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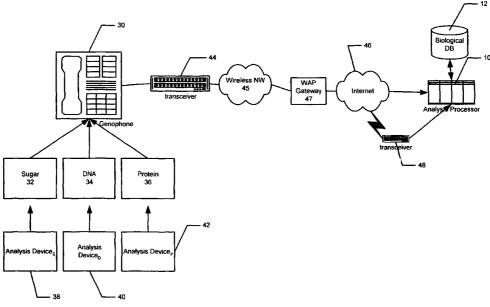
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(54) Title: SYSTEM AND METHOD FOR GENOMIC AND PROTEOMIC AGRICULTURAL DISEASE ASSESSMENT VIA EXPRESSION PROFILE COMPARISON



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(57) Abstract: A system and method of genomic and proteomic disease assessment via expression profile comparison whereby a baseline expression profiled is created by a user by depositing a biological sample on an analysis device. The biological information is read on an analysis device reader and transmitted to an analysis center where it is stored. The user deposits subsequent biological samples, which are compared to the stored sample that is originally taken. The analysis center compares the initial expression profile with subsequent expressions profiles to determine the health of the source of the sample. The biological sample can be from plants. The analysis device reader can be a wired or wireless device connected to a personal computer which in turn is connected to the Internet. In an alternate embodiment, the analysis device reader is in a cellular type telephone for wireless transmission. In yet another embodiment, the analysis device reader is in a kiosk which dispenses analysis devices and where it can be used by anyone with a credit token. Interpreted information is then returned to the appropriate person with advice on the meaning of the interpreted results, other sources of expert assistance and counseling where necessary.



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Title of Invention: System and Method for Genomic and Proteomic Agricultural

Disease Assessment via Expression Profile Comparison

Field of the invention

This invention relates generally to genomic or proteomic testing. More particularly this invention provides a system and method for measuring the expression of the genome and other biological factors over a network, which could lead to disease prediction and prevention in plants.

Background Of The Invention

Mapping of the human genome has been in process by both the government and private industry for the past ten years. At the same time new research has lead to specific tests for conditions that are evidenced by genes and certain gene expressions. Further the methods for the detecting of genomic, proteomic and other biological factors have dramatically improved.

Similarly, genetic engineering and research is extremely active in the agricultural marketplace where both plants and animals are the subject of genetic engineering and commercialization.

Research is rapidly progressing on DNA chips from, for example, Affymetrix, and RNA and protein chips available from, for example, Ciphergen, which will allow genes, their expression and proteins to be identified on a particular chip. Further Micro Arrays such as those of Nycomed Amersham / Amersham Pharmacia Biotec allow gene detection via very small detectors, thereby reducing the size of the overall detector package. Further, advances in fiber optic probes for example by Illumina, Inc. now allow 250,000 discrete sensors to fit on a probe the diameter of a pin head for proteomic studies. For purposes of this application, such chips, arrays and probes are referred generally as "Analysis Devices." Other similar technologies are available from PE Biosystems, Nycomed Amersham, Nanogen, Hyseq, Caliper, Clinical Micro Sensors. Specifically, Nanogen possesses electronic concentration and hybridization technology that is suited to the present invention. Such technology

