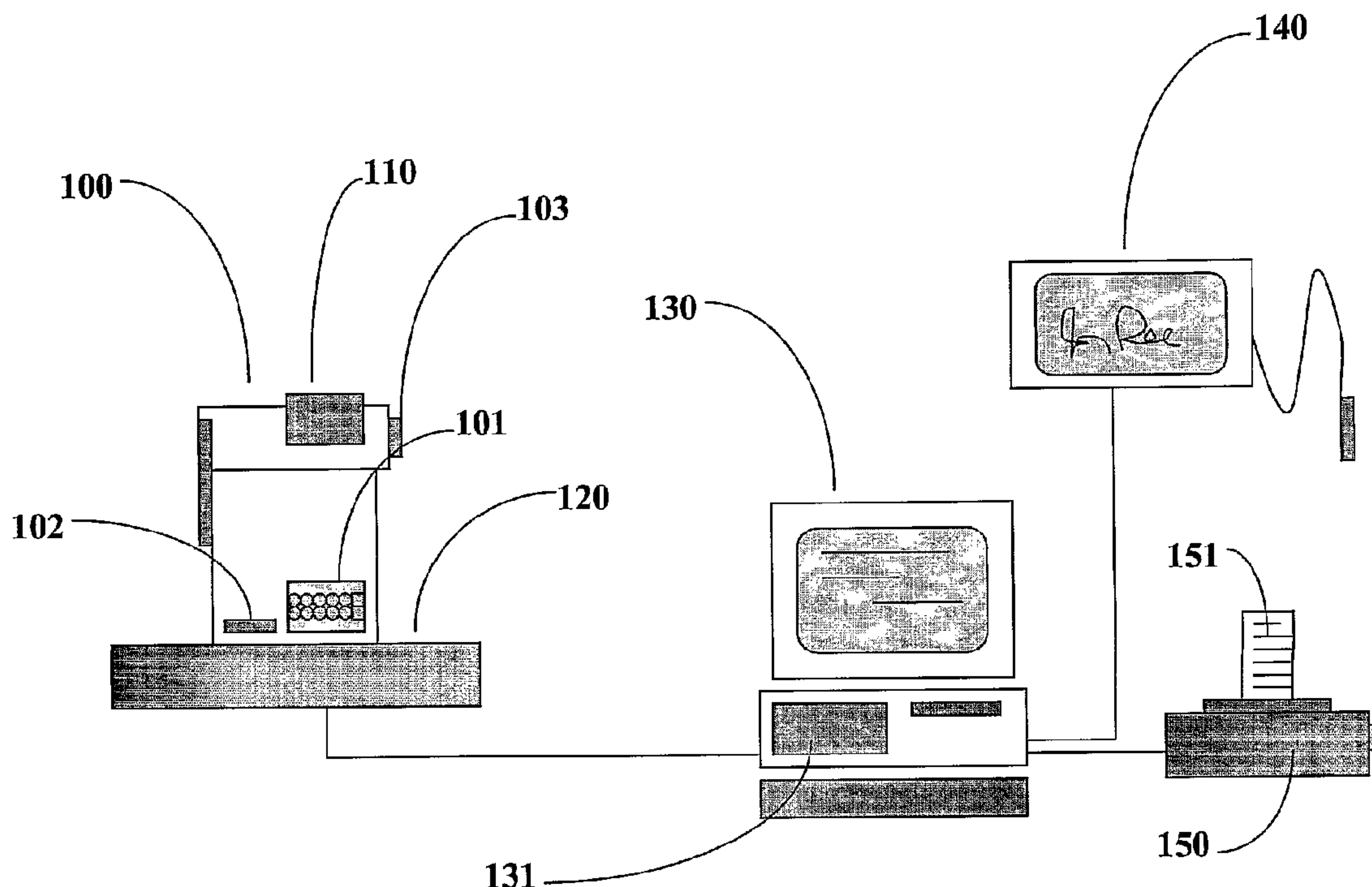




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(54) Titre : PROCEDE, APPAREIL ET PROGRAMME INFORMATIQUE DE COLLECTE ET SECURISATION DE CHAINE D'INFORMATION SUR LA CHAINE DE POSSESSION ASSOCIEES A UN SPECIMEN ET GENEREES VIA LA COLLECTE D'UN SPECIMEN
(54) Title: METHOD, APPARATUS, AND COMPUTER PROGRAM PRODUCT FOR COLLECTING AND SECURING CHAIN OF CUSTODY INFORMATION RELATED TO A SPECIMEN AND GENERATED VIA SPECIMEN COLLECTION



(57) **Abrégé/Abstract:**

A specimen collection system, container device, and a method and computer program product for collecting and securing chain of custody (COC) information related to a specimen is provided. The system, method, and computer program product guides a collector to collect a complete COC data set related to a specimen, detect at least one substance in the specimen using a testing device operably engaged with a specimen container configured to receive the specimen, and direct the complete COC data set to an RFID device or bar code label operably engaged with the specimen container.



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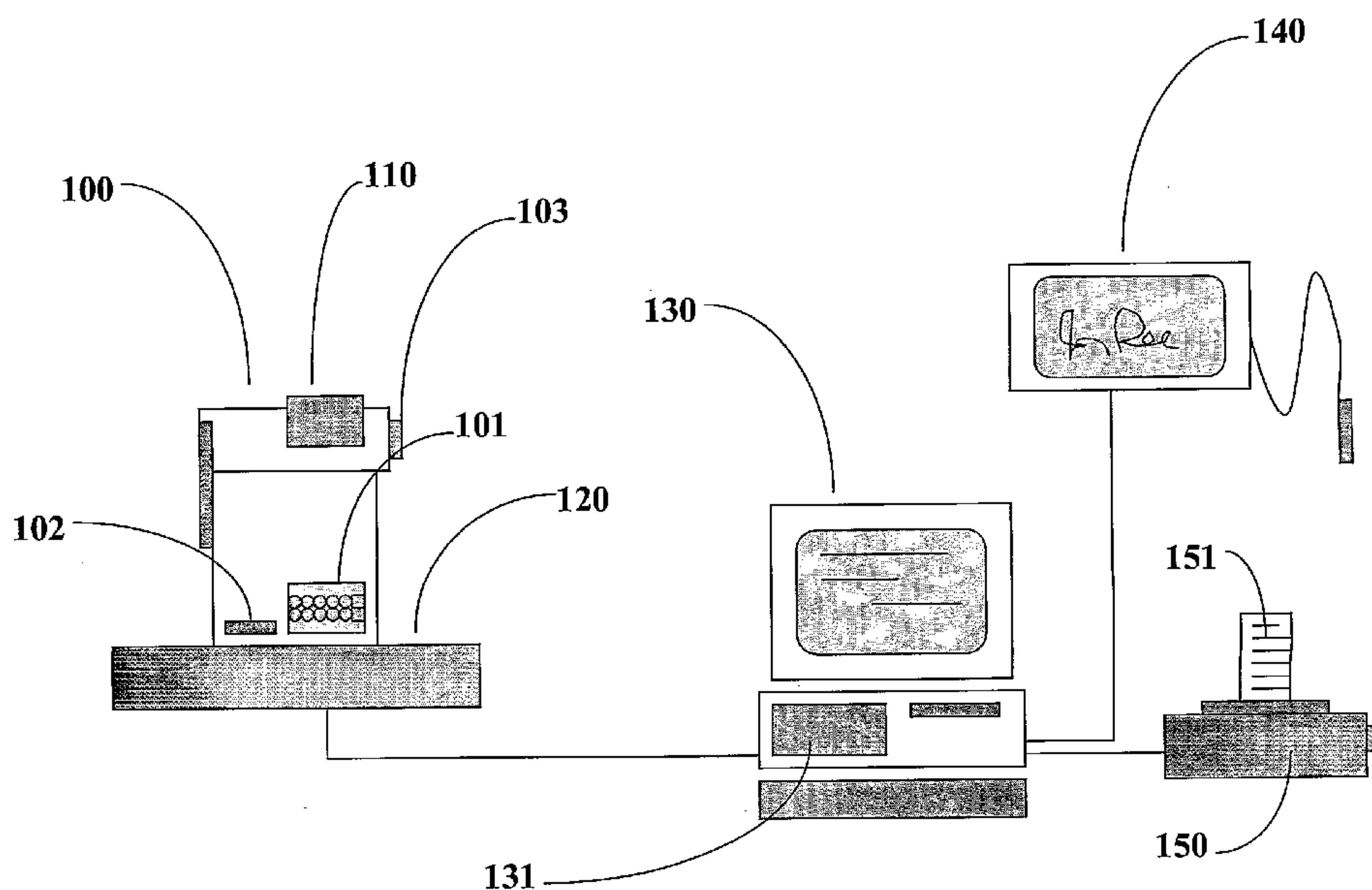
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(57) Abstract: A specimen collection system, container device, and a method and computer program product for collecting and securing chain of custody (COC) information related to a specimen is provided. The system, method, and computer program product guides a collector to collect a complete COC data set related to a specimen, detect at least one substance in the specimen using a testing device operably engaged with a specimen container configured to receive the specimen, and direct the complete COC data set to an RFID device or bar code label operably engaged with the specimen container.

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METHOD, APPARATUS, AND COMPUTER PROGRAM PRODUCT FOR
COLLECTING AND SECURING CHAIN OF CUSTODY INFORMATION
RELATED TO A SPECIMEN AND GENERATED VIA SPECIMEN
COLLECTION

FIELD OF THE INVENTION

The present invention relates generally to collecting and securing a chain of custody data set related to a specimen obtained during specimen collection and/or testing such that the chain of custody data set is completely entered, electronically stored, and made selectively accessible using bar code or RFID technology using, for instance, a printed 2-dimensional (2D) bar code or RFID device operably engaged with a specimen container.

BACKGROUND OF THE INVENTION

It is common for employers to collect biological specimens including, but not limited to, for example, urine specimens, from existing or prospective employees in order to screen the specimens for substances, such as cocaine, marijuana, and other illegal drugs. In addition, athletic organizations often utilize such specimens to test for banned performance-enhancing drugs and/or hormones. These organizations often employ their own staff or contract employees to collect and pre-test these specimens on-site using, for instance, pre-packaged test strips or test containers, such as the QuickScreen Multi-Panel drug test (Catalog #9178T) available commercially from Phamatech, Inc. Such on-site testing, sometimes called "point-of-collection" testing (POCT), provides a time saving and money-saving pre-screen for the specimens, as only those specimens that result in a "positive" for the target substance(s) need to be tested further at an off-site laboratory. Furthermore, POCT testing can provide a preliminary result in about 5-10 minutes wherein test specimens sent to off-site laboratory facilities may not yield results for 5-10 days. It is also common for documentation and evidentiary purposes to store "positive" POCT specimens at an off-site laboratory or storage facility and it is therefore crucial that chain-of-custody

data set related to the specimen is complete as well as properly collected, stored, and secured. In other cases, these organizations simply collect such specimens for later testing at a laboratory (lab-based testing).

Existing methods for collecting and storing chain of custody information during POCT and/or collection and subsequent lab-based testing include the generation of chain of custody documents identifying, for example, the donor, the collector, the time of collection, any collection site identifiers, and (if applicable) preliminary POCT results. These documents are generated at the collection and/or POCT site on paper, and additional COC documents must be produced at a secondary testing/storage site (internal COC forms) for aliquots taken from the from the original specimen. Repeating the COC data entry in this manner is time consuming, labor intensive, and more susceptible to error (either by transposition of data or failure to input important data). In addition, there is no control for ensuring that the COC data set is complete (*i.e.*, the paper forms generated may be missing vital COC data related to the specimen).

