AUTOMATED SAMPLING AND ANALYSIS USING A PESONAL SAMPLER DEVICE

FIELD OF THE INVENTION

[0001] The present invention generally relates to the field of medical systems. More particularly, the present invention relates to the field of sampling systems and automated sampling analysis.

BACKGROUND OF THE INVENTION

[0002] The most common side effect of chemotherapy treatment is bone marrow suppression. The treatment induces a decrease in neutrophils (an abundant type of granular white blood cells) count and thus become the rate-limiting factor in chemotherapy treatment. Maintaining neutrophils level within a normal range is mandatory for the success of the treatment and for avoiding lethal toxicity. Therefore, blood count tests are a routine procedure for cancer patients, for example, properly and safely maintaining their treatment schedule.

[0003] Blood counts and blood components tests are presently made only in certified laboratories either by venous sampling or by drawing peripheral blood. On a daily basis, a blood count may be an inconvenient activity for patients, such as cancer patients and the like. The necessity, to go to the lab, on a daily basis, where a member of the medical personnel, such as a physician or a nurse, has to find the right venous access that causes physical pain, loss of working days, loss of money and time for the patient as well as for the insurance system.

[0004] A patent number US2005130236, by Goldman Richard M. discloses a home health care blood chemistry apparatus that requires only a "pin prick" sample of

a patient's capillary blood. The sample is applied to a test strip including a sample receiving pad and sample analysis pads. The blood sample is applied to the sample receiving pad and flows, by surface tension, and capillary flow to the separate analysis pads that are in parallel with each other and in series with the sample-receiving pad. Each sample pad contains reagents that are specific to producing an optically detectable effect for a specific blood component. The optical effects are detected by a reflectance meter that is used in conjunction with the test strip. The optical effects are converted to digital data, and stored in a storage device associated with the meter, for transmission to a health care.

[0005] A patent number JP60162955 by Matsushita Hajime, Shinudou Isao and Yabe Riyouhei discloses an automatic analysis device for blood cells. A blood from a patient is smeared on slide glass and is dyed to prepare a dye specimen. The blood cells on the specimen are magnified by an optical microscope and taken as a three-color image by a camera. The image is digitally stored. The specific quantity of the blood cells is calculated from the blood cell image. The white blood cells, red blood cells and platelets are analyzed and detected by an automatic blood cell classifying system.

[0006] Goldman and Matsushita do not disclose a method or a system that provides automated and computerized analysis of the data stored by the reflectance meter or the microscope. Furthermore, Goldman and Matsushita do not discuss as for how the results of the data analysis are transmitted or received and by whom.

SUMMARY OF THE INVENTION

[0007] The present invention is a system and a method for blood sampling and sample-analysis that is suited for blood counts or for blood components tests of various types of blood cells and blood components. According to some embodiments of the present invention, the present invention may further suit analysis of urine samples.

[0008] The system comprises a sampler device, sampler preparation unit, a transmission unit and an analysis unit. A patient may take a self blood-sample by pin pricking his finger, for example, and place the sampled blood drops on a sample strip. The patient may then insert the strip into the sampler. The sampler may chemically prepare the sample and photograph it using a photography unit that includes a camera that is installed in the sampler. After the sample has been photographed, the resulting sample image may be transmitted to the analysis unit that may analyze the image through an image-processing algorithm. The analysis results may be automatically transmitted to the patient and to a medical authority, such as the patient's physician, a nurse, a clinic and the like, for further medical analysis, decision-making and treatment.

[0009] According to embodiments of the present invention, the photography unit may include a digital camera, a solid-state detector and like, without requiring photography by a microscope.

The sampler that is a self blood-testing device may include a housing unit – for placing and holding the sample strip, a sample-preparation unit – for preparing the sample to be photographed, a photography unit – to photograph the sample and allow digital storage of the sample image. The sampler may further include a connector that may allow connection to a communication network and a power connection to allow

connection to a power source. The sample-preparation unit prepares the sample by an automated or a manual process that includes smearing, drying and staining the sample.

BRIEF DESCRIPTIONS OF THE DRAWINGS

[0010] The subject matter regarded as the invention will become more clearly understood in light of the ensuing description of embodiments herein, given by way of example and for purposes of illustrative discussion of the present invention only, with reference to the accompanying drawings, wherein

Fig. 1 is a schematic illustration of a system for blood sampling and sample-analysis, according to some embodiments of the present invention.

