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(54) Title: SYSTEM FOR LABELING AND ENCODING PATHOLOGY SPECIMENS

10

20

MAIN MENU

22

ACCESSION

24

COMPLETE ACCESSION

26

GROSSING

28

MICROSCOPIC EXAM

(57) Abstract: In a method of managing medical specimens in which a unique identifier is assigned to a specimen (22), a record of the specimen is created and associated with the unique identifier and an identification of a patient from whom the specimen was taken (24). At least one label is permanently affiliated with the specimen. The record of the specimen is accessed by scanning the label. Information about the specimen and a diagnostic determination based on the specimen is added to the record of the specimen (26).
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
SYSTEM FOR LABELING AND ENCODING PATHOLOGY SPECIMENS

BACKGROUND OF THE INVENTION

5 REFERENCE TO MATERIAL SUBJECT TO COPYRIGHT PROTECTION

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REFERENCE TO A MICROFICHE APPENDIX

A microfiche appendix containing program source code used in one embodiment of the invention, a user’s manual for the program code and an example of a simulation produced by the program code, is submitted herewith. The microfiche comprises 14 fiches and 800 frames.

1. **Field of the Invention**

20 The present invention relates to medical systems and, more specifically, to a system for administering pathology specimens.

2. **Description of the Prior Art**

25 Existing pathology specimen management systems involve attaching specimen number labels to specimens. The labels are typically removed from preprinted forms that require the user (e.g., the technician or the pathologist) to enter relevant information by hand. Once the form is filled out, a member of the administrative staff enters the relevant information into the patient’s medical history. A copy of the form is also sent to the pathologist’s bookkeeping department for entry into the billing system.
Such systems typically do not associate a unique identifier of the specimen with the patient and are, therefore, susceptible to mistakes. Furthermore, existing systems do not provide an efficient system for the recording of patient-specific information and for accurate patient billing. Therefore, considerable time is wasted and the patient is exposed to risk resulting from clerical mistakes.

Therefore, there is a need for a pathology specimen management system that automatically associates a specimen with a patient record.

**SUMMARY OF THE INVENTION**

The disadvantages of the prior art are overcome by the present invention which, in one aspect, is a method of managing medical specimens in which a unique identifier is assigned to a specimen. A record of the specimen is created and associated with the unique identifier and with an identification of a patient from whom the specimen was collected. At least one label including a machine scanable encoding of the unique identifier is generated. The label is permanently affiliated with the specimen. The record of the specimen is accessed by scanning the label. Information about the specimen and a diagnostic determination based on the specimen is added to the record of the specimen.

In another aspect, the invention is a series of operational steps to be performed on a computational device used to manage medical specimens. The computer generates a unique identifier associated with each specimen and creates a record of each specimen, while associating the record with the unique identifier. The computer causes at least one machine readable label including a bar code encoding the unique identifier to be printed. The computer also receives an input from a bar code scanner, wherein the input is a scan of the machine readable label, decodes the input to determine which unique identifier is encoded on the machine readable label and indicates to an output device which specimen has been scanned, based on the unique identifier. Then the computer receives from an input device specimen-specific information about the
specimen and stores the input in the record of the specimen. The computer also prints a report including the specimen-specific information about the specimen.

These and other aspects of the invention will become apparent from the following description of the preferred embodiments taken in conjunction with the following drawings. As would be obvious to one skilled in the art, many variations and modifications of the invention may be effected without departing from the spirit and scope of the novel concepts of the disclosure.

10 BRIEF DESCRIPTION OF THE FIGURES OF THE DRAWINGS

FIG. 1 is a flow chart showing flow from the main menu to several procedures.

FIG. 2 is a flow chart showing the accessioning procedure.

FIG. 3 is a flow chart showing the grossing procedure.

FIG. 4 is a flow chart showing the microscopic exam procedure.

20 DETAILED DESCRIPTION OF THE INVENTION

A preferred embodiment of the invention is now described in detail. Referring to the drawings, like numbers indicate like parts throughout the views. As used in the description herein and throughout the claims, the following terms take the meanings explicitly associated herein, unless the context clearly dictates otherwise: the meaning of “a,” “an,” and “the” includes plural reference, the meaning of “in” includes “in” and “on.”

The invention is directed to a system for managing pathology specimens and information relating thereto. The invention applies to both cytology specimens (typically fluids) and to surgical specimens (typically tissues), although some of the steps employed for surgical specimens are not required for cytology specimens. As
shown in FIG. 1, the invention 10 presents the user with a main menu 20, which offers the user a choice of several procedures, including: accessioning 22, completing accessioning 24, grossing 26 and microscopic exam 28. Accessioning 22 involves entering information about a new specimen into the system. Completing accessioning 24 is a procedure in which the user adds such information as: demographic information; physician’s identifier; insurance numbers; whether previous pathology is available and other administrative information. Grossing 26 involves entering information about the source and appearance of a specimen. Microscopic exam 28 allows for entry of results of a microscopic examination.