Some methods for collecting and storing chain of custody information utilize Radio Frequency Identification (RFID) technology to electronically store chain of custody information, thereby avoiding or minimizing the use of paper COC documents. Such a method is disclosed, for example, in U.S. Patent Application Publication No. 2003-0183683 to Stewart ("the Stewart application") which is incorporated by reference herein in its entirety. The disclosed method in the Stewart application, however, may lead to erroneous and/or incomplete COC data entry. For example, the Stewart application does not disclose providing controls for avoiding the incomplete entry of COC data. In addition, bar code labels are sometimes utilized to attach chain of custody or other identifying information related to a specimen to a specimen container in a compact format, thereby avoiding or minimizing the use of paper COC documents. However, conventional bar code printing software may not include prompts for collecting a complete set of COC data or other information that should be collected to complete the COC data set. In addition, conventional COC data collection systems do not include data entry software that guides a specimen collector through approved procedures for properly collecting and documenting a biological sample.

Thus, there exists a need for a collection and/or testing system that provides an intuitive and easy-to-use interface so that an employee may properly collect and/or analyze (in the case of POCT) specimens and be constrained to enter complete and correct COC data into the COC data set. In addition, there exists a need for a specimen collection system associating certain components with the specimen container so as to minimize specimen handling and to closely maintain the COC data with respect to the specimen.

SUMMARY OF THE INVENTION

The above and other needs are met by the present invention which, in various embodiments, provides a collection system, method, computer program product, and container device for collecting and securing a chain of custody (COC) data set related to a specimen generated during specimen collection for either lab-based testing or POCT, wherein the data within the COC data set is input by a collector and a specimen is provided by a donor. More particularly, a collection system, in one embodiment, comprises: a specimen container for receiving the specimen; an RFID device operably engaged with the specimen container and configured to receive the COC data set; and a computer device capable of communicating with the RFID device. The computer device may be configured to guide the collector to determine data within the COC data set and to guide the collector to input complete data for the COC data set into the computer device. The computer device may also be configured to send the COC data set with complete data to the RFID device for storage therein.

In other embodiments, the specimen container of the collection system may also have a testing device operably engaged therewith for detecting at least one substance in the specimen by directly interacting with the specimen. The specimen container may also have a temperature device operably engaged therewith to determine a temperature of the specimen. In other embodiments, the collection system may further comprise a transceiver in communication with the RFID device and may also process the COC data set with respect to the RFID device.

The method and computer program product embodiments of the present invention are directed to collecting and securing a complete COC data set related to a specimen collected at a specimen collection site, wherein the data within the COC

data set is input by a collector and the specimen is provided by a donor. In one embodiment, the method comprises the following steps: guiding the collector, via a computer device, to determine the data within the COC data set and to input the complete data for the COC data set in to the computer device, and directing the COC data set with complete data to an RFID device, wherein the RFID device is operable engaged with a specimen container configured to receive the specimen.

In other embodiments, the method and computer program product embodiments of the present invention may comprise additional steps of: detecting at least one substance in the specimen using a testing device operably engaged with the specimen container so as to be capable of directly interacting with the specimen; and inputting a result provided by the testing device into the computer device, wherein the result is included in the COC data set. In other embodiments, wherein the COC data set is to be transferred to a bar code label (such as a 2D bar code label), the method and computer program product embodiments may further comprise directing the COC data set to a printer operably engaged with the computer device, wherein the printer may be configured to print the COC data set as a bar code label configured to be capable of operably engaging a specimen container configured to receive the specimen.

The container device embodiments of the present invention provide a container device for receiving a specimen collected during specimen collection and/or testing where the specimen is provided by a donor. More particularly, the container device comprises a testing device configured to detect at least one substance in the specimen, the testing device being capable of directly interacting with the specimen.

In other embodiments, the container device of the present invention may also comprise an RFID device configured to receive a COC data set that is related to the specimen, wherein the data with the COC data set is input by a collector. In some advantageous embodiments of the container device, the RFID device may be further configured to direct a result provided by the testing device to the RFID device for retention therein. The container device may also further comprise a temperature device or tamper-evident device operably engaged therewith.

Thus, embodiments of the present invention guide the collector to determine data within a COC data set, and to input complete data into the COC data set via a

computer device at a specimen collection site such that the data set may be printed or otherwise transferred to a bar code label (such as a 2D bar code label) or other device that may be operably engaged with a specimen container. In some embodiments, a specimen container is provided with which an RFID device is operably engaged such
5 that there is a reduced risk of mislabeling a specimen container with incomplete and/or inaccurate data within the COC data set. In addition, some advantageous embodiments include a specimen testing device and/or a temperature device so as to provide on-site (POCT) test capabilities that require no additional steps on the part of the collecting technician, such as recording the lot number and expiration date of a
10 testing device or temperature device that is separate from the specimen container. The testing device also provides that preliminary POCT test results remain associated with the corresponding specimen.

Embodiments of the present invention provide these and other advantages as further discussed herein.

15

BRIEF DESCRIPTION OF THE DRAWINGS

Having thus described the invention in general terms, reference will now be made to the accompanying drawings, which are not necessarily drawn to scale, and wherein:

20 **FIG. 1** is a schematic of one embodiment of the specimen collection and/or testing system of the present invention;

FIG. 2 is a schematic representation of a chain of custody data input screen according to one embodiment of the present invention, depicting categories of chain of custody data that may be collected during the course of specimen collection and/or
25 POCT;

FIG. 3 is a flowchart illustrating the various steps of the specimen collection and/or testing method for collecting and securing chain of custody data according to one embodiment the present invention;

FIG. 4 is a flowchart illustrating various steps for operating a specimen
30 collection and/or testing system including guiding a collector to determine and input chain of custody data, receiving chain of custody data, and directing the chain of

custody data set to the RFID device, according to one embodiment of the present invention;

5 **FIG. 5** is a flowchart illustrating various steps for operating a specimen collection and/or testing system including guiding a collector to determine and input chain of custody data, receiving chain of custody data, directing the chain of custody data set to the RFID device, directing a collector (using a testing device) to detect a substance in the specimen, and directing a result provided by the testing device to the RFID device, according to one embodiment of the present invention;

10 **FIG. 6** is a flowchart illustrating various steps for operating a specimen collection and/or testing system including guiding a collector to determine and input chain of custody data, receiving chain of custody data, directing the chain of custody data set to the RFID device, directing a collector (using a testing device) to detect a substance in the specimen, directing the result provided by the testing device to the RFID device, receiving an electronic signature from a donor, and receiving an
15 electronic signature from a collector, according to one embodiment of the present invention;

FIG. 7 is a schematic of an input screen according to one embodiment of the present invention illustrating the collector being guided to input chain of custody data related to the lot number and expiration date of the testing device used in POCT
20 testing;

FIG. 8 is a schematic of an input screen according to one embodiment of the present invention illustrating the collector being guided in the collection of a specimen from a donor according to a standard operating procedure;

25 **FIG. 9** is a schematic of an input screen according to one embodiment of the present invention illustrating the collector being directed to read a result provided by a testing device interacting with the specimen;

FIG. 10 is a schematic of an input screen according to one embodiment of the present invention illustrating the collector being guided to input chain of custody data in a specimen collection;

30 **FIG. 11** is a flowchart illustrating the various steps of the specimen collection and/or testing method for collecting and securing chain of custody data to be printed on a bar code label according to one embodiment the present invention;

FIG. 12 is a flowchart illustrating various steps for operating a specimen collection and/or testing system including guiding a collector to determine and input chain of custody data, receiving chain of custody data, and converting the chain of custody data set to bar code data, according to one embodiment of the present invention;

FIG. 13 is a flowchart illustrating various steps for operating a specimen collection and/or testing system including guiding a collector to determine and input chain of custody data, receiving chain of custody data, converting the chain of custody data set to bar code data, directing a collector (using a testing device) to detect a substance in the specimen, and directing a result provided by the testing device to a computer device for conversion to bar code data, according to one embodiment of the present invention; and

FIG. 14 is a flowchart illustrating various steps for operating a specimen collection and/or testing system including guiding a collector to determine and input chain of custody data, receiving chain of custody data, converting the chain of custody data set to bar code data, directing a collector (using a testing device) to detect a substance in the specimen, directing the result provided by the testing device to a computer device for conversion to bar code data, receiving an electronic signature from a donor, and receiving an electronic signature from a collector, according to one embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present inventions now will be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all embodiments of the invention are shown. Indeed, these inventions may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Like numbers refer to like elements throughout.

Embodiments of the present invention are described herein in conjunction with the collection of specimens for the subsequent detection of the existence of commonly-abused drugs. One skilled in the art will appreciate, however, that the embodiments of the present invention can be utilized in a variety of other

applications, including the collection and testing of various types of biological specimens that may be collected for lab-based testing and/or tested via POCT technologies, such as, for instance urine samples, blood samples, cheek swabs, sweat samples or other biological fluid samples. In addition, the embodiments of the present invention may be utilized in the collection of specimens such as hair specimens for use in criminal investigations or forensic investigations. In addition, embodiments of the present invention are discussed with respect to chain of custody (COC) data related to collected specimens, for instance, to show that proper COC protocols were met in the handling of evidence by police investigators, coroners, medical personnel, and other authorities involved in criminal investigations and/or specimen collection and testing. Thus, one skilled in the art will appreciate that the exemplary embodiments disclosed and described herein are not intended to be limiting in any manner with respect to the present invention.

FIG. 1 shows one embodiment of a collection system according to the present invention which comprises: a specimen container **100**, an RFID unit **110**, a transceiver **120** configured to read and/or write data to the RFID unit **110**, and a computer device **130** configured to receive data, such as, for instance chain of custody data related to a specimen. The RFID unit **110** may be operably engaged with the specimen container **100** or in other embodiments, may be selectively attachable to or non-removably engaged with the specimen container **100**. According to other advantageous embodiments, the collection system may include a computer device **130** capable of communicating with the RFID unit **110** without the use of a separate transceiver **120**.

In other advantageous embodiments, the specimen container **100** may also be provided with a testing device **101** capable of detecting one or more substances in the specimen. The testing device **101** may be provided separate from the specimen container, and exposed to the specimen contained therein to perform a point-of-collection (POCT) test of the specimen. Testing devices suitable for interacting with a specimen contained in a specimen container include, for instance the QuickScreen Catalog # 9178T from Phamatech, Inc. which provides a testing device **101** on a card form having a plurality of windows defined therein. The windows define color-change reactive test areas that visually indicate the presence of substances in the

specimen upon the physical interaction of the test areas with the specimen, such as, by dipping the card into a liquid specimen. In some embodiments, the testing device 101 may further comprise test sticks configured to be dipped into a liquid biological specimen. In other embodiments, the testing device 101 may be further configured to
5 interact with other types of biological samples, both liquid and solid, in order to visually indicate the presence of substances in the specimen. For instance, the testing device 101 may be configured to interact with hair samples, sweat samples, saliva samples, blood samples, and/or other types of biological specimens.

