician ordering the test, together with the supervising nurse and the nurse who collects the specimen, together with the clinical laboratory to which the sample will be sent, the type of test requested, the way in which the sample was obtained, the present diagnosis, and the critical identification number. This identification number is also entered on the tear tab portion which is inserted in the specimen carrier. In operation, the nurse collecting the specimen, detaches the tear tab and inserts it in the specimen carrier along with the specimen before sending the specimen to the clinical laboratory.

FIG. **2** illustrates my invention at "Laboratory Data Control Station," wherein a pinion gear **25** has moved the specimen carrier to the appropriate position for automatic sipping by sipping tube **26.** Elevator rod **27** is injected through elevator opening **28** defined by the base of the specimen carrier. This elector rod elevates the test tube **16** to a predetermined height to enable the automatic analytic instrument to sip a discrete sample from the bulk sample contained in this specimen carrier. At the same time the machine readout **29** correlates the identification provided on tear tab **12** and the results of the analysis from the analytical instrument and forwards the two to the computer memory bank. The identification means **17,** together with the tear tab **12,** are illustrated by the dotted lines in the specimen carrier. Additionally, this would allow the supernatant height to be detected and obviates the need to decant the sample from the initial tube holder into a special holder for the analytical instrument.

Referring again to FIG. **1,** the upper portion of the specimen carrier **13** is provided with two abutments **30** and **31** which extent outwardly from the center axis of the carrier in opposite directions. The carrier is also dimensionally stable and its weight is dynamically and statically balanced about the three major center lines for centrifugation. The primary center being the center axis for the test tube or standard container **16.** This enables the clinical lab technician to insert the specimen together with the specimen carrier into a centrifuge for centrifugation without the necessity of labeling the test tube separately, removing the test tube from the carrier, centrifuging it, and then decanting the specimen into a specific machine carrier for an analytical instrument and transferring the number from the specimen container to the new specialized recepticle for the automatic clinical analyzer. Thus the lab technician does not have to transfer a single entry throughout all of the analysis of the specimen and the identification number and the specimen remain together throughout all operations.

The carrier is not dependent upon any one system of automatic analysis. It is designed to be compatible with all systems and has no features which are unduly restrictive, which would limit it to a single system.

Any of the present commercial systems may be modified by addition of the transport means to utilize the carrier, and indeed two different types of analyzers may be used at different stations. Thus, the carrier is compatible with its own system, and other systems of manufacture and manual analysis.

The carrier itself is self-supporting and rugged, virtually indestructible and is dimensionally stable. Its performance is not hindered by variations in atmospheric conditions of temperature, pressure, or relative humidity. It is washable, autoclavable, and can be cold sterilized. It is not a custom carrier inasmuch as the central opening for the test tube **16** is adaptable to various test tubes. The carrier is constructed of electrically impervious material and cannot store charge or be affected by electric, magnetic, or optical fields.

FIG. **5** illustrates the specimen carrier in a connected chain of carriers for use in an automatic clinical analyzer. The carrier is transported past the "Laboratory

Data Control Station" by means of the transmission means **23** illustrated in FIG. **1**, which may be engaged by a pinion gear as illustrated in FIG. **2**, or it may be engaged by a bicycle chain clip holder, an endless belt, a gear train, or a pneumatic, electromagnetic, or hydraulic drive. The guide rail opening **22** is designed to follow guide rail **32** to enable the drive mechanism to precisely center the specimen carrier for automatic sipping as illustrated in FIG. **2**, and to assist the machine reader **29** in reading the identification presented on tear tab **12.** The specimen carriers are connected together by means of clips **33** which engage the openings **34** defined in the top of the specimen carrier. The openings **39** are used as illustrated in FIG. **4** to move a plurality of samples from the nursing station to the clinical laboratory, or for use in the manual processing of a number of samples in the clinical laboratory. The holder **35** is panel shaped with a broad flat horizontal surface to support the specimen carriers and an upstanding flange **36** to provide a back and brace. This brace is then equipped with two pairs of parallel rods **37** and **38** and the specimen carrier is mounted on the hand carrier by inserting the rods **37** or **38** into the openings **39** defined in the base of the specimen carrier. Thus a large number of specimen carriers may be manually transported from station to station quickly and conveniently.

FIG. **5** also discloses a method and means of flagging the individual specimen carriers to alert the technicians or the automatic analyzer to special conditions. A plurality of openings generally shown at **51** are placed between the clip openings **34** and the opening for the test tube **16.** In operation a plurality of pins **52** may be inserted in the opening **51** to code certain information. The coded information may be placed in a binary code as shown by the row of binary numbers **53** or it may be placed in a numerical or analogue code as indicated at **54.** A microswitch arrangement **55** positioned on the control station **29** is utilized to read out the presence or absence of pins **52.** Thus if the micro-switch assembly **55** sensed flag pins in the first, second, and fourth openings the binary code read out would be **1101** or **13.** Alternately, each of the openings **51** could be utilized to determine a specific type of information, i.e., that this specimen carrier has a high priority or special handling.

Additionally, the openings **51** and pins **52** could be utilized to enter certain information which is visible to the operator or laboratory technician, but which cannot be sensed by the control station **29.** In essentially morphologic tests, the laboratory technician could enter the results of the tests in a binary code on the upper portion of the specimen carrier by inserting the appropriate pins **52** into openings **51.** Thus when the carrier passes through a control station which would normally utilize the results of the morphologic test in conducting its specific analysis, the information would be available by means of the flagpins and read out means **55.** In an emergency, information could be directly coded into the control station **29** even though the master computer program has no provisions for a morphologic entry at this station.

As can be seen, the openings **51** and pins **52** can be used for a wide variety of purposes such as indicating high priority or special handlings specimens, indicating special billing or charges for the analysis, indicating the number of carriers in a carrier train, or to enter certain manually derived information into the analyzing station.