As shown in FIG. 2, in the accessioning procedure 22, the user initially inputs an identification of the patient 110 into the system (such an identification could, for example, be the patient’s social security number) and the system performs a test 112 to determine if a record of the patient already exists on the system. If the result is “no,” then the system performs a test 124 to determine if the user wishes to create a new record for the patient. If the result of this test is “no,” then execution returns to the input patient ID block 110 (indicating that the previous entry was incorrect). If the user has indicated that a new record is to be created, then the system will create 126 a new patient record. Once a patient record is found to exist, the system will wait 114 for a command to open the new record and then determine 116 the next available specimen number. The system will then create 118 a record of the specimen and associate the specimen record with both the specimen number and the identification of the patient. The user then enters 120 the number of specimens being submitted (if multiple specimens are being submitted, as is typical with a surgical procedure) and the number of labels required (although the system could default to a number of labels based on the specimen type and number, etc.). The system will then issue a command 122 to a label printer to print the required number of labels so that each label includes the specimen number in machine-readable format. Typically, this will take the form of a bar code label. The labels are then affixed to the specimen by the user. The labels are peel-and-stick labels that are applied to the container holding the specimen or to the slide on which the specimen is mounted.
The system will search 128 for the patient history and, if found, will print 132 a copy of the patient history and a record of consultation form, if the user so desires. Then the system receives from the user an identification of each specimen 134. For each specimen, the user enters the specimen source code 136 and a code corresponding to the method employed to collect the specimen 138. The specimen source code may be determined from a pull down menu. For example, an alphabetical listing of sources may be accessed by pressing “ALT T” and a listing of sources by category may be accessed by pressing “ALT C.” Examples of specimen sources include “skin of finger” or “sole of foot.” Similarly, the method code would relate to the method employed in collecting the specimen (e.g., through punch biopsy, etc.). Pull down menus are also employed in retrieving method codes. The data for steps 134, 136 and 138 is repeated 139 for each specimen. The user then enters 140 any additional notes of relevance to the specimen and the system generates a grossing template for the specimen 142.

As shown in FIG. 3, the grossing procedure 200, which is typically done for surgical specimens, but not for cytology specimens, begins by entering the specimen number 210, which could be done by scanning the specimen label with a bar code scanner or entered manually on the keyboard. This causes the system to pull up a grossing template previously generated by the system. The user then enters 212 on the appropriate location of the template how the specimen was received (e.g., frozen, air dried, fresh, etc.) and a gross description 214 of the specimen is entered. Such a description would include the dimensions, shape and color of the specimen and could be entered by (1) selecting defaults (e.g. a specimen collected by needle biopsy is typically cylindrical); (2) clicking on common descriptions from a pull-down menu; or (3) manually entering the description via a keyboard. The information entered on the template is stored 216 in the specimen record and a test 218 is performed to determine whether the user desires to have printed a grossing report, a record of consultation report, or both. If the user so desires, the system issues a printer command 220 indicating that the desired reports are to be printed.

As shown in FIG. 4, the microscopic exam procedure 300 begins by the user entering the specimen number 310, which may be done by scanning the bar code on the
specimen label or by manually entering the number on a keyboard. The system displays a menu 312 of specimens (in the case of multiple specimen surgical specimens) and the user selects the specimen being examined by pointing and clicking. A test 322 is performed to determine if a specimen has been chosen. If the result of the test is “yes,” then, the system opens a microscopic exam screen 314 for the specimen onto which the user enters codes 316 corresponding to the results of the microscopic examination. These diagnosis codes could be manually entered or selected from a pull-down menu. For example, the codes could indicate the condition of cells or the type of nuclei, the codes could also indicate a diagnosis at a microscopic level. Multiple codes could be entered for any given specimen, as multiple conditions could be present. The system then expands 318 the codes to full text and the user then enters 320 any necessary modifiers used to describe the specimen. Execution then returns to step 312 while the user continues to select specimens.

When the result of test 322 is “no,” the system queries 324 the user to determine if further editing of the input is desired. If the result of test 324 is “yes,” then the system opens a screen 326 that allows the user to indicate whether a telephone consultation is required and whether the user desires to edit already entered codes. Next, in the thread of execution is a test 328 that determines whether the user wishes to print reports and if the result of test 328 is “no” then the procedure ends. Otherwise, if the answer is “yes,” then the system issues a print command 330 that causes the desired reports to be printed and the procedure ends.

All of this information is then stored in the specimen record and may be printed in a report by the user. Once entered, the system accesses a look-up table based on the source code and the diagnosis codes for each specimen and automatically generates for each specimen an ICD 9 code, of the type required by most insurance companies, and generates billing information based thereon.

Source code for one commercial embodiment of the invention, along with a user’s manual explaining the use thereof, may be found in the microfiche appendix. This code will operate, for example, on an IBM®-compatible personal computer.
running FOXPRO® in either a DOS® or WINDOWS® environment. Typically in communication with the computer would be at least one bar code printer and a bar code scanner, of the type typically know to the art.