In other embodiments, the POCT testing device 101 may be disposed in or
10 otherwise engaged with, for instance, the inner surfaces of the specimen container 100. Such testing devices are integrated with a specimen container in some specimen containers having no RFID unit or other data collection mechanism such as in QuickScreen Catalog #9177x and #9178x from Phamatech, Inc. In such
15 embodiments, the surfaces of the specimen container and or the testing device may define apertures, or include other mechanisms for providing interactive communication directly between the testing device and the specimen. In other
20 embodiments, the testing device 101 may be operably engaged with the interior or other surface of the specimen container so that the testing device 101 may directly interact with the specimen contained therein. In some embodiments of the collection system, and specimen container that include the testing device 101, the testing device
25 101 may include an indicator mechanism using, for example, symbols and/or color changes that become visible on the surface of the testing device 101, or through the specimen container 100 (which may be composed of translucent and/or transparent material) to indicate the presence of one or more substances in the specimen as
30 detected by the testing device 101. The testing device 101 may be configured to detect, for instance, drugs such as PCP, amphetamines, methamphetamines, methadone, THC (THCA), THC metabolites, cocaine (benzoyl-ecgonine), cocaine metabolites, oxycodone, morphine, ecstasy, propoxyphene, opiates, methaqualone, benzodiazopenes, other narcotics, and combinations thereof. One skilled in the art
will appreciate that the testing device 101 may also be configured to include, for example, an assay and/or a test strip suitable for detecting and indicating the presence of any of a variety of substances that may be present in a specimen. According to

some embodiments, the testing device **101** may be an electronic device configured to detect and indicate the presence of substances within the specimen. In embodiments where the testing device **101** is an electronic device, the testing device may be further configured to communicate with the RFID device **110** and/or the computer device **130** of the present invention to provide a test result as part of the data in the complete COC data set.

In yet another advantageous embodiment, the specimen container **100** may be provided with a temperature device **102** operably engaged with the specimen container **100**, that is configured to determine and/or display the temperature of the specimen. The temperature device **102** may indicate temperature ranges by, for instance, a color-coded strip visible to the collector on the exterior of the specimen container. In some embodiments the temperature device may also comprise a mercury thermometer having a Celsius or Fahrenheit numerical scale. In yet another embodiment, the temperature device **102** may be an electronic device, such as a thermistor, that may be digitally coupled to the RFID device **110** such that the temperature data history of the specimen may be stored as part of the COC data set.

In other advantageous embodiments, the specimen container **100** may also be provided with a tamper-evident device **103** configured to seal and/or provide tamper-evident information in case the specimen container **100** is opened after the tamper-evident device has been affixed thereto. The tamper evident device **103** may comprise, for example, an adhesive sticker, tape, or another appropriate tamper-evident mechanism.

As illustrated in **FIG. 1**, a collection system according to one embodiment of the present invention may include a transceiver **120** configured to process the COC data set with respect to the RFID device **110** operably engaged with the specimen container **100**. The transceiver **120** may be connected via a wire or wireless connection, to a computer device **130**, such as, for instance, a personal computer, PDA, or other processing unit suitable for receiving and processing data related to the specimen. As such, the computer device **130** may be used to input COC data related to the specimen, the donor, the collector, and the testing device **110** as well as the result of a POCT test to detect one or more substances in the specimen. The computer device **130** may also be configured to store the COC data set in a memory **131** and/or

selectively direct the COC data set to the RFID device 110 operably engaged with the specimen container 100. In addition, the computer device 130 may be configured to include a password-protected user-interface, such that the computer device 130 cannot be accessed by unauthorized personnel. The transceiver 120 and computer device 130 are also capable of receiving a COC data set from the RFID device 110 operably engaged with the specimen container 100, such that a user of the collection system may access and process the data within the COC data set contained in the RFID device and/or copy the COC data set contained in the RFID device. Thus, the transceiver 120 and computer device 130 are capable of copying a COC data set from a first RFID device operably engaged with a first specimen container containing a given specimen, storing the data in memory 131, and transferring the COC data set to a second RFID device operably engaged with a second specimen container in cases where, for instance, the given specimen requires separation into two separate specimen containers, such as aliquot tubes used to confirm POCT tests at a secondary testing site.

A collection system in one embodiment of the present invention may also include an electronic pad 140, or other appropriate device, configured to capture electronic signatures of the donor and/or collector and transfer this information electronically to the computer device 130 for storage in the memory 131, and/or transfer the information to an RFID device 110 via a transceiver 120. In addition, a collection system in one embodiment of the present invention may also include a printer device 150 configured to be capable of printing a bar code label 151 coded with the COC data set such that the bar code label 151 may be affixed to a surface of the specimen container 100.

FIG. 2 depicts an input screen for a COC data set with respect to the computer device 130 executing an associated computer program product according to one embodiment of the present invention. A user interface showing the COC data contained within a COC data set is also provided. In some embodiments, such as that depicted in the input screen of FIG. 2, the collector may be guided to completely input data associated with a complete COC data set. For instance, the input screen may include a donor identification field 200 for receiving donor identification information, such as, for example, the donor's Social Security number or employee number, first

and last name, and the method by which the collector at the POCT site identified the donor. This feature of the present invention is necessary in POCT testing environments where the collector is required to identify the donor providing the specimen, either by photo identification, or by sight if the collector knows name and
5 likeness of the donor. The donor identification field **200** may also require an electronic signature from the donor, that may be captured, for instance, on an electronic pad **140** in communication with the computer device **130**.

The input screen also may include a collector identification field **210**, including the collector's name and electronic signature, which may be captured
10 electronically on an electronic pad **140** in communication with the computer device **130**. In addition, the input screen may also include transceiver ("reader") status field **220** which may also include controls (such as, for instance, virtual "buttons") for processing COC data with respect to the transceiver **120** and RFID device **110**. Such processing may include, for instance, sending a complete COC data set to an RFID
15 device **110** or reading a complete COC data set from an RFID device **110**.

The input screen may also include specimen information data **230**, wherein the collector may indicate whether the specimen was divided into two separate specimen containers **100** and whether the temperature of, for instance, a urine specimen, as indicated by a temperature device **102**, is within the range specified for the specimen
20 by applicable urine specimen guidelines. In addition, in the case of urine specimens, the specimen information field **230** may include notations regarding anomalies in collecting the specimen. For instance, if the donor experiences "shy bladder" the collector may make this notation in the specimen information field **230** of the input screen.

25 The data input screen depicted in FIG. 2 may also require preliminary POCT test result data, via a field screening data field **240**, where the collector may input and store a result of a preliminary screening, as detected during POCT screening of the specimen, using, for instance, the testing device **101** described in conjunction with FIG. 1. The field screening data field **240** may also include a check box for a
30 negative POCT result (where none of the substances being tested for are present in the specimen). The POCT result entered into the field screening data field **240** may then be transferred to the RFID device **110** via, for instance, the transceiver **120**, so that the

POCT result data are included as part of the COC data set related to the specimen. Thus, if the specimen is shipped to a second laboratory site for further screening and/or storage, a second transceiver **120** and associated computer device **130** located at the second laboratory site may be used to read the complete COC data set (including POCT results) so as to determine if further confirmation testing is needed (for example, in cases where the field screening data field **240** indicates a “positive” result for any of the target substances).

Data from the testing device **101** may also be included as part of the input screen in a test kit information field **250**. The collector may be required to input, for example, the identifying lot number and expiration date of the testing device **101** used to perform POCT tests on the specimen. In embodiments of the present invention where the testing device **101** is operably engaged with the specimen container **100**, the collector may also record the lot number and expiration date of the specimen container/testing device apparatus in the test kit information field **250**.

The input screen depicted in FIG. **2** may also include a collection site data field **260**, a Medical Review Officer (MRO) data field **270**, and an employer information data field **280** (for embodiments of the present invention used to collect specimens from current or prospective employees of that employer). This information may include, for example, addresses; site codes; names of employer, MRO, and/or collection site; and phone and fax numbers for the employer, MRO, and/or collection site, as shown in FIG. **2**.

FIGS. **1**, **3**, and **11** illustrate a method for collecting and securing chain of custody data for a specimen collected during point-of-collection testing according to one embodiment of the present invention. First, in step **300**, the collection system guides the collector to collect a complete set of COC data, and to input the data into the computer device **130**. The collector may input the COC data via keystrokes on a keyboard in communication with the computer device **130** such that the data fields of the input screen of FIG. **2** are completed. In other embodiments, the collector may input COC data via a touch-screen monitor or other input device in communication with the computer device **130**. Step **300** may include the collection of the donor’s electronic signature (Step **301**), the collector’s electronic signature (Step **302**), and /or the POCT Screening result (Step **303**) obtained in the optional detecting step **310**.

One skilled in the art will appreciate that COC data in the data set may vary depending on the purpose of collecting the specimen as well as the standard operating procedures of the collection and/or testing site. One skilled in the art will also appreciate that the required fields of the COC data set (depicted in FIG. 2) and the
5 computer program product of the present invention (described below) may be modified to guide the collector to properly input a complete COC data set as depicted in step 304. This may be accomplished, for instance, by preventing the collector from directing an incomplete COC data set to the RFID device. In some cases, such as
10 urine specimen screening for drugs as requested by an employer, the complete COC data set will include data substantially similar to the data depicted in FIG. 2. In this case, the COC data set may include the collection of data specific to POCT testing of urine specimens, such as data related to minimum specimen amounts 305 and whether the donor exhibited “shy bladder” 306 that interfered with the POCT testing procedure.

15 In some advantageous embodiments of the present invention, step 310 is performed, wherein the collector determines whether one or more substances are present in the specimen using, for example a testing device 101 that may be operably engaged with the specimen container 100, as previously discussed.

Thereafter, in some embodiments of the present invention, step 320 may also
20 be performed, wherein the collector inputs the results of the detecting step 310 as COC data to form a complete COC data set. In one embodiment, the results of the detecting step 310 may be entered in the “field screening” data field 240 depicted in the input screen depicted in FIG. 2.

In step 330 the collector directs the complete COC data set, collected and
25 entered during step 300 and optionally during step 320, to the RFID device 100 via, for instance a transceiver 120. This step may be accomplished using, for instance, the reader status field 220 shown in FIG. 2 by clicking on a button in the reader status section labeled “Write to Tag” as shown in the reader status field 220. In addition, the collector at this step may also use the input screen to read data from the RFID device
30 110 via the transceiver 120 by clicking on the “Read from Tag” button in the reader status field 220 as illustrated schematically in step 331 of FIG. 3. According to other method embodiments, (as illustrated schematically in FIG. 11), in step 510 the

collector may direct the complete COC data set from the computer device 130 to a printer 150 configured to print the COC data set as a bar code label 151 that may then be affixed, for instance, to the specimen container 100. The printer 151 (and computer device 130 operably engaged therewith) may be configured to convert the COC data set into a bar code label 151 wherein the bar code printed on the label is in a number of different bar code formats which may include, but are not limited to: two-dimensional (2D) bar code; code 128; PDF-417; data matrix; or other bar code formats suitable for encoding the complete COC data set. In addition, FIG. 11 further illustrates optional step 511 wherein the computer device 130 or other device (such as, for instance, a laser scanner or other bar code reader) may be used to read the complete set of COC data from the bar code label 151 that may be affixed to the specimen container 100 such that a clinician or other personnel may receive a body of text corresponding to the complete set of COC data.