Fig. 2 is a schematic illustration of a sampler, according to some embodiments of the present invention.

Fig. 3 is a schematic illustration of a smearing device that is installed within the sampler, according to some embodiments of the present invention.

Fig. 4 is a schematic flow diagram of a method for blood sampling and sample-analysis, according to some embodiments of the present invention.

[0011] The drawings together with the description make apparent to those skilled in the art how the invention may be embodied in practice.

[0012] An embodiment is an example or implementation of the inventions. The various appearances of "one embodiment," "an embodiment" or "some embodiments" do not necessarily all refer to the same embodiments. Although various features of the invention may be described in the context of a single embodiment, the features may also be provided separately or in any suitable combination. Conversely, although the invention may be described herein in the context of separate embodiments for clarity, the invention may also be implemented in a single embodiment

DETAILED DESCRIPTIONS OF SOME EMBODIMENTS OF THE INVENTION

[0013] The present invention is a system and a method for blood or urine sampling and sample-analysis. The system comprises a sampler **100** device, a transmission unit **500** and an analysis unit **200**. Patient **10** may take a self blood-sample by pin pricking his finger, for example, and place the sampled blood drops on a sample strip **115**. Patient **10** may then insert strip **115** into sampler **100**. Sampler **100** may chemically and mechanically prepare the sample and photograph the sample using a photography unit **120**. After the sample has been photographed, the sample image may be transmitted to analysis unit **200**, where the results of the image analysis may be automatically transmitted to patient **10** and to a medical authority **20** for further analysis, decision-making and treatment.

[0014] While the description below contains many specifications, these should not be construed as limitations on the scope of the invention, but rather as exemplifications of the preferred embodiments. Those skilled in the art will envision other possible variations that are within its scope. Accordingly, the scope of the invention should be determined not by the embodiment illustrated, but by the appended claims and their legal equivalents.

[0015] Reference in the specification to "one embodiment", "an embodiment", "some embodiments" or "other embodiments" means that a particular feature, structure, or characteristic described in connection with the embodiments is included in at least one embodiments, but not necessarily all embodiments, of the inventions. It is understood that the phraseology and terminology employed herein is not to be construed as limiting and are for descriptive purpose only.

[0016] The principles and uses of the teachings of the present invention may be better understood with reference to the accompanying description, figures and examples. It is to be understood that the details set forth herein do not construe a limitation to an application of the invention. Furthermore, it is to be understood that the invention can be carried out or practiced in various ways and that the invention can be implemented in embodiments other than the ones outlined in the description below.

[0017] It is to be understood that the terms "including", "comprising", "consisting" and grammatical variants thereof do not preclude the addition of one or more components, features, steps, or integers or groups thereof and that the terms are to be construed as specifying components, features, steps or integers. The phrase "consisting essentially of", and grammatical variants thereof, when used herein is not to be construed as excluding additional components, steps, features, integers or groups thereof but rather that the additional features, integers, steps, components or groups thereof do not materially alter the basic and novel characteristics of the claimed composition, device or method.

[0018] If the specification or claims refer to "an additional" element, that does not preclude there being more than one of the additional element. It is to be understood that where the claims or specification refer to "a" or "an" element, such reference is not be construed that there is only one of that element. It is to be understood that where the specification states that a component, feature, structure, or characteristic "may", "might", "can" or "could" be included, that particular component, feature, structure, or characteristic is not required to be included.

[0019] Where applicable, although state diagrams, flow diagrams or both may be used to describe embodiments, the invention is not limited to those diagrams or to the

corresponding descriptions. For example, flow need not move through each illustrated box or state, or in exactly the same order as illustrated and described.

[0020] Methods of the present invention may be implemented by performing or completing manually, automatically, or a combination thereof, selected steps or tasks. The term "method" refers to manners, means, techniques and procedures for accomplishing a given task including, but not limited to, those manners, means, techniques and procedures either known to, or readily developed from known manners, means, techniques and procedures by practitioners of the art to which the invention belongs. The descriptions, examples, methods and materials presented in the claims and the specification are not to be construed as limiting but rather as illustrative only.