1 is embodied in a disposable cartridge comprising a semiconductor microchip and

- 2 electrical and fluidic connections for use in analysis equipment. The following U.S.
- 3 patents discuss this technology, the contents of the below listed patents are
- 4 incorporated herein by reference in their entirety:
- 5 U.S. Patent No. 6,099,803 "Advanced active electronic devices for molecular
- 6 biological analysis and diagnostics "
- 7 U.S. Patent No. 6,071,394 "Channel-less separation of bioparticles on a
- 8 bioelectronic chip by dielectrophoresis "
- 9 U.S. Patent No. 6,068,818 "Multicomponent devices for molecular biological analysis
- 10 and diagnostics"
- U.S. Patent No. 6,051,380 "Methods and Procedures for Molecular Biological
- 12 Analysis and Diagnostics"
- 13 U.S. Patent No. 6,048,690 "Methods for Electronic Fluorescent Perturbation for
- 14 Analysis and Electronic Perturbation Catalysis for Synthesis "
- 15 U.S. Patent No. 5,849,486 "Methods For Hybridization Analysis Utilizing
- 16 Electronically Controlled Hybridization"
- 17 U.S. Patent No. 5,605,662 "Active Programmable Electronic Devices for Molecular
- 18 Biological Analysis and Diagnostics"
- Other analysis techniques also exist and are suitable for use with the present
- 20 inventions. For example, patent no. 6,045,676 was issues to Mathies et al. for a
- 21 "Electrochemical detector integrated on microfabricated capillary electrophoreses
- 22 chips" for use in detecting molecules. The contents of this patent are incorporated
- 23 herein by reference in its entirety.
- The LabCD manufactured by Gamera Bioscience Corp. also represents
- 25 technology that is suitable to sample preparation that would find use in the present
- invention. The capabilities and format of the LabCD are describe in U.S. Patent No.
- 27 6,063,589 which is incorporated herein by reference in its entirety.
- These analysis devices can then be used to determine if the particular gene
- 29 in question is working properly with other genes, or if other biological factors are

present which may be indicative of certain physiological conditions.

These devices can also be used to map vegetative genome and to develop understanding regarding how they are expressed in a plant's physiology or in its fluids (for example, but not limited to secretion, metabolites, juices and other fluids). For example it would be very useful for certain individuals such as, farmers (small or large), nurseries, but not limited to (agricultural professionals), to obtain a plant's expression profile of the plant's genes so that it can be used for assessing the plant's normal versus abnormal condition states. If, for example, a farmer knows the difference between the normal expression of genes and the deviations from normal which are statistically important, that could prevent for example, poor harvests, late harvests and other conditions that are reflected by a mutated gene, which mutation may also be good for the plant's growth. It would also be useful to have the plant's expression profile, which would be a baseline or standard, for subsequent comparison of normal versus abnormal conditions.

This expression profile would be useful to determine if a particular crop is suffering a type of stress that is related to disease or to growing conditions before those conditions manifest themselves in a loss of the crop.

Summary Of The Invention

It is therefore an objective of the present invention to produce a specific tool in the form of a genophone, a computer with associated reader, and a standalone station, which will read an analysis device which will, in turn, measure the expression of genes and other biological parameters in the secretion, metabolites, juices and fluids of plants.

It is another objective of the present invention to establish a baseline of the gene expression, and expression of other biological factors such as, but without limitation, small molecules, peptides and metabolites for healthy plants of many species so that plant health can be monitored during the various cycles.

It is yet another objective of the present invention to create a standard expression map for the plant species that are to be monitored using an analysis

device so that expression of every gene and other biological factors can be identified and compared with previous samples from the same monitored plant.

It is a further objective of the present invention to characterize gene expression or other biological indicators at a disease stage for comparison to a "standard" expression profile for plants.

It is yet another objective of the present invention to characterize the expression of individual gene expression profiles periodically during the life-cycles of plants of interest, and to store that data on a dedicated site for subsequent review and comparison.

It is a further objective of the present invention to have an individual analysis device read at a convenient site, at a site other than a laboratory, in public places, and in hand held devices and have that information transmitted to a central analysis site over a network which could be the Internet, an intranet, a wireless network or some other network able to transmit data.

It is still another objective of the present invention to collect expression profile information together with species history information to produce a database relating to expression patterns and variation to phenotype state and prognosis.

It is a further objective of the present invention to have an Internet analysis site and database of plant metabolism maps, clinical data and other biological indicators and conditions with conclusions and interpretations associated with the differential expression of certain genes and other biological parameters.

It is yet another objective of the present invention to allow agricultural professionals to collect and digitize (or render in some other transmittable form) sample expressions profiles (or other biological information) at the farm, or via some hand held device to provide that digitized individual expression profile (or other biological information) over a network to a central analysis site, and to have that analysis site provide an interpretation of the plant's expression profile with conclusions regarding the plant's condition.