According to one embodiment of the present invention, as illustrated in FIG. 4, the computer device 130, executing an appropriate computer program product, implements a method for collecting and securing chain of custody data for a specimen whereby, in block 410, a processing portion is configured to guide the collector to determine and input chain of custody (COC) data into the computer device 130. In block 420, another processing portion is configured to receive the COC data, and in block 430, another processing portion is configured to direct the completed COC data set to the RFID device 110 via, in some instances, a transceiver 120. In an alternate embodiment, the computer device 130, executing an appropriate computer program product, may (as shown in FIG. 12) execute alternate step 610 wherein a processing portion may be configured to convert the completed COC data set to a bar code format such that the COC data set may be printed on a bar code label 151 (in, for instance, two-dimensional (2D) bar code) that may be printed by a printer 151 operably engaged with the computer device 130. In addition, the bar code label 151 may then be affixed to a surface of a specimen container 100 so as to attach the COC data set information directly to the pertinent specimen. Thus, the bar code label 151 may then be interrogated by a laser scanner or other bar code reader device such that the COC data set may be recovered from the bar code label when the specimen

container 100 is received by, for instance, an off-site processing or testing lab (as depicted in FIG. 11, step 511).

The processing portion for guiding, depicted in block 410, may also be configured, for instance, to direct the computer device to provide an on-screen guide to the collector to direct the collector to enter lot number and expiration data for the testing device 101 used to detect a substance in the specimen. An example of such a guide for the collecting of COC data is depicted in FIG. 7. The processing portion for receiving, of block 420, may be further configured to direct reception of COC data input via computer keystrokes on a keyboard, clicks of a mouse on virtual control “buttons” that are produced on the input screen, such as that depicted in FIG. 2, or via other appropriate user-interface techniques, such as, for example, voice recognition software coupled to a microphone. The processing portion for guiding of block 410 may also be configured to provide visual and textual prompts for guiding the collector, for example, on the amount of a specimen that should be collected. Such an instructional guide is illustrated in the context of collection of a urine specimen in FIG. 10. The processing portion for guiding of block 410 may also be configured to guide the collector in dealing with and recording data related to, for example, a donor’s “shy bladder,” wherein the donor may be unable to provide a urine specimen in the presence of the collector. (The presence of the collector is typically required by specimen collection procedures to ensure the validity of tests on the urine specimen). In this case, the processing portion for guiding of block 410 may also be configured to provide an instructional window on the input screen in response to the collector checking a “shy bladder” box in the specimen data 230 of the input screen. An example of “shy bladder” instructions for the collector is shown in the instructional window of the present invention in FIG. 12. Finally, the processing portion for directing of block 430 may be configured to transmit COC data from, for instance, the memory 131 of the computer device 130, via a wire or wireless connection (such as, for instance, IR, RF, or other wireless connection) to an RFID device 110 operably engaged with the specimen container 100 as previously described. In some instances, the COC data may be directed from the memory 131 to the RFID device 110 via a transceiver 120. In other instances, the COC data may be transferred from the memory 131 of the computer device 130, via a wire or wireless connection (such as,

for instance, IR, RF, or other wireless connection) an to a printer **150** configured to print the COC data set in a bar code format on a bar code label **151** that may be affixed to a surface of the specimen container **100**.

As illustrated in, FIG. **5** and FIG. **13**, the computer device **130**, executing an
5 appropriate computer program product, implements a method for collecting and securing chain of custody data for a specimen whereby, the processing portions of blocks **410**, **420**, and **430** (or alternatively, block **610**) configured to guide the collector, receive the COC data, and direct the completed COC data to the RFID device or to a printer **150** configured to produce a bar code label **151**, as previously
10 discussed, precede the processing portions of blocks **440** and **450** respectively. The processing portion of block **440** is configured to direct the testing device **101** to perform a POCT test to: detect to the presence of a substance in the specimen, determine the result of the test, and input the test result into, for example, the field screening data field **240**, shown in FIG. 2 such that the test result is stored in the
15 memory **131** of the computer device **130**. The processing portion of block **440** is compatible with embodiments of the present invention wherein the testing device **101** includes, for instance, electronic components configured to electronically determine the present of substances in the specimen as well as electronic components configured to communicate directly with the computer device **130** and/or RFID device **110**. As
20 shown in block **450**, another processing portion is configured to direct the computer device **130** to send the test result (as part of, for example, the complete COC data set) to the RFID device **110** for storage therein. As discussed above, in some instances the COC data may be directed from the memory **131** to the RFID device **110** via a transceiver **120**. Alternatively, as shown in FIG. **13**, a processing portion shown in
25 block **620** may direct the electronic test results for substances within the specimen to the computer device **130** and/or an attached printer **150** such that the test results may be included with the COC data set and the resulting bar code label **151** that may be printed to contain the COC data set.

The processing portion for directing, of step **440**, may further be configured to
30 direct the computer device **130** to display as part of the input screen (such as that shown in FIG. 2) the field screening data field **240**. In this embodiment, the collector performs a preliminary drug test on a urine specimen by exposing a test kit strip, such

as for example, a test strip Catalog # 9178T provided by PhamaTech, Inc. to a specimen to detect the presence of one or more substances that may be present in the specimen. The collector may then read the preliminary results of the test as directed by the computer program product of the present invention. For example, the processing portion for directing, in block 440, may be configured to produce an instruction screen such as that shown in FIG. 9 instructing the collector on how to properly read a result from the testing device 101 being used at the testing site. Furthermore, processing portion for directing, in block 450, may be further configured to direct the test result (such as, for instance, positive test results for drugs detected in a urine specimen) by determining the appropriately checked boxes depicted in the field screening data field 240 depicted on the input screen of FIG. 2. The processing portion for directing of block 450 may further be configured to direct the test result to the RFID device 110. In other embodiments, as shown in FIG. 13, block 620 shows a processing portion for directing the test result to the computer device 130 such that the test result may be passed on to a printer device 150 operably engaged with the computer device 130 and configured to be capable of printing a bar code label 151 suitable for affixing to a surface of the specimen container 100.

In accordance with the method and computer program product flowchart depicted in FIGS. 6 and 14, the computer program product of the present invention may further include executable portions for directing the computer device 130 to receive an electronic signature from a donor and a collector. Block 460 depicts the receiving of a donor's electronic signature, and block 470 depicts the receiving of a collector's electronic signature. For instance, the processing portions for receiving of blocks 460 and 470 may be configured to display an input screen such as that shown in FIG. 2, including a donor's information field 200 and a collector's information field 210. Furthermore, the computer device 130 may be further connected to an electronic pad 140, the electronic pad 140 configured to receive a written signature provided by the donor and/or collector using, for instance, a stylus configured to digitize a written signature. Furthermore, the collector may click on the "Capture" button depicted in donor and collector information fields 200 and 210, respectively, of FIG. 2 in order to transfer the electronic signatures from the electronic pad 140 to the memory 131 of the computer device 130.

Many modifications and other embodiments of the invention will come to mind to one skilled in the art to which this invention pertains having the benefit of the teachings presented in the foregoing descriptions and the associated drawings.

Therefore, it is to be understood that the invention is not to be limited to the specific
5 embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

10

WHAT IS CLAIMED IS:

1. A collection system adapted to collect and secure a chain of custody data set related to a specimen collected during specimen collection, data within said chain of custody data set being adapted to be input by a collector and said specimen being adapted to be provided by a donor, said collection system comprising:
- a specimen container for receiving said specimen;
 - an RFID device operably engaged with said specimen container, said RFID device being configured to receive said chain of custody data set;
 - a computer device capable of communicating with said RFID device and configured to guide said collector to determine said data within said chain of custody data set and to input complete data for said chain of custody data set into said computer device, said computer device also being configured to send said chain of custody data set with complete data to said RFID device for retention therein.
2. A collection system according to Claim 1, further comprising a transceiver in communication with said RFID device and configured to process said chain of custody data set with respect to said RFID device.
3. A collection system according to Claim 1, further comprising a testing device, said testing device being operably engaged with said specimen container so as to be capable of directly interacting with said specimen and said testing device being configured to detect at least one substance in said specimen.
4. A collection system according to Claim 3, wherein said testing device is configured to detect a substance selected from the group consisting of:
- PCP;
 - amphetamines;
 - methamphetamines;
 - methadone;
 - benzodiazopenes;
 - barbiturates;

THC;
THC metabolites;
THCA;
cocaine;
5 cocaine metabolites;
ecstasy;
oxycodone;
propoxyphene;
methaqualone
10 opiates; and
combinations thereof.

5. A collection system according to Claim 1, further comprising a
temperature device operably engaged with said specimen container, said temperature
15 device being configured to determine a temperature of said specimen.

6. A collection system according to Claim 1, wherein said RFID device is
non-removably engaged with said specimen container.

20 7. A collection system according to Claim 1, further comprising a
tamper-evident device operably engaged with said specimen container.

8. A method for collecting and securing a chain of custody data set
related to a specimen collected during specimen collection, data within said chain of
25 custody data set being adapted to be input by a collector and said specimen being
adapted to be provided by a donor, said method comprising the steps of:

guiding said collector, via a computer device, to determine said data within
said chain of custody data set and to input complete data for said chain of custody
data set into said computer device; and

30 directing said chain of custody data set with complete data to an RFID device,
said RFID device being operably engaged with a specimen container configured to
receive said specimen.

9. A method according to Claim 8, further comprising detecting at least one substance in said specimen with a testing device operably engaged with said specimen container so as to be capable of directly interacting with said specimen.

5

10. A method according to Claim 9, further comprising inputting a result provided by said testing device into said computer device, said result being included in said chain of custody data set.

10 11. A computer program product capable of directing the collection and securement of a chain of custody data set related to a specimen, data within said chain of custody data set being adapted to be input by a collector and said specimen being adapted to be provided by a donor, the computer program product comprising a computer-readable storage medium having computer-readable program code portions
15 stored therein, the computer-readable program code portions comprising:

an executable portion for guiding said collector to determine data within said chain of custody data set and to input complete data for said chain of custody data set into a computer device; and

20 an executable portion for directing said chain of custody data set to a transceiver configured to direct said chain of custody data set to an RFID device operably engaged with a specimen container configured to receive said specimen.

12. A computer program product according to Claim 11, further comprising:

25 an executable portion for directing a testing device to detect at least one substance in said specimen, said testing device being operably engaged with said specimen container so as to be capable of directly interacting with said specimen received therein; and

30 an executable portion for directing a result provided by said testing device to an RFID device operably engaged with said specimen container.

13. A computer program product according to Claim 11, further comprising:

an executable portion for receiving data selected from the group consisting of:
an electronic signature from said donor, an electronic signature from said collector,
5 and combinations thereof.

14. A container device adapted to receive a specimen collected during point-of-collection testing, said specimen being adapted to be provided by a donor, said container device comprising a testing device configured to detect at least one
10 substance in said specimen, said testing device being capable of directly interacting with said specimen received therein.

15. A container device according to Claim 14, further comprising an RFID device configured to receive a chain of custody data set related to said specimen, data
15 within said chain of custody data set being adapted to be input by a collector.

16. A container device according to Claim 15, wherein said testing device is further configured to direct a result provided by said testing device to said RFID device for retention therein.

20

17. A container device according to Claim 14, wherein said testing device is configured to detect a substance selected from the group consisting of:

PCP;
amphetamines;
25 methamphetamines;
methadone;
benzodiazopenes;
barbiturates;
THC;
30 THC metabolites;
THCA;
cocaine;

cocaine metabolites;
ecstasy;
oxycodone;
propoxyphene;
5 methaqualone
opiates; and
combinations thereof.

18. A container device according to Claim 14, further comprising a
10 temperature device configured to determine a temperature of said specimen.

19. A container device according to Claim 15, wherein said RFID device is
non-removably engaged therewith.

15 20. A container device according to Claim 16, further comprising a
tamper-evident device operably engaged therewith.