[0021] Meanings of technical and scientific terms used herein are to be commonly understood as by one of ordinary skill in the art to which the invention belongs, unless otherwise defined. The present invention can be implemented in the testing or practice with methods and materials equivalent or similar to those described herein.

[0022] Any publications, including patents, patent applications and articles, referenced or mentioned in this specification are herein incorporated in their entirety into the specification, to the same extent as if each individual publication was specifically and individually indicated to be incorporated herein. In addition, citation or identification of any reference in the description of some embodiments of the invention shall not be construed as an admission that such reference is available as prior art to the present invention.

[0023] Fig. 1 schematically illustrates a system for blood sampling and sample-analysis, according to some embodiments of the present invention. The system comprises sampler **100**, transmission unit **500**, and analysis unit **200**. Patient **10** may

place the sampled blood drops or urine drops on a sample strip **115** and inserts sample strip **115** into sampler **100**. Sampler **100** may chemically and mechanically prepare the sample; photograph the prepared sample and transmit the photographed sample image along with patient's **10** related information to analysis unit **200**. Analysis unit **200** may then analyze the sample image using computerized software algorithms and output the results of the analysis as "results" data. Analysis unit **200** may transmit the results to patient **10** and to a medical authority **20** such as the patient's **10** physician, a nurse, a clinic and the like. Medical authority **20** may use those results for supervising patient's **10** physical condition on daily basis, for example and for deciding upon further treatment.

[0024] According to embodiments of the present invention, the sample image and patient's **10** related information may be stored and transmitted as digital data by sampler **100** and by analysis unit **200**. Patient's **10** related information may be patient's **10** personal details such as name, identification number, date of birth, medical history and the like. Patient's **10** related information may also include information relating to the details of transmission of data such as date and time of transmission, validation of transmission and receiving of data and the like.

[0025] According to embodiments of the present invention, to produce the blood drops for the sampling, patient **10** may be required to pin prick his finger, using a needle or any other pricking device. The pricking devices as well as sample strips **115** may be attached to sampler **100** when purchasing sampler **100** and may further be accessible as a separate unit.

[0026] According to embodiments of the present invention, transmission unit **500** may be any device that enables network communication and transmission of data, as long sampler **100** enables connection with transmission unit **500**. Transmission unit

500 may also be an integrated part of sampler **100** where the sample image photographed by sampler **100** is automatically transmitted to analysis unit **200**.

[0027] . . . According to embodiments of the present invention, transmission unit may be a network device such as a cellular phone, a computer, a laptop and the like.

[0028] According to embodiments of the present invention, analysis unit **200** may be any network device that allows computation such as a computer, a processing chip attached to a cellular phone or to sampler **100**, a laptop and the like. The analysis may be carried out through at least one software application installed within analysis unit **200**, where the application may include image processing. According to other embodiment of the present invention, the analysis and image processing may be carried out through hardware such as a processor chip and the like.

[0029] Fig. 2 schematically illustrates sampler **100**, according to some embodiments of the present invention. Sampler **100** may comprise housing unit **110**, a photography unit **120**, a sample-preparation unit **130**, a network connector **150** and a power **140** connection.

[0030] According to embodiments of the invention as illustrated in Fig. 2, housing unit **110** may provide housing for inserting sample strip **115** through an opening **112** and holding sample strip **115** while the sample is prepared and photographed.

[0031] According to embodiments of the invention as illustrated in Fig. 2, preparation unit **130** may prepare the sample for photography, by smearing the sample – to provide a large surface for photographing; drying the sample and staining the sample.

[0032] According to embodiments of the invention as illustrated in Fig. 2, photography unit **120** may include a photographing device such as a digital stills camera, a digital video camera, a solid state detector for visible light waves (such as a

solid-state Charged Coupled Device known as a CCD camera) and the like. Photography unit **120** may enable storing and transmitting the photographed sample image to Analysis unit **200**.

[0033] According to embodiments of the invention as illustrated in Fig. 2, connector **150** may be any device that allows transmission of data to transmission unit **500**, such as a Universal Serial Bus (USB) connector, a Video Graphic Array (VGA) connector, and the like. Connector **150** may include cablings, and may be directly connected to photography unit **120** at one end and to transmission unit **500** at the other end.