While the present invention has been described with reference to specific embodiments having a plurality of means for a machine readable identification, it will be obvious to those skilled in the art that the various combinations may be interchanged in various manners to provide other combinations of identification means and transmission means. It should be noted that the embodiments illustrated are presented by way of example only, and not in any limiting sense. The invention, in brief, comprises all of the embodiments and modifications coming with the scope and sphere to the following claims.

What is claimed is:

1. A reusable carrier for use in coupling a medical sample to be analyzed with an identification code while conducting said analysis, comprising,

a. a stable base member,

b. support means extending upwardly from said base member to support a separate test tube container in an upright position, said test tube containing said sample to be analyzed, said support means providing structural support for said test tube while the sample in said test tube is being analyzed,

c. means for receiving and displaying a separate coded identification marker at the time said test tube and said sample are placed in said carrier,

d. transmission means mounted on said carrier to engage a corresponding transmission means in an automatic analyzer, said transmission means being adapted to transport the carrier and its container from station to station during analysis, said transmission means comprising a rack and guide means, said rack adapted to be engaged by transmission means in a control station to transport the carrier and its container from station to station.

2. A reusable carrier as claimed in claim **1** wherein said carrier base member defines an elevator opening to enable an elevator operated by said automatic analyzer to raise the container to a predetermined height.

3. A carrier train comprising:

a. at least two carriers each of said carriers having a stable base member, support means extended upwardly from the base member to support a separate test tube container in an upright position, said test tube containing a sample to be analyzed, said support means providing structural support for said test tube while the sample of said test tube is being analyzed and means for receiving and displaying a separate coded identification marker at the time said test tube and said sample are placed in said carrier,

b. coupling means for joining said carriers together, said coupling means comprising an upper spring clip which engages upper openings defined by said carriers.

4. A method of coupling a medical sample to be analyzed with a coded identification means while conducting a plurality of analyses comprising

a. drawing and placing a bulk sample to be analyzed in a container at a first location near a medical patient.

b. preparing a coded means for identifying said bulk sample to be analyzed at a first location near a medical patient,

c. inserting both the container and the coded means for identification into a carrier adapted to support said container, said identification means being mounted to identify both the sample and the carrier at the time said bulk sample is taken at a first location near a medical patient,

d. transporting said bulk sample, container, carrier, and identification to a plurality of locations for conducting a plurality of analyses, said sample, container, carrier and identification remaining together from the first location through the completion of the last of said analyses at said second location,

e. sipping discrete samples from said bulk sample for automatic analysis, said bulk sample remaining in its original container through the completion of the last of said analyses at said second location,

f. Combining the results of said automatic analyses and the identification carried by said coded means.

5. A method of conducting an analysis as claimed in claim **4** which further comprises reading said coded identification by optical scanning, wherein said identification is coded on said marker.

6. A method of conducting an analysis as claimed in claim **4** which further comprises reading said coded identification by magnetic sensing, wherein said identification comprises at least one permeable character.

7. A method of conducting an analysis as claimed in claim **4** which further comprises reading said coded identification by punch card indicia wherein said identification is punch coded on said marker.

8. A method of conducting an analysis as claimed in claim **4** which further comprises transporting said carrier from station to station by a transmission means and guide means molded on said carrier.

9. A method of conducting an analysis as claimed in claim **4** which further comprises elevating said container to a predetermined height to enable the automatic processing machinery to sip discrete samples from the bulk sample.

10. A method of conducting an analysis as claimed in claim **4** which further comprises recording the identification carried by said identification marker in a central memory bank for reference in separate analysis operations and separate printouts of test results, medical histories, and customer bills.

11. A method of conducting an analysis as claimed in claim **4** which further comprises centrifuging the bulk sample in the container, after said container has been placed in said carrier and identified by before said automatic analysis is begun.

12. A method of conducting an analysis as claimed in claim **4** which further comprises optically analyzing said bulk sample by projecting an optically deformable beam through an opening defined in said carrier, said beam passing through the container and said bulk sample.

13. A reusable carrier for use in coupling a medical sample to be analyzed with an identification code while conducting said analysis, comprising

a. a stable base member,

b. support means extending upwardly from said base member to support a separate test tube container in an upright position, said test tube containing said sample to be analyzed, said support means providing structural support for said test tube while the sample in said test tube is being analyzed,

c. said support means defining at least one opening in said carrier immediately adjacent said test tube to enable an analyzing beam generated externally of said carrier to impinge upon said test tube,

d. a planar identification marker for displaying said identification code, said marker identifying said sample from the time it is drawn from a patient to the completion of said analysis,

e. guide means for slidably receiving and securing said planar identification marker, said means being defined by the walls of said upwardly extending support means.

14. A reusable carrier as claimed in claim **13** which further comprises transmission means mounted on said carrier to engage a corresponding transmission means mounted on said carrier to engage a corresponding transmission means in an automatic analyzer, said transmission means being adapted to transport the carrier and its test tube from station to station during analysis.

15. A carrier as claimed in claim **13** wherein said support means further defined a first and second engaging abutments, said abutments adapted to engage a standard centrifuge.

16. A carrier as claimed in claim **15** wherein said first and second engaging abutments comprise projecting lips extending outwardly from the center axis of said carrier in opposite directions, said lips being mounted on the uppermost portion of the support means to engage a centrifuge trunnion ring.

17. A carrier as claimed in claim **13** wherein said identification means further comprises at least one optically readable character.

18. A carrier as claimed in claim **13** wherein said identification means further comprises at least one magnetically readable character.

19. A carrier as claimed in claim **13** wherein said identification means further comprise a surface defining at least one punch coded opening.

* * * * *