21. A method for collecting and securing a chain of custody data set
related to a specimen collected during specimen collection, data within said chain of
20 custody data set being adapted to be input by a collector and said specimen being
adapted to be provided by a donor, said method comprising the steps of:

guiding said collector, via a computer device, to determine said data within
said chain of custody data set and to input complete data for said chain of custody
data set into said computer device; and

25 directing said chain of custody data set to a printer operably engaged with said
computer device, said printer configured to print said chain of custody data set as a
bar code label configured to be capable of operably engaging a specimen container
configured to receive said specimen.

30 22. A method according to Claim 21, further comprising receiving data
selected from the group consisting of: an electronic signature from said donor, an
electronic signature from said collector, and combinations thereof.

23. A method according to Claim 21, wherein said chain of custody data set is printed as a bar code label in a format selected from the group consisting of:

- code 128;
- 5 PDF-417;
- data matrix;
- and combinations thereof.

24. A computer program product capable of directing the collection and
10 securement of a chain of custody data set related to a specimen, data within said chain of custody data set being adapted to be input by a collector and said specimen being adapted to be provided by a donor, the computer program product comprising a computer-readable storage medium having computer-readable program code portions stored therein, the computer-readable program code portions comprising:

- 15 an executable portion for guiding said collector to determine data within said chain of custody data set and to input complete data for said chain of custody data set into a computer device; and

- an executable portion for directing said chain of custody data set to a printer operably engaged with said computer device, said printer configured to print said
20 chain of custody data set as a bar code label configured to be capable of operably engaging a specimen container configured to receive said specimen.

25. A computer program product according to Claim 24, further comprising:

- 25 an executable portion for receiving data selected from the group consisting of: an electronic signature from said donor, an electronic signature from said collector, and combinations thereof.

26. A computer program product according to Claim 24, wherein said
30 chain of custody data set is printed as a two-dimensional (2D) bar code label.

27. A computer program product according to Claim 24, wherein said chain of custody data set is printed as a bar code label in a format selected from the group consisting of:

- code 128;
- 5 PDF-417;
- data matrix;
- and combinations thereof.

10

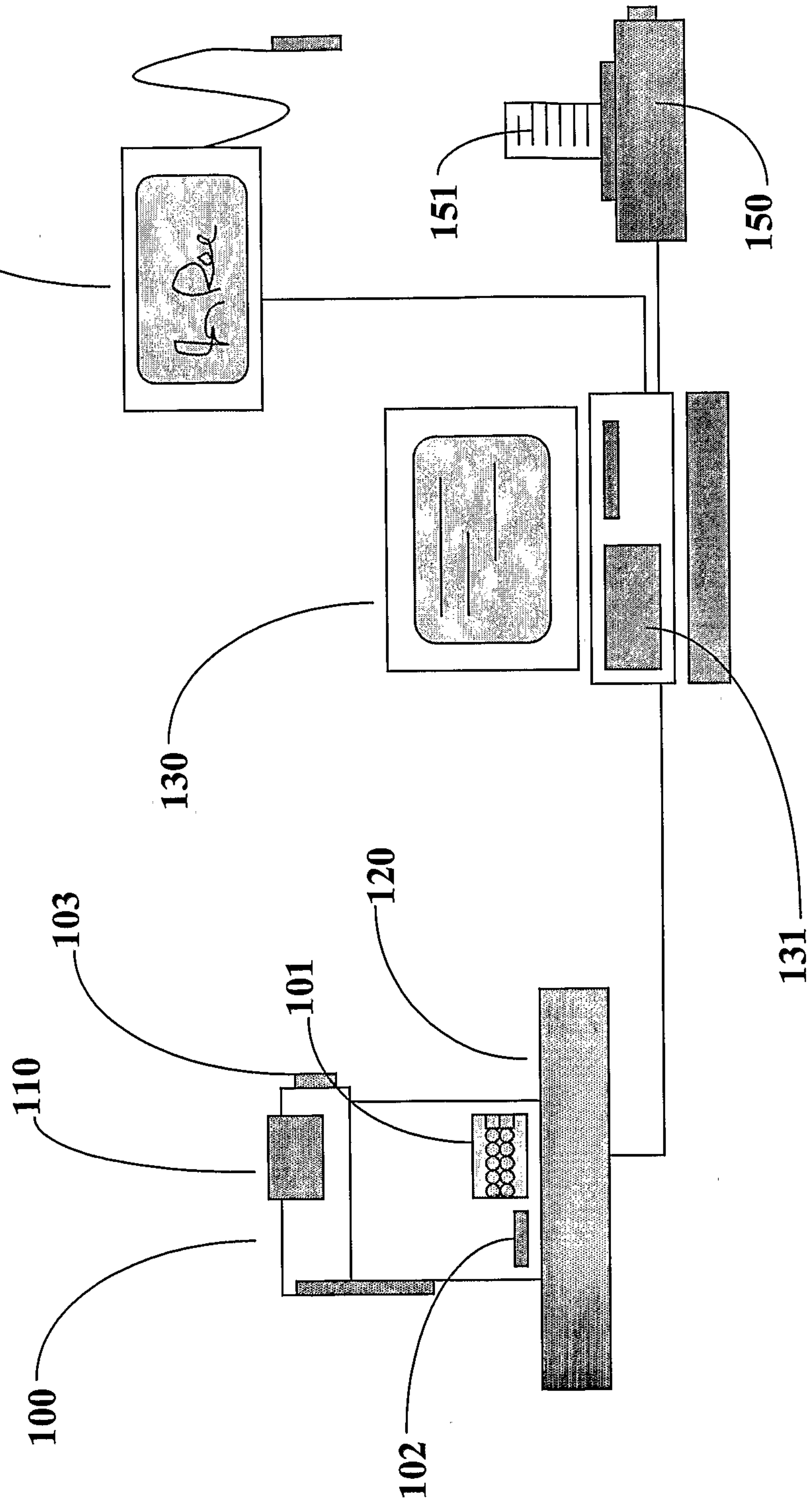
Fig. 1

Fig. 2

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Labcorp Collection

File Options Help

280

Employer

Name: City: Telephone: FAX:

Address: State: Zipcode:

Address:

270

MRO

Name: City: Telephone: FAX:

Address: State: Zipcode:

Address:

260

Collection Site

Name: City: Telephone: FAX:

Address: State: Zipcode:

Address:

Site ID: Order #: Form Type:

Account #: Location Code:

Accession #:

200

Donor's Information and Signature

SSN: Employee ID: First Name: Last Name: Donor ID'd by: Capture Clear

210

Collector's Information and Signature

Name: Capture Clear

250

Testkit Information

Lot Number: Expiration Date: Remarks:

240

Field Screening

PCP AMP THC COC OPI BARB BENZ METH MTD Negative

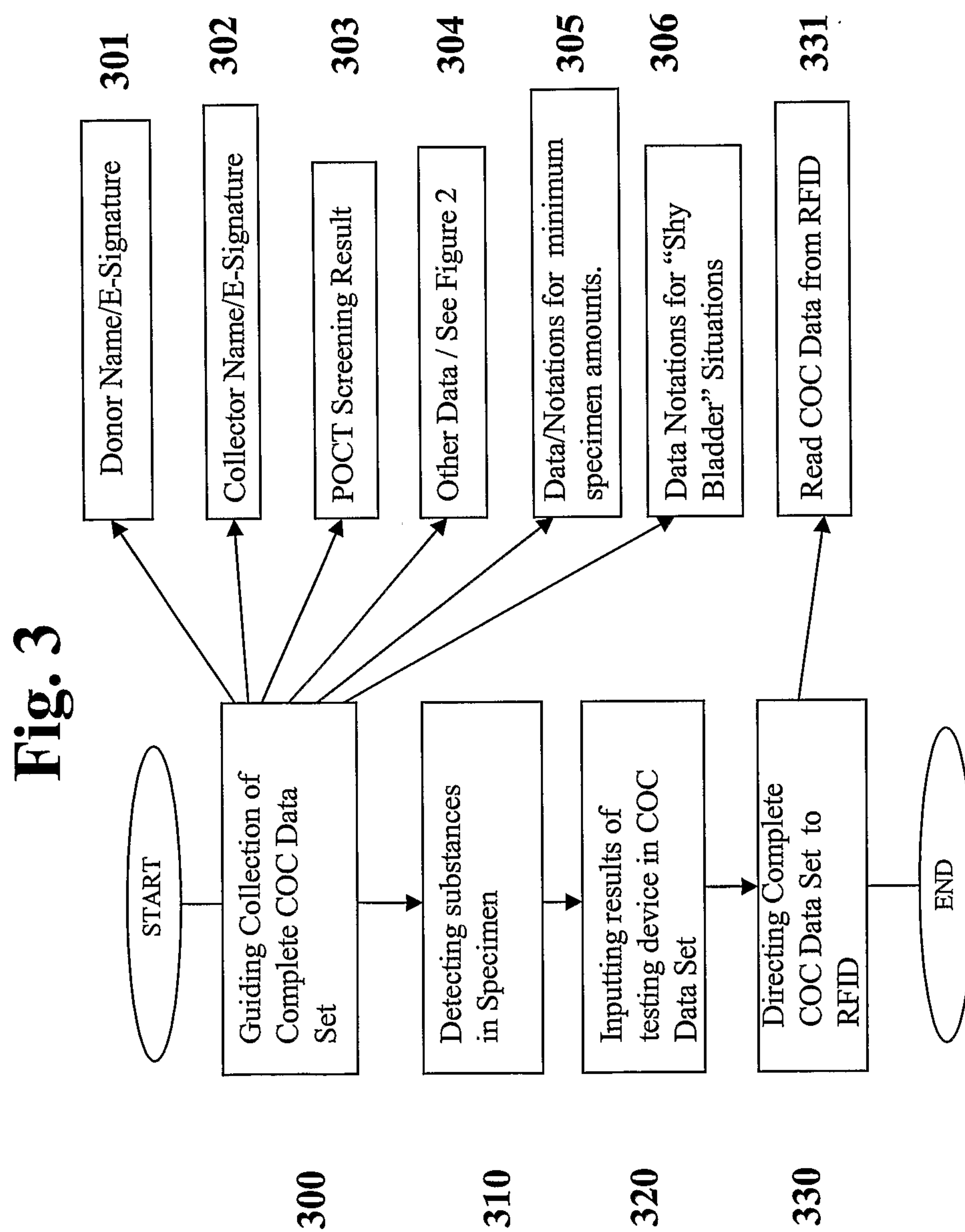
230

Specimen

Shy Bladder? Split Bottle? Check for Yes? Temperature In Range? C Yes C No Reason For Test: Tags Written: Connect Disconnect Read from Tag Print Form Write to Tag