[0034] According to embodiments of the invention as illustrated in Fig. 2, power **140** may be any connection to any power source such as an Alternative Currant (AC) electric source, a battery and the like.

[0035] Fig. 3 schematically illustrates a smearing device **131** of sample-preparation unit **130**, according to some embodiments of the present invention. To smear the sample-smearing device **131** is installed within sampler **100**. Smearing device may include at least one smearing piece **135** and a smearing base **134**. Sample strip **115** may be placed on base **134** through housing unit **110**, where the blood sample itself faces upwards. Smearing piece **135** may then be moved manually or automatically, in a substantially horizontal direction across the sample at least one time, to smear the sample into a flattened shape that will increase the surface of the sample.

[0036] Drying the sample may be carried out through an air opening threaded at sampler **100**, by a fan, a combination of a fan and an air opening or any other drying mechanism, according to embodiments of the invention.

[0037] Sampler **100** may automatically carry out all smearing, drying and staining of the sample, once sample strip **115** is inserted into opening **112**, according to embodiments of the present invention. For example, patient **10** may insert sample strip **115** and the sample will be automatically prepared and photographed by sampler **100**.

[0038] According to embodiments of the present invention, some parts of sampler **100** may be removable to allow replacement of all parts that come in contact with the sample. For example, smearing piece **135**, the staining device and parts of housing unit **110** may be removable. The removable parts may be designed and packaged as a kit that may be placed in sampler **100**, For example, a drawer-like kit that comes in hygienically sealed packages that can be inserted into a drawer-like opening in sampler **100**, where the kit is designed to install all the kit's parts in their right place in sampler **100**.

[0039] According to embodiments of the present invention, sampler **100** may include operation buttons that may provide patient **10** control over different stages of sampler **100**. For example, "on" and "off" button that connects and disconnects sampler's **100** power **140** supply; a smearing button that provides control over number of smearing moves of smearing piece **135**, a photo button that controls the photography option and the like. Sampler **100** may further include indicators that indicate whether the sample is prepared and patient **10** can press the photographing button, for example.

[0040] Fig. 4 schematically illustrates a method for blood sampling and sample-analysis using sampler **100**, transmission unit **500**, and analysis unit **200**, according to some embodiments of the present invention. The method comprises the steps of:

- placing the sample on a sampling strip **71**, where the sample is at least one drop of blood that has been taken by patient **10**;
- inserting the strip into the housing unit **72** ;
- smearing the sample **73**, wherein a smearing device that is installed within the sampler smears down the sample;
- drying the sample **74**, wherein the sample is placed facing an air opening for a predetermined period of time to allow it to dry or any other drying device;
- staining the sample **75**, wherein the sample is stained by a staining device that is installed within sampler **100**;
- photographing the sample **76** by photography unit **120**;
- transmitting the patient's related information and the sample image **77** that was photographed by photography unit **120**, wherein sampler **100** transmits the data to analysis unit **200** through transmitting unit **500**;
- analyzing the sample image **78**, wherein analysis unit **200** analyzes the image transmitted to it by sampler **100**.

Analysis unit **200** may transmit the results to patient **10** and to medical authority **20** for further analysis, where patient **10** and medical authority **20** may use any type of communication and network devices to receive the results, such as a cellular phone with a network connection, a computer, a laptop.

[0041] According to embodiments of the present invention, for urine samples, the above description of the method may not include the step of smearing the sample. Sampler **100** may be modified to suit urine sample preparation and not include the smearing device.

[0042] According to embodiments of the present invention, the results may be transmitted through a message that may be, for example an Email message, a Short

Messages Service (SMS) message, Multimedia Messaging Service (MMS) message and the like.

[0043] According to embodiments of the present invention, photography unit **120** may be external to sampler **100**. For example, photographing the sample may be carried out through a cellular phone that includes a camera, where the cellular phone may be used as both photography unit **120** and transmission unit **500**.

[0044] According to other embodiments of the present invention, transmission unit **500** may be integrated into sampler **100**, where the sampler **100** may allow transmission of the sample image and related patient's information. Additionally to this embodiment, sampler **100** may further include a receiver unit that may allow sampler **100** to encompass more functions of the process, where sampler **100** automatically prepares the sample, photograph the sample, transmits the sample image and receives the analysis results. The receiver unit may include, for example, a receiver and a screen, to allow presentation of visual or textual messages.