It is yet another objective of the present invention to provide an analysis

tool comprising a browser and analyzer that will allow the data to be transmitted to the analysis site, analyzed according to the plant's standard expression data stored in a specific biological database, and to have a response generated to be sent to the agricultural specialist in a electronic, magnetic, written or audio form so that such persons can get results of the analysis right away on the comparison and differences from the standard expression profile. These and other objectives for the present invention will become apparent from a detailed review of the specification that follows.

The present invention comprises a plurality of analysis devices and other detection means that can be produced and distributed to individuals and professionals in the agricultural sciences in great quantities. It is the intention of the present invention to produce such analysis devices in sufficient quantities so that they can be made available to all who desire them in a cost effective fashion. Over time it is expected that the cost of such analysis devices will decease dramatically and therefore allow analysis devices to be available to anyone desiring to characterize the expression of the genome of a particular plant or crop or other biologically related information.

These analysis devices are used by an agricultural professional for determining a plant's control or "standard" expression profile of the plant's genes or other biological indicators that are to be monitored. A sample of secretion, metabolite, or other sample from a plant is obtained and placed in / on the analysis device. The analysis chip, for example, contains probes for all plant genes linked to the surface of the chip. Such chips are capable of detecting the presence of other nucleic acids (specifically messenger RNA), which are present in the solution via homology hybridization. Analysis Chips may contain small fragments of the genes (oligonucleotides) or expressed sequence tags (ESTs) or RNA molecules or their fragments as well as proteins or their fragments. Other detector devices will have similar mechanisms for detecting the biological indicator of interest. Other types of devices include, and without limitation, a "lab-on-a-chip" with microchannel

separation of biological materials (DNA, RNA, protein, hormone, small molecule, peptide, metabolite) with subsequent electrochemical or electric, such as those of

3 Clinical Micro Sensors or optical, such as those of PharmaSeq detection. Such

4 technology also includes 3D silicon particles of cubic or spheric shape, which could

carry detection molecules (DNA, RNA, antibodies). The amplification via polymerase

chain reaction (PCR) or other methods may be required for enhancing the strength of

the signal in biological sample.

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These above methods are not meant as a limitation. For example, immunoassays, small molecule sensors for metabolites, peptides, hormones and other measures are also within the scope of the present invention. The emphasis in all cases however, is to measure these response variables and record the status at a variety of times in the lifespan or growing season of the plant or crop so that predictions of future health can be made.

The expression or recording of these biological indicators can then be digitized or put in some other transmittable form at the farm or at a convenient location, on the analysis device reader or other device to make the genetic expression or recording of biological indicators of the plant in the form that is transmittable via the network. Based on the reading, a digitized record of the expression profile of the genome of the plant, which includes transcriptome (all molecules of RNA expressed in the cell as well as in the body), proteome (i.e. the proteome is the summary of all proteins) or other biological indicator is then created. As part of the present invention, the hand held device or computer attached device or real time monitoring station will detect genetic variations of the plants including, but not limited to, Single Nucleotide Polymorphisms (SNPs) as well as genetic variations in genes of another nature. Those can be compared for a particular plant over time - giving a chance to build a time-correlation of the progression of the disease. Clinical data will be used to compare populational data of norm versus disease. SNPs could be detected in devices developed by Hyseq or Sequenom, or other manufacturers.

Genetic variation noted above can be accomplished on a general basis where many genes are detected and analyzed or, when suggested via background or species history, on a specific SNP analysis based upon expression work done previously. This could be done at the farm or at an analysis station or at a regional laboratory.

The present invention comprises an analysis and database site that exists on a network, preferably but without limitation on the Internet, that has extensive information on plant genomes of interest and the meaning of various genetic expressions and mutations as well as metabolism maps. An agricultural professional wishing to have an expression profile or a specific crop reviewed, read, and interpreted will send a digitized record created at the analysis device reader over the Internet, or via some other wired or wireless network to the analysis site. The software routines for analysis and interpretation at the analysis site will then read the digitized or transmittable record and interpret that record providing feedback to the agricultural professional over the Internet, over an intranet, a wireless network or via any other means (such as voice) for conveniently reporting such information to the agricultural professional. A standard PC could also be used for storage and interpretation as well as warning the agricultural professional.