220

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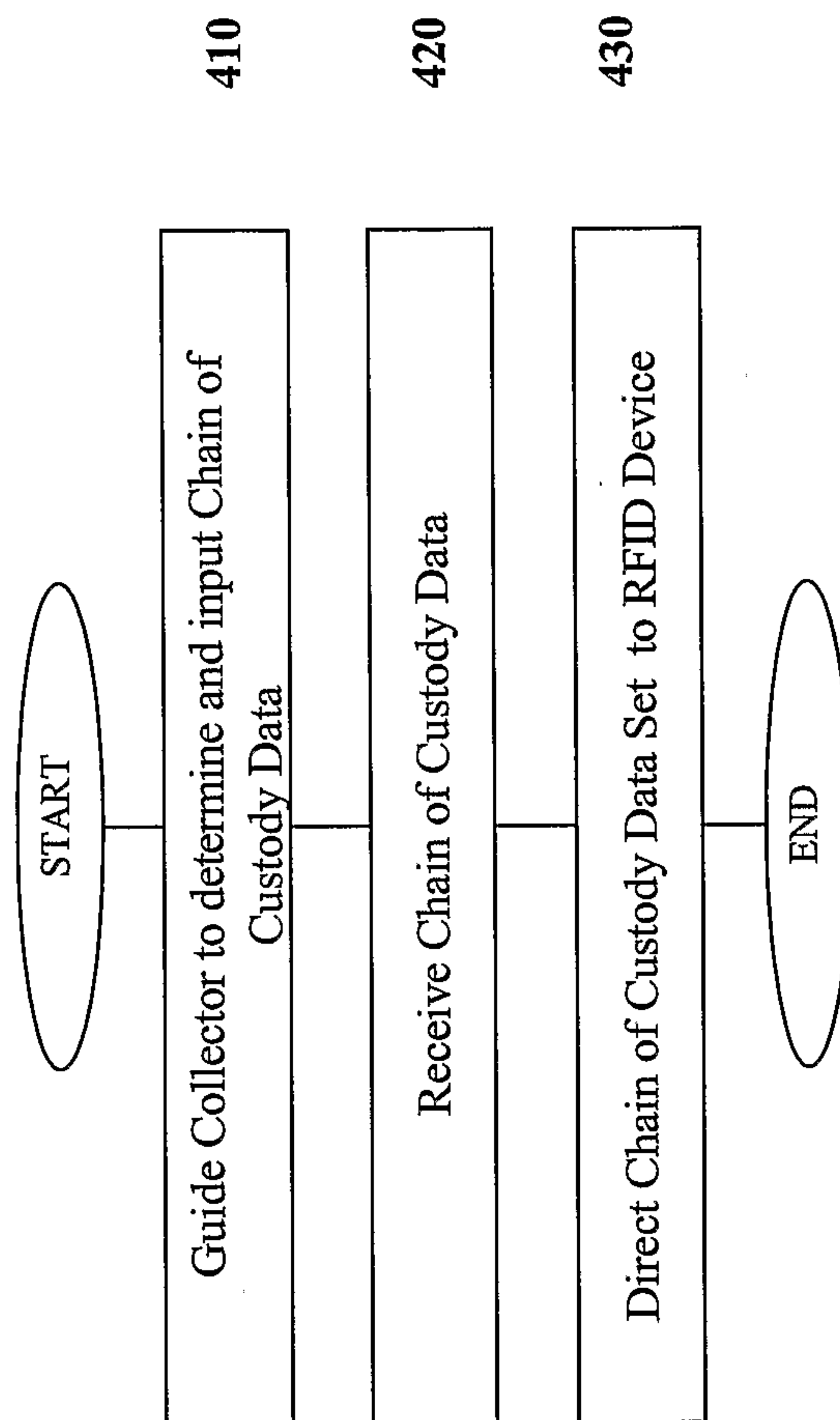
Fig. 4

Fig. 5

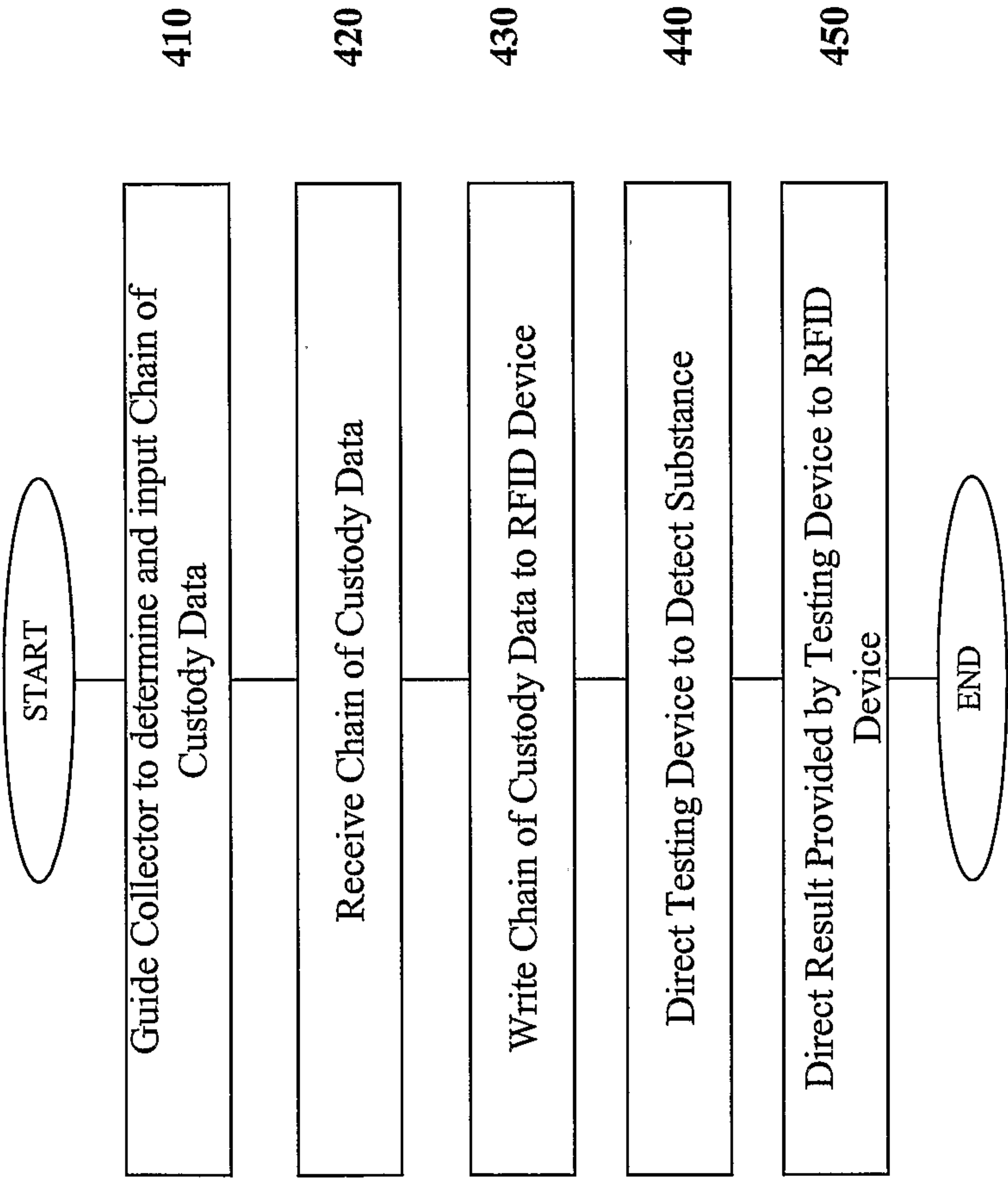
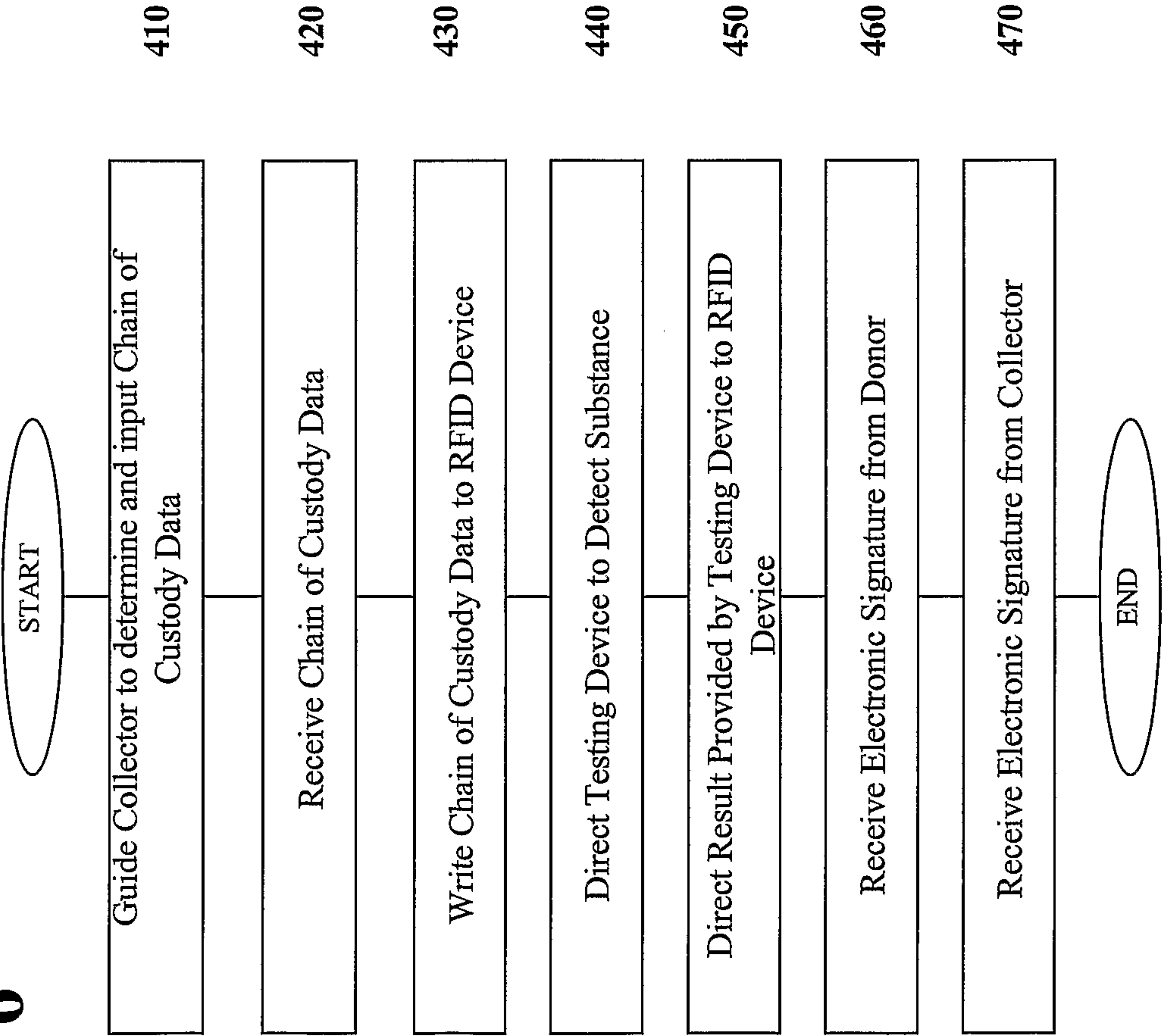


Fig. 6



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Fig. 7

Labcorp Collection

File Options Help

Employer

Name: ABC COMPANY

Address: 123 MAIN STR

Address:

City: ANYWHERE

State: NC

Zipcode: 26609

Telephone: 1234567890

FAX: 1232567888

Donor's Information and Signature

SSN:

Employee ID:

First Name:

Last Name:

MRO

Name: DR. STEWART

Address: CHOICEPOINT

Address: 888 SEED STRE

City:

State:

Zipcode:

Collection Site

Name: ABCORP PSC

Address: 1904 ALEXAND

Address:

City:

State:

Zipcode:

Site ID: 99998

Account #: 894123

Accession #:

Order #:

Location Code:

Testkit Information

Lot Number:

Expiration Date:

Field Screening

☐ PCP

☐ AMP

☐ THC

☐ COC

☐ OPI

☐ BARB

☐ BENZ

☐ METH

☐ MTD

☐ Negative

☐ Shy Bladder?