The above described embodiments are given as illustrative examples only. It will be readily appreciated that many deviations may be made from the specific embodiments disclosed in this specification without departing from the invention. Accordingly, the scope of the invention is to be determined by the claims below rather than being limited to the specifically described embodiments above.
CLAIMS

What is claimed is:

1. A method of managing medical specimens, comprising the steps of:
   a. assigning a unique identifier to a specimen;
   b. creating a record of the specimen and associating the record with both the unique identifier and an identification of a patient from whom the specimen was collected;
   c. generating at least one label including a machine scanable encoding of the unique identifier;
   d. permanently affiliating the label with the specimen;
   e. accessing the record of the specimen by scanning the label; and
   f. adding information about the specimen and a diagnostic determination based on the specimen to the record of the specimen.

2. The method of Claim 1, further comprising the steps:
   a. receiving an indication of a source for the specimen;
   b. generating a specimen source code corresponding to the source; and
   c. storing the specimen source code in the record.

3. The method of Claim 2, further comprising the steps of
   a. receiving an indication of a diagnosis for the specimen;
   b. generating a diagnosis code corresponding to the diagnosis; and
   c. generating an insurance code based on the specimen source code and the diagnosis code.

4. The method of Claim 1, further comprising the step of automatically generating billing codes relevant to the specimen based on a specimen source code and a diagnosis code.
5. The method of Claim 1, further comprising the step of printing information contained in the record as part of a diagnostic report, the diagnostic report including a machine scanable encoding of the unique identifier.

6. The method of Claim 1, wherein the step of generating at least one label comprises printing on the label a bar code as an encoding of the unique identifier.

7. The method of Claim 1, wherein the affiliating step includes affixing the label to a container containing the specimen.

8. The method of Claim 1, wherein the affiliating step includes affixing the label to a slide on which the specimen is mounted.

9. The method of Claim 1, wherein the affiliating step includes affixing the label to a requisition.

10. A series of operational steps to be performed on a computational device used to manage medical specimens, comprising the steps of:
   a. generating a unique identifier associated with each specimen;
   b. creating a record of each specimen and associating the record with the unique identifier and an identification of a patient from whom the specimen was taken;
   c. printing at least one machine readable label including a bar code encoding the unique identifier;
   d. receiving an input from a bar code scanner, wherein the input is a scan of the machine readable label;
   e. decoding the input to determine which unique identifier is encoded on the machine readable label;
   f. indicating to an output device which specimen has been scanned, based on the unique identifier;
g. receiving from an input device specimen-specific information about the specimen and storing the input in the record of the specimen; and

h. printing a report including the specimen-specific information about the specimen.

11. The operational steps of Claim 10, further comprising the step of printing the bar code encoding the unique identifier on the report.

12. The operational steps of Claim 10, wherein the specimen-specific information comprises diagnostic information.

13. The operational steps of Claim 10, wherein the specimen-specific information comprises a description of the specimen.

14. The operational steps of Claim 10, further comprising the step of receiving patient-specific information about a patient from which the specimen was taken and storing the patient-specific information in the record.

15. The operational steps of Claim 14, wherein the patient-specific information comprises information identifying the patient.

16. The operational steps of Claim 14, wherein the patient-specific information comprises medical historical information regarding the patient.

17. A system for managing medical specimens, comprising:
   a. means for assigning a unique identifier to a specimen;
   b. means for creating a record of the specimen and associating the record with the unique identifier and with an identification of a patient from whom the specimen was taken;
   c. means for generating at least one label including a machine scanable encoding of the unique identifier;
d. means for permanently affiliating the machine readable label with the specimen;

e. means for accessing the record of the specimen by scanning one of the plurality of machine readable labels;

f. means for adding information about the specimen and a diagnostic determination based on the specimen to the record of the specimen; and

g. means for printing information contained in the record as part of a diagnostic report, the diagnostic report including an indication of the unique identifier.
BEGIN GROSSING PROCEDURE

ENTER SPECIMEN NUMBER

ENTER HOW RECEIVED

ENTER INFORMATION ONTO GROSSING TEMPLATE

STORE IN RECORD

PRINT REPORTS?

Yes
PRINT DESIRED REPORTS

No

END GROSSING PROCEDURE

FIG. 3
BEGIN MICRO PROCEDURE

ENTER SPECIMEN NUMBER

DISPLAY MENU OF SPECIMENS

EDIT SCREEN?

OPEN SCREEN TO BE EDITED

No

SPECIMEN CHOSEN?

Yes

OPEN MICRO SCREEN

ENTER CODES

EXPAND CODES

ENTER ANY NECESSARY MODIFIERS

No

PRINT REPORTS?

Yes

ISSUE PRINT COMMAND

No

END MICRO PROCEDURE

FIG. 4
INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/04006

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G06F 17/00, 17/60
US CL : 235/375, 385

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 235/375, 385, 376

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST, WEST

search terms: tube, barcode, ballots

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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Further documents are listed in the continuation of Box C. See patent family annex.

Date of the actual completion of the international search: 26 SEPTEMBER 2000

Date of mailing of the international search report: 18 OCT 2000

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Form PCT/ISA/210 (second sheet) (July 1998)
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