Such an invention can also be used to simply provide an expression profile for a plant when that plant is healthy. This "standard" or "baseline" gene expression profile is then stored at the analysis site for later use. This will be important since expression of genes varies with disease and also varies over the plant's life-cycles. Further when a plant is not healthy, that agricultural professional can create a new gene expression profile, read and digitize the Analysis device results, provide the results to the analysis site over the Internet, or to a standard PC, compare the digitized results to that plant's baseline or standard gene expression profile, and make some determination on what has changed and what the impact of that change actually is. Agricultural professionals will want to establish baseline profiles for crops to be monitored. Once information is developed based on the gene expression

profiles, analysis results can be reported to the field where corrective action can take place. Analysis of results prior to reporting is accomplished by organizations having databases specific to the species involved. For example, a database for agricultural products could be maintained by the USDA.

The control gene expression profile or other biological characteristics will also have other uses. From time to time, over a period of years, an agricultural professional can provide a new series of digitized or otherwise recorded biological indicators to the analysis site central database and determine how the plant species expression profile is changing. This may suggest certain interventions on the part of the agricultural professional.

The present invention provides for a flexible series of methods and associated apparatus allowing agricultural professionals to create a record of the plant's gene expression (RNA and protein) to broaden profiles and other genomic and biological information in a convenient fashion. For example, one embodiment of the present invention provides for an analysis device reader to be attached or connected to a PC for subsequent reading and providing information over a network, which is preferably, but without limitation, the Internet. In another embodiment, analysis device readers may be located with agricultural professionals to provide such information for subsequent analysis when a personal computer and analysis chip reader is not available.

Yet another alternate embodiment allows for a single purpose analysis device reader which can provide genetic information over a network. Such a device may be a single purpose device optimized to look for a specific gene, metabolite or other indicator of a condition. Yet another alternate embodiment allows for the wireless presentation of analysis device information over a radio network, for example over a cellular network. In this alternate embodiment a form of wireless or cellular type device, hereinafter referred to as a genophone, allows genetic or other biological information to be provided over wireless and/or cellular type networks to an analysis center.

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Yet another alternate embodiment of the present information allows for a kiosk type operation whereby an analysis device dispenser is located in a centralized location for the input of plant information such as at a regional agricultural extension center. In use, an individual would simply use a credit card or, preferably a smart card having specific encrypted identification information, that is linked to a credit card processing company such as American Express ®, VISA®, MasterCard®, or other for billing services. The agricultural professional simply inserts the credit/smart card and, after credit verification, would receive an analysis device upon which a biological sample from a plant could be deposited. The analysis device would then be read by the kiosk analysis device reader and information from the reading sent to the analysis site. Thereafter, the agricultural professional can enter information either at the kiosk location or, using coded information that is present on the smart card, the agricultural professional can cause the results of the analysis to be sent back to the agricultural professional via the US Mail, via electronic mail, or via any other selected delivery service which the user prefers including voice transmission to a selected telephone number or voice mail. In any case, such information is sent to the person involved together with information on how to locate source to assist in proper interpretation or the data. In certain instances, scientific resources would also be identified depending upon the outcome or projected outcome to help the agricultural professional understand the results received.

The present invention also comprises a genome and health information-specific encrypted browser for individual use. This browser, when used with the personal computer or in use with video phones or the like, allows genomic and other biological information from the individual to be appropriately delivered directly to an analysis site as well allows rapid and encrypted access to specific species and gene analysis sites. In this fashion agricultural professionals will not need to expend significant effort in browsing the World Wide Web for information to support conclusions or preliminary analyses made concerning the plant's expression profile.

Using the encrypting browser, the agricultural professional can access a

database of genomic and other biological information of the present invention that comprises the plant's control expression profiles and management of the plant's history, all of which will be encrypted. However, in addition there will be a database of metabolic pathways which will be used to characterize the protein or other expression molecules and characterize and tell what role the protein that is detected has in the overall health picture of the plant. It is part of the present invention to develop a secure bank-type of mechanism, which will allow for the secured transaction of the genomic and proteomic information of various crops and plants.