☐ Split Bottle?

Check for 'Yes'

Temperature In Range?

☒ Yes

☐ No

Reason For Test

Tags Written

Connect

Disconnect

Read from Tag

Print Form

Write to Tag

The Collector records the Lot # and Expiration Date of the Testing Device

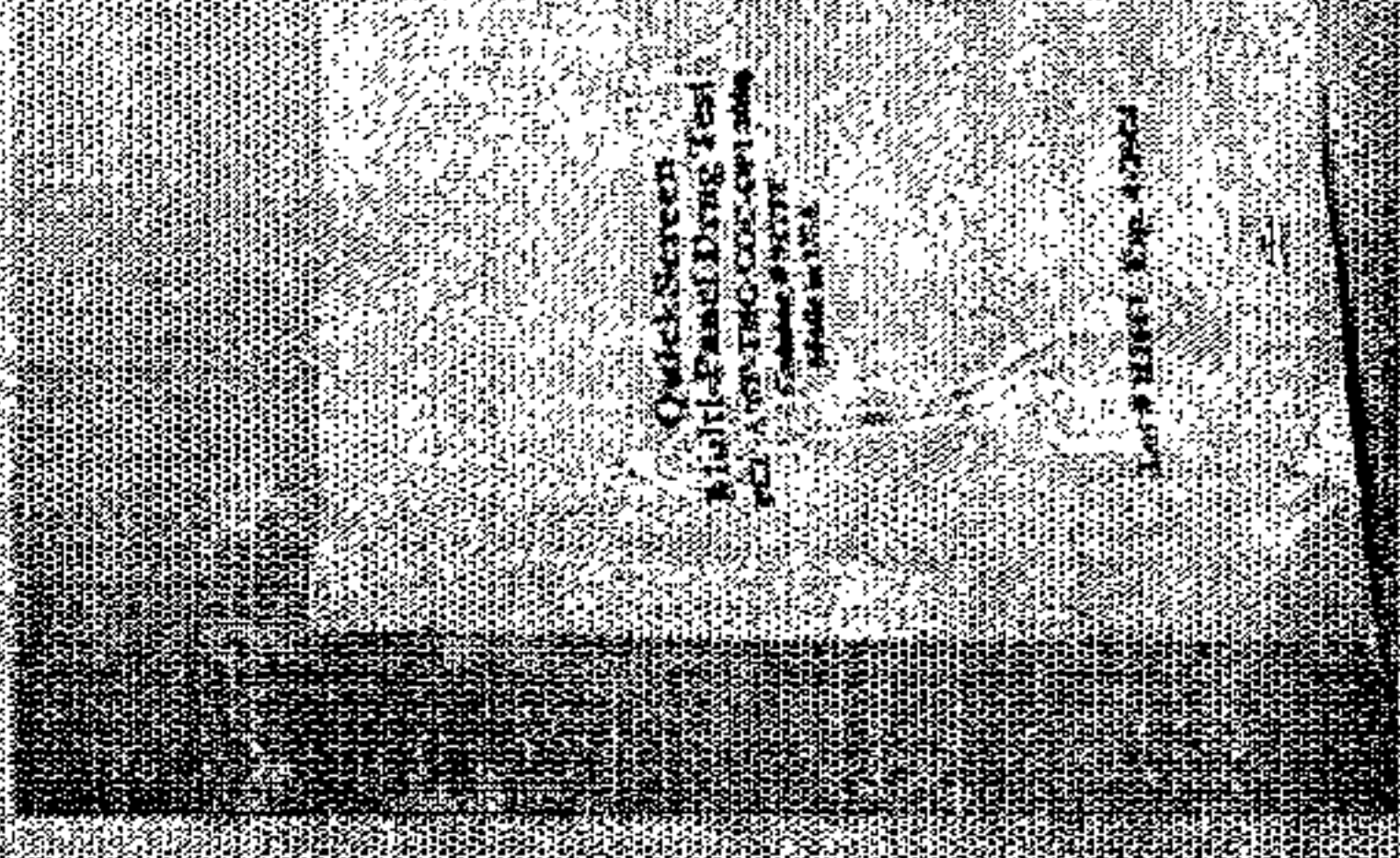


Fig. 8

Labcorp Collection

File Options Help

Employer

Name: **ABC COMPANY**

City: **ANYWHERE**

Telephone: **1234567890**

Address: **123 MAIN STR**

State: **NC**

FAX: **1232567888**

Zipcode: **26609**

MRD

Name: **DR. STEWART**

City: **ATLANTA**

Telephone: **1233334444**

Address: **CHOICEPOINT**

State: **GA**

Address: **888 SEED STRE**

Zipcode: **36788**

Collection Site

Name: **LABCORP PSC**

City: **DURHAM**

Address: **1904 ALEXAND**

State: **NC**

Address:

Zipcode: **27709**

Site ID: **999998**

Account #: **894123**

Order #:

Accession #:

Location Code:

Testkit Information

Lot Number: **H2661**

Expiration Date: **12-2005**

Remarks:

Field Screening

☐ PCP ☐ BENZ

☐ AMP ☐ METH

☐ THC ☐ MTD

☐ COC ☐ OPI

☐ BARB ☐ Negative

Donor's Information and Signature

SSN:

Employee ID:

First Name:

Last Name:

Donor ID'd by:

Split Bottle?

Check for 'Yes'

Temperature In Range?

☐ Yes ☐ No

Reason For Test:

Tags Written:

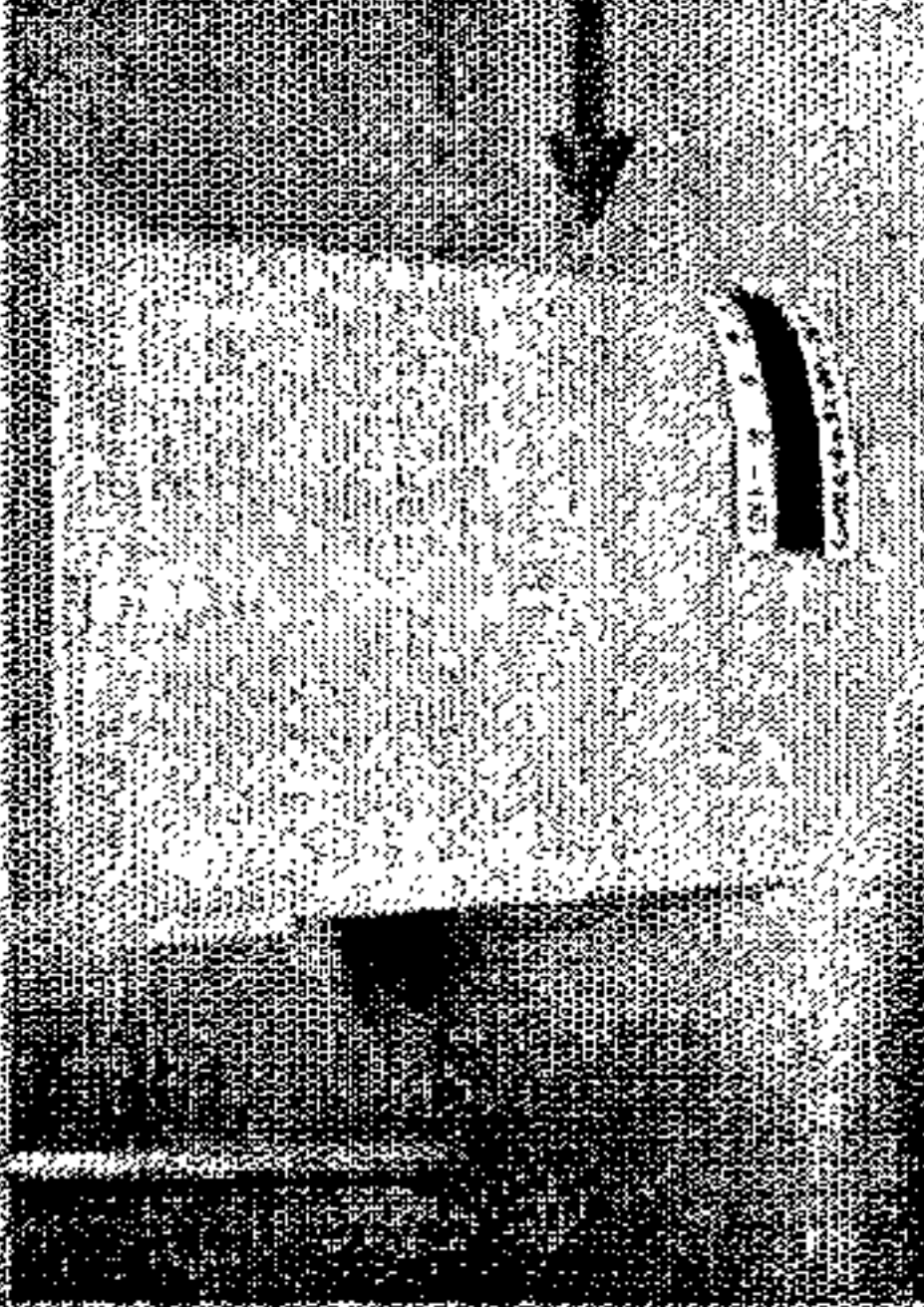
Disconnect

Read from Tag

Print Form

Write to Tag

The Collector provides the donor with the specimen Container and requests the donor to provide a minimum of 45 mL of urine.



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Fig. 9

Labcorp Collection
File Options Help

Employer: **ABC COMPANY** City: **ANYWHERE** Telephone: **1234567890** SSN: **145678900**
Address: **123 MAIN ST** State: **NC** FAX: **1234567890** Employee ID: **7400** Donor's Information and Signature

Reading the Results

Collector Instructions:
2 lines means
"NEGATIVE" ... 1 line
means "POSITIVE"

*Even a faint line should be
considered a line.*

***DO not read the result
until the result ready
light appears.***

*Note: If you do NOT get lines in the
control window for all drugs, you
possibly may have a defective
product. Use another panel and
contact LabCorp at 800-800-4522
ext. 3988 to report the incident.
Keep the panel so that you can send
it in for QC testing.*

A result should NOT be read after the result expired window turns red.

Write to Tag

Pre Employment

Fig. 10

Labcorp Collection

FileOptionsHelp

Employer

Name: [ABC COMPANY]City: [ANYWHERE]Telephone: [1234567890]

Address: [123 MAIN STR]State: [NC]FAX: [1232567888]

Address: Zipcode: [26609]

MRO

Name: [DR. STEWART]City: [ATLANTA]Telephone: [4223234444]

Address: [CHOICEPOINT]State: [GA]

Donor's Information and Signature

SSN: Employee ID: First Name: Last Name: Donor ID: [b]b

COLLECTOR INSTRUCTIONS

Urge the employee to drink up to 40 ounces of fluid, distributed reasonably throughout a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink. If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site before the collection process is complete, you must discontinue the collection, note the fact in the "Remarks" box, and immediately notify LabCorp at 800-800-4522 ext. 3988. This is a refusal to test.

Expiration Date: [12-2005]

Remarks:

☐ COC

☐ OPI

☐ BARB

☐ Negative

Specimen

☐ Shy Bladder?

☐ Split Bottle?