[0045] According to embodiments of the present invention, Analysis unit **200** may be integrated in sampler **100**. The analysis of the sample image may be carried out, for example, on-chip, where the chip is installed within sampler **100**. The resulting analysis may be automatically transmitted to patient **10** and to medical authority **20**.

[0046] While the invention has been described with respect to a limited number of embodiments, these should not be construed as limitations on the scope of the invention, but rather as exemplifications of some of the preferred embodiments. Those skilled in the art will envision other possible variations, modifications, and applications that are within the scope of the invention. Accordingly, the scope of the

invention should not be limited by what has thus far been described, but by the appended claims and their legal equivalents.

1. A system comprising:

a housing arranged to receive a sample;

a sample-preparation unit arranged to prepare the sample for imaging by smearing and drying the sample to enhance cell visibility;

an imaging unit arranged to generate at least one digital image of the smeared and dried sample; and

an analysis unit arranged to analyze the at least one digital image,

wherein the sample-preparation unit is arranged to operate automatically upon receiving the sample, and

wherein the imaging unit is arranged to operate automatically upon the preparation of the sample.

2. The system of claim 1, wherein the analysis unit is arranged to count cells in the at least one digital image.

3. The system of claim 1, wherein the sample-preparation unit is further arranged to stain the sample to enhance cell visibility.

4. The system of claim 1, wherein the analysis unit is arranged to operate automatically upon the imaging of the prepared sample.

5. The system of claim 1, wherein the housing is arranged to receive the sample on a sample strip, and wherein the sample-preparation unit is arranged to prepare the sample on the sample strip.

6. The system of claim 1, wherein the sample is a blood sample.

7. The system of claim 1, wherein the sample is a urine sample.

8. The system of claim 1, wherein the cells are neutrophils.

9. The system of claim 1, wherein the sample-preparation unit, the imaging unit and the analysis unit are integrated within the housing.

10. The system of claim 9, arranged to be used by a patient at home for periodical analysis of patient samples.

11. The system of claim 1, wherein the sample-preparation unit and the imaging unit are integrated within the housing and connected via a communication link to the analysis unit, which is remote from the housing.

12. The system of claim 11, wherein the communication link comprises at least one of: a cellular network; and the Internet.

13. The system of claim 12, wherein the integrated sample-preparation unit and imaging unit are arranged to be used by a patient at home for periodical imaging of patient samples.

14. The system of claim 1, wherein the sample-preparation unit comprises a smearing piece and a smearing base, wherein the housing is arranged to direct an inserted sampling strip onto the smearing base, and wherein the smearing piece is arranged to pass through the sample against the smearing base at least once, and to smear the sample onto the sampling strip.

15. The system of claim 1, wherein the imaging unit comprises at least one of: a camera; and a solid state detector.

16. The system of claim 2, wherein the analysis unit is further arranged to compare a number of the counted cells to a specified clinical threshold.

17. The system of claim 1, further comprising a display arranged to present results of the analysis by the analysis unit.

18. The system of claim 1, further comprising a communication module connected via a communication link to a communication device, the communication module arranged to communicate results of the analysis by the analysis unit for evaluation by a medical authority.

19. The system of claim 18, wherein the communication link comprises at least one of: a cellular network; and the Internet.

20. A method comprising:

receiving a biological sample;

preparing the sample, automatically upon sample receipt, for imaging by smearing and drying the sample to enhance cell visibility;

generating, automatically upon sample preparation, at least one digital image of the smeared and dried sample; and

analyzing the at least one digital image.

21. The method of claim 20, wherein the analyzing comprises counting cells in the at least one digital image.

22. The method of claim 20, wherein the preparing the sample further comprises staining the sample to enhance cell visibility.

23. The method of claim 20, wherein the analyzing is carried out automatically upon the image generation.

24. The method of claim 20, further comprising communicating the at least one digital image via a communication link, and wherein the analyzing is carried out on the communicated images.

25. The method of claim 20, further comprising communicating results of the analysis to a medical authority.

26. The method of claim 20, further comprising comparing a number of the counted cells to a specified clinical threshold.