Such a facility could be established with a partner (i.e. American Express).

In the case of agricultural applications an agricultural genome sequence comparison database is also a part of the present invention and allows plant control expression profiles as well as subsequent expression profiles to be compared to various standard expression profiles for analysis purposes.

Further, the database will contain subsequent databases and/or links to clinical data, clinical trials in practice, "live" consulting with experts as well as chat rooms to discuss with others genomically, biologically, and medically important information relating to the type of plant concerned.

Any information that an agricultural professional wishes to store that is particular to the individual's concern (about the crop's past harvests or diseases) can be stored in the individual storage area of the database in an encrypted form so that only the individual who has placed that data in the database can have access to the data.

The genophone described above will have a series of capabilities. For example it will be able to read DNA or RNA using an appropriate DNA or RNA chip and transmit that information over the wireless network to the analysis center. These chips mentioned above are not meant as a limitation. Other analysis devices as noted earlier will provide for other clinical targets as well such as peptides, hormones and metabolites. Further, the genophone will have a separate protein analysis cartridge, including those which could have antibodies, enzymes or other protein

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detection systems and separate sugars or other biological molecules specific to plants, analysis cartridge each of which will be capable of receiving the associated device for deposit of a sample and analysis of the proteins, sugars and other metabolites as appropriate. It is further anticipated that these cartridges could integrated in one single cartridge or unit. This "cartridge" can be a variety of forms and the form is not meant as a limitation. In other forms it employs the various detection technologies discussed (above). For example, the cartridge may be an attachment to the genophone, or it may be its separate instrument or device with its own communications capability for providing information over a network. Cartridge may have different sets of detection mechanisms specific for a particular gene of the gene product or group of genes and their products, which could lead to different types of diseases, (i.e., a cartridge for monitoring gene expression which could lead to diseased crops). Cartridges with different types of disease "preventive" expression and other monitoring could combine different types of diseases on one cartridge. In addition, specific disease state monitoring can be accomplished by the equipment of the present invention. Thus monitoring plant physiology, genotype, primary metabolites produced can be achieved. Agricultural professionals can assess the efficacy of the treatment and the extent to which treatment should continue. The professional will also be able to assess whether the mutation is advantageous, that is, a change in the plant that should be encouraged rather than cured. Expression analysis of the type disclosed with the present invention is well within the current state of the art. For example, a GeneChip™ is an analysis probe array manufactured by Affymetrix® which can detect MRNA transcripts at a few copies per cell. It can also identify concentration levels and simultaneously monitor thousands of genes. This GeneChip™ system is typically scanned by an HP GeneArray scanner to view an expression analysis. Yet another potential technology for analysis is the Assembled Array™ manufactured by Illumina,

Inc. This array provides thousands of sensors to analyze DNA, RNA, and protein.

1 Yet another example of chip analysis technology is the ProteinChip™ which is

- 2 available from Ciphergen. Other analysis devices such as the GeneChip™
- 3 instrument system, also available from Affymetrix which provides a platform for
- 4 analyzing GeneChip probe arrays. In short, certain of the building blocks are readily
- 5 available for the present invention.

Brief Description Of The Figures

Figure 1 illustrates the overall architecture of the present invention

Figure 1A illustrates the stand-alone analysis device reader

Figure 2 illustrates the genophone embodiment of the present invention

Figure 3 illustrates the kiosk embodiment of the present Invention

Detailed Description Of The Invention

The present invention is a system and method for creation of expression profiles of plants, establishing a control expression profile for a plant, and comparing subsequent expression profiles to the control expression profile for analysis purposes. For purposes of this detailed description of the invention, the procedures when dealing with plant genomic information will be discussed. These samples are analyzed via chips in the same manner as that disclosed in plant analysis. Any reporting that is done will be in terms of the plant in question.