Check for "Yes"

Temperature In Range?
☒ Yes ☐ No

Reason For Test:

Reader Status

Tags Written:

Connect

Disconnect

Read from Tag

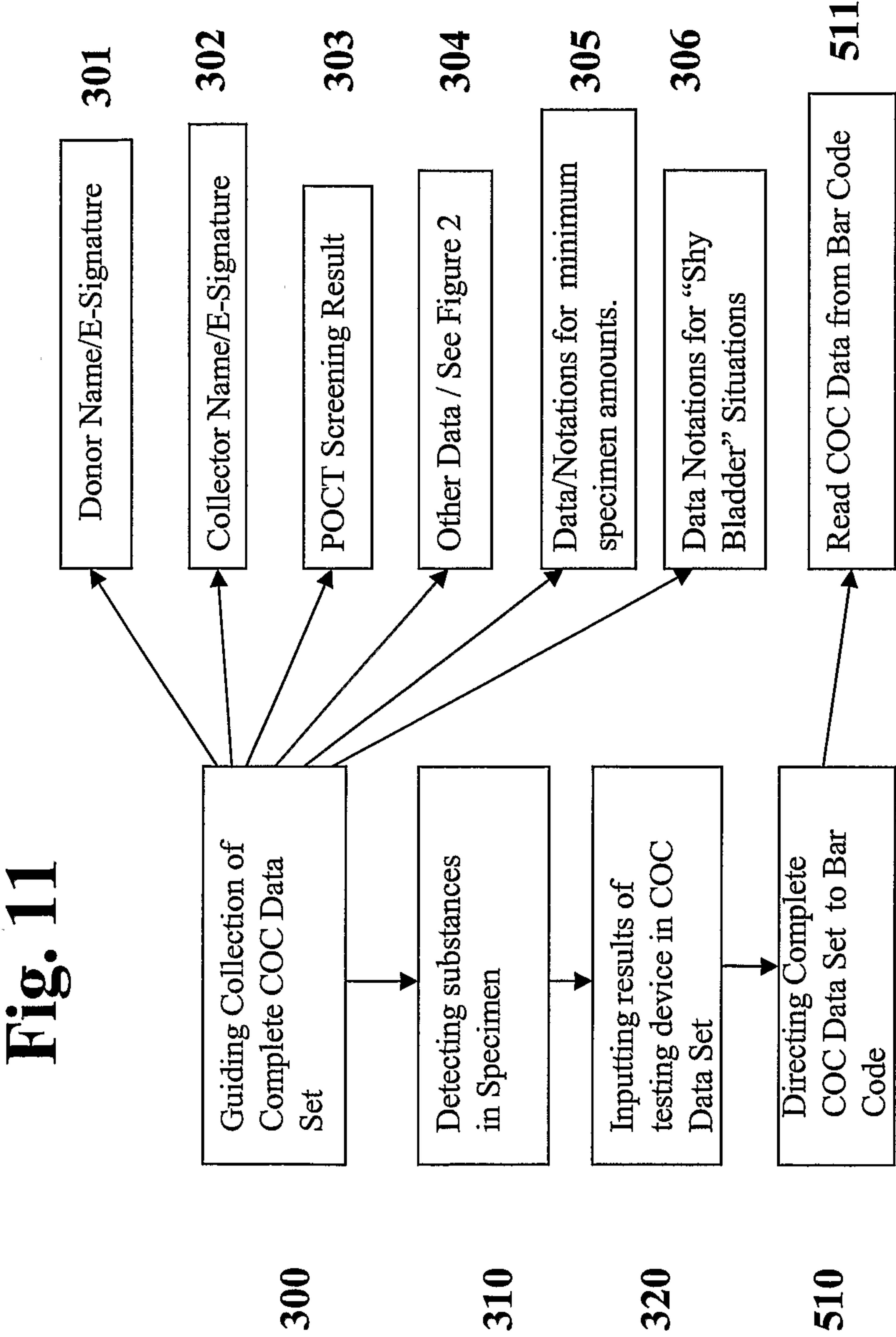
Print Form

Write to Tag

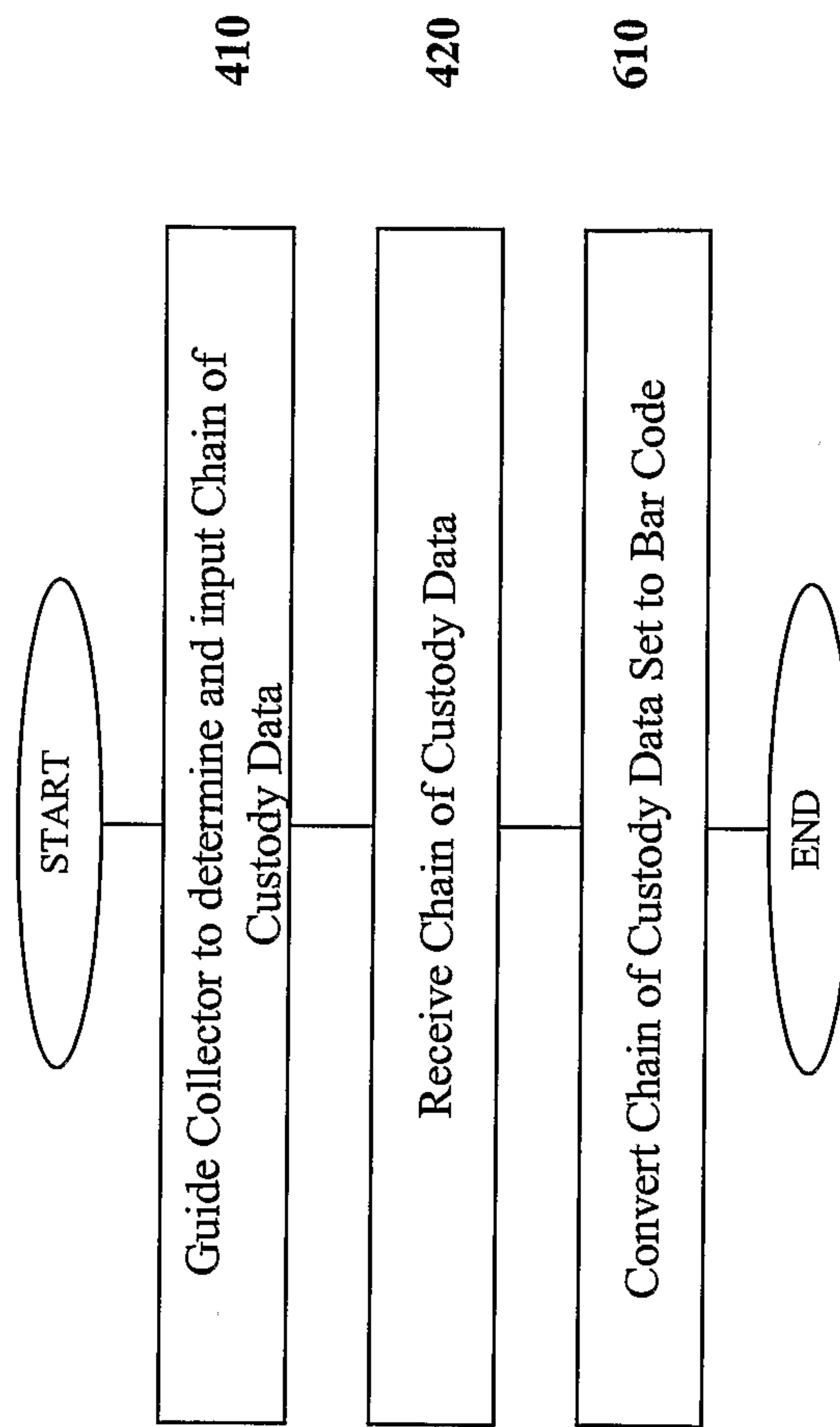
Upon receipt of the specimen from the donor, the Collector conducts a visual inspection to determine volume, color & temperature of the specimen.

If Shy Bladder, click here.

The Collector reads the temperature of the specimen.



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Fig. 12

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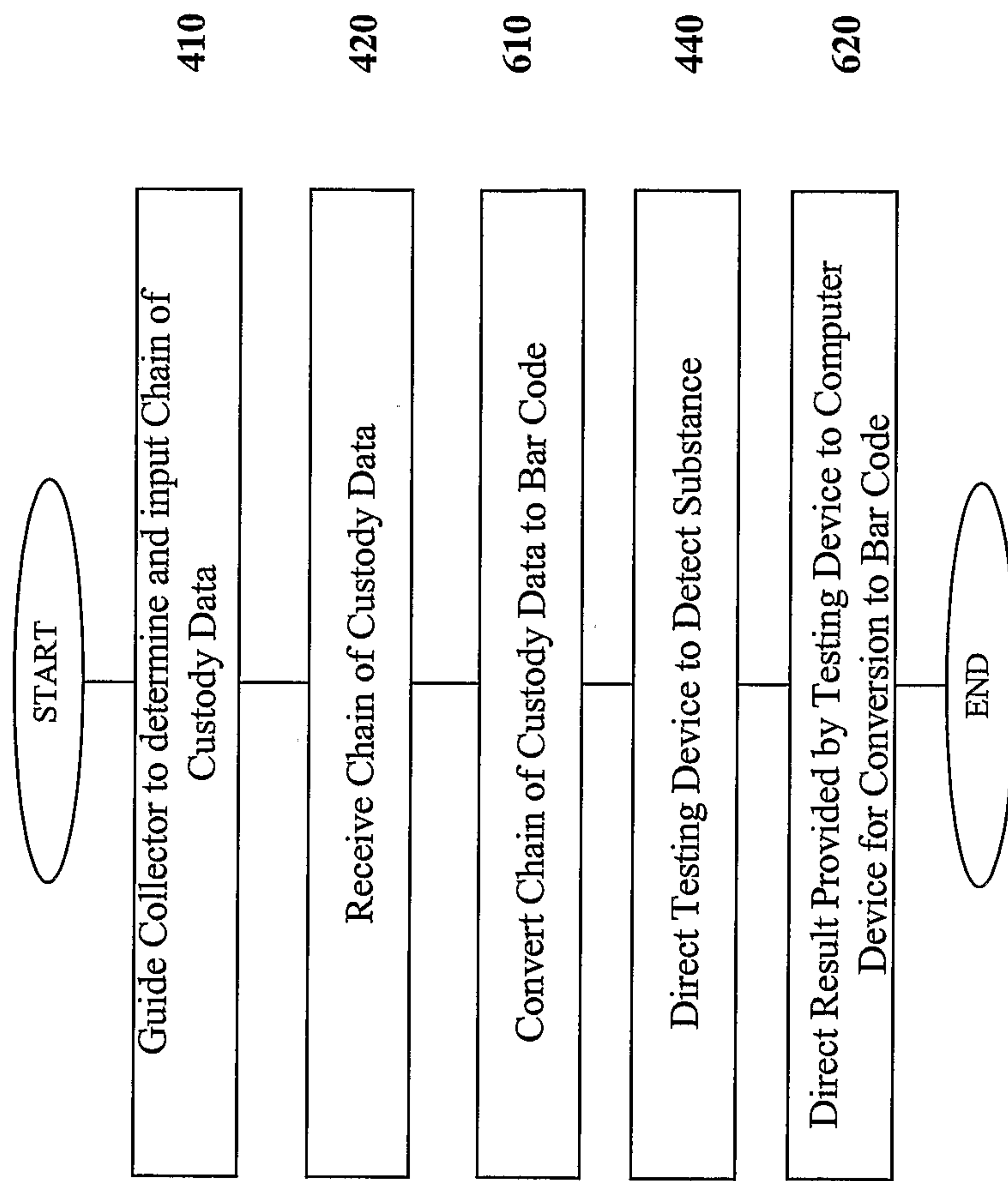
Fig. 13

Fig. 14