Referring to Figure 1, a control biological sample for the plant species in question will be provided on analysis devices 22, 24, and 26. The analysis devices will be input to analysis device readers 16, which, in one instance are connected to PCs 14, 20 at user locations. It is also considered to be within the scope of the present invention to have an analysis device reader / communicator 28 which is a stand-alone unit that reads analysis device 26 and provides that information over the Internet 18 or some other wired or wireless network adapted to convey such information or analyze the biological sample "on the spot" providing limited read out of the presence and / or quantity of the expression of gene or other biological factors, for example and without limitation, particular proteins and their amount (See Figure

1A below). For example, an intranet may be constructed to send and receive such information among a variety of sites at a large organization. For example, a farmers' co-operative has particular interest in the health of its crops. Such an organization would not necessarily use the Internet but would use its own network for the transmission of such gene expression information when measurements are taken in the field. In other situations, a cellular network may be used to transmit the desired information. Analysis device reader 16 reads analysis devices 22, 24 and presents a digitized, or otherwise transmittable record of the individual gene expression or other biological information to the PC 14, 20 at the users location. It should be noted that the "users" location may be a home based unit, a unit in a tractor, or a unit at a convenient location such as a regional agricultural facility. These PCs will further comprise software for communicating with the analysis site.

It is anticipated that connections to the Internet for reporting of these gene expression readings will be both wired as in the case of processor **20** connecting to Internet **18** and wireless as in the case of processor **14** connecting to a wireless fashion to Internet **18** or via other wireless special purpose devices optimized for the expression profile reporting of the present invention.

The expression profiles will then be provided to an analysis site 12 over a network such as, and without limitation, the Internet 18 and stored in database 10 identifying the record only in a numeric fashion in order to preserve the unanimity of the individual providing the information. Agricultural professionals can report as many different gene or other biological expressions as desired since those expressions will vary by the time of day, over a period of years, and with changing individual conditions. Analysis site 12 receives the information from each individual and based upon expression, protein, messenger RNA etc. detected, analyze and compare those results to information stored in the biological database. The analysis site 12 can create a reading of the gene expression of the plant together with an interpretation of any particular conditions that might exist.

Information relating to the interpretation of the gene expression of the plant is then provided by analysis site **12** over the Internet **18** back to the individual's processor **14**, **20** for the person's information. Alternatively, information from the interpretation of the genomic expression can be provided to the user via mail.

It is expected, that as analysis device prices decrease, such analysis devices will be readily available at a reasonable cost to all individuals who desire to use this process. Furthermore, it is also expected that each plant's genes will be sequenced (all or in part) which will allow the creation of the "Individualized Analysis Devices." Those will be used not only to establish the agricultural professional's control and to obtain the genome expression reading, but also to track any individual changes in the plant's genes. The difference in the expression of the plant's genes as well as detection of the specific changes (including but not limited to mutations) may unravel the condition in the event that the plant is not healthy, at different cycles, and as other significant events occur which may affect the plant's overall health. All results from individual analysis device readings will be stored in the biological database for access by the individual or an agricultural professional over time.

It is also suggested by the present invention that the analysis device may be used for detecting any endemic viral or bacterial gene or other biological expressions occurring in the plant's physiology, which could result in disease or other malfunction of the plant.

In addition to tracking the plant's expression profiles, by virtue of understanding each plant's gene expression, treatments can be recommended to an individual that will be best suited to change or correct that plant's gene expression or deal with a manifested condition. For example there may be a gene expression, which pre-disposes a plant to react adversely to certain soils. Thus as part as the interpretation of the gene and other biological expression of the plant, recommendations for treatment can be made to the individual. Further, based upon individual gene expression, "targeted" treatments could be designed which work in an optimal fashion for the particular plant, as well as target "preventive" treatments.

From an economic standpoint, agricultural professionals will be able to purchase analysis devices **22**, **24**, and **26** at a reasonable cost once these chips are readily made available to millions of individuals. Each time a reading is interpreted by the genomic processor the agricultural professional can be charged for that particular interpretation.

It is also anticipated that certain agricultural professional organizations will want to have their crop's gene expression profile information stored anonymously in the analysis site database. Storage over the years can also be charged to the agricultural professional so that the analysis site processor operator can continue to provide the valuable interpretation and storage services.

Referring to Figure 1A, the analysis device reader 16 in a stand-alone mode (as first noted above) is illustrated. In certain instances and where an individual does not want to have genomic or other biological factor information transmitted over a network, a stand-alone analysis device reader 16 can be used. This analysis device reader uses the analysis device 24 to collect a biological sample. The analysis device 24 is placed in the analysis device receptacle 70, which is powered by a stand-alone power supply 62. This power supply can be single use or rechargeable battery supply, and may also be plugged into household current to recharge batteries or to simply power the stand-alone device.

The analysis device reader 16 comprises analysis logic 64 for interpreting the analysis device readings. Thereafter, the reading may be stored in a memory 66 in the case where the user wants to have an historical record of readings over a period of time. The analysis device reader 16 also comprises a screen or display 68 for providing a limited readout of the presence of or quantity of the biologic factor or substance being collected by the analysis device 24. In this fashion, for example, if a particular biological factor is not present, and this is not troubling for the user, the results do not have to be sent over a network and risk a disclosure of the fact that such a test is being conducted by the user. Alternatively, if the results of the

1 readout are such that the user desires to send information, the analysis device

- 2 reader also comprises a communication port 68 which may be connected to a
- 3 network for transmitting information stored in memory over the network as described
- 4 in Figure 1 (above). The display, analysis logic power supply and readout
- 5 capabilities are generally disclosed in U.S. Patent No. 5,837,546, which is
- 6 incorporated herein in its entirety. However, the capability to analyze the genetic,
- 7 proteomic and other biological factors described herein constitutes a novel capability
- 8 within the current state-of-the-art.

By virtue of the memory in the analysis device **16** certain limited expression comparisons can be made from one reading to another. When a difference above a certain threshold occurs between two readings the analysis logic **64** can inform the user of the detection of that difference via the readout / display **68**. Thereafter, if the user chooses that information can be sent to an analysis processor (Figure 3, 12) via the comm. port **68**.

Referring to Figure 2 the genophone of the present invention is illustrated. The genophone **30** is a form of cellular communications device having its own transceiver **44** connected to the cellular network **45** which in turn subsequently is linked to analysis processor **12** via a wireless application protocol (WAP) gateway **47** and thence over the Internet **46** to the analysis site. The characteristics of the WAP gateway are described in U.S. Patent No. 5,327,529, whose contents are incorporated herein by reference in their entirety. The linkage to the analysis processor can also be via the wireless network directly where the analysis center is capable of receiving an electronic signal from the genophone over its own wireless transceiver or alternatively the genophone can ultimately connect to an Internet service provider via a WAP gateway, as noted above, and electronic information concerning data collected can then be presented to the analysis via the Internet as described earlier.

reader 32, DNA reader 34, and protein reader 36 although these readers are not meant as limitations. For example it is fully anticipated that as the bio/genomic science becomes more refined, other combination readers having this combinations or others are also anticipated. Each cartridge will have an associated analysis device illustrated as a sugar chip 38, a DNA chip 40 and/or a protein chip 42. As noted earlier, these chips are not meant as a limitation. Analysis for peptides, small molecules, hormones, and metabolites are yet further examples, and are not meant as limiting, of the types of indicators that can be monitored using the present

invention.

Referring to Figure 3 a kiosk-oriented embodiment of the present invention is illustrated. Central to this embodiment for expression profiling is a form of kiosk 60 which would reside in a more or less public area such as at a regional co-operative, at offices of the USDA or other locations that provide agricultural assistance. In this embodiment an individual possessing a credit card or, preferably, a smart card 62, which would be associated with a credit card issuer such as VISA®, MasterCard® and American Express® would have individualized identification information stored, in encrypted form, on the smart card 62. An agricultural professional who wishes to establish a control expression profile for a particular crop or to simply create an expression profile at that point in time would use the smart card to begin the over all process of establishing an expression profile in much the same way that an individual now uses a credit card and automated teller machine to begin a financial transaction.

The individual would insert the smart card **62** in the kiosk **60**. Once appropriate credit was established with a credit facility **66**, which is the normal type of electronic credit transaction that establishes that an individual has a certain amount of credit and has entered the appropriate security information either via a key board or through some biometric measurement, the kiosk **60** is permitted to perform further functions.

After the kiosk receives the appropriate authorizations from the credit facility for the financial aspect of the transaction, the kiosk provides analysis device **64** to the individual. As noted above the analysis device may be a sugar analysis, DNA analysis, and/or a protein analysis device as appropriate although this is not meant as a limitation. Analysis for peptides, small molecules, hormones, and metabolites also occur. The user deposits a biological sample for the crop in question on the analysis device and reinserts the analysis device into the analysis device reader in the kiosk. Thereafter an analysis device reader in the kiosk reads the information on the analysis device in much the same way that individual cartridges read the chip in the genophone embodiment first noted above. Once the information on the analysis device is read, the digital information, or other transmittable information, which characterizes the biological sample is passed over a network to the analysis processor **12**, which creates the desired expression profile. As noted earlier, the kiosk itself may be a cellular or wireless device that communicates with the analysis site in a wireless fashion.

Information can be entered, by the user, at the kiosk, regarding the location to which the information is to be sent. Thus the user can specify that resulting information be sent to an associated e-mail address, be sent over the mail system to the user, to be reported via voice or delivered in other ways known to those skilled in the art.

Similar to the genophone noted above, the kiosk can also communicate to the analysis center over a cellular or other wireless type network. Thus without limitation, the kiosk can report its results to the analysis via wired network, wireless networks, cellular networks, and other communications methods known in the trade including satellite communications as well.

Encryption of the resulting data can be accomplished by an appropriate encryption key stored on the smart card of the agricultural professional and conveyed to the kiosk for subsequent encryption to the analysis center.

As part of the database operations of the present invention, individual

expression profile information in a secure fashion. In addition, once specific conditions are assessed by virtue of expression profile comparison, the analysis processor of the present invention will review all files in its database and send the latest health news that relates to the diseases or conditions evidenced by the expression profiles stored in the database. In this fashion, and individual with, for example, diabetes, can receive the latest information that breaks relating to this condition or on the latest equipment available for maintaining a healthy state. Such information can be delivered via pager, wireless telephone, PDA, and or email.

The organization that is responsible for the analysis processor will also receive notices of research projects requiring test subjects. When such notice is given, the database of the present invention be searched and, if authorized by the affected individual, those whose conditions are to be the subject of such medical research will be provided notice of the need for test subjects. Again, in this fashion the database will be able to alert those with specific conditions or expression profiles of the opportunity to participate in such studies.

The ramifications of this invention are significant. For example, while DNA, protein, mRNA, sugars and the like have been mentioned as items to be monitored, so can small molecules, peptides, hormones and metabolites. These items will also serve to establish a baseline when the individual is healthy and can later be monitored as potential precursors to a disease state(s).

Further, as the monitoring of the present invention takes place, the information gleaned can be stored in an anonymous way in a database so that individual variation can be interpreted not just with respect to other measurements from the same individual, but can also be interpreted in the context of larger demographic results.

Additionally, monitoring of those individuals undergoing therapy of various types is very important where there is a possibility of an adverse drug reaction or where a narrow therapeutic range is desirable for the drug in question. Real time monitoring of various indicators as noted in the present invention can help to avoid

such adverse drug reactions. A genome and biological factor assessment apparatus and method in alternate embodiments has now been shown. It will be apparent to those skilled in the art that other applications and businesses can benefit from this model of DNA chip reading and genome information storage without departing from the scope of the invention as disclosed.

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2 1. A system for genomic and proteomic agricultural disease assessment via expression profile comparison comprising:

- a first analysis device for establishing an expression profile and on which is deposited a first biological sample from an organism:
- An analysis device reader for reading biological information from the first biological sample:
- a first network connected to the analysis device reader for transmitting the biological information;
- an analysis processor connected to the network for receiving the biological information;
- storage connected to the analysis processor for storing the biological information and for storing baseline expression information; and instructions stored in the analysis processor for comparing the stored biological information to subsequent biological information.
 - The system for genomic and proteomic agricultural disease assessment via expression profile comparison of claim 1 wherein the biological information is proteomic information.
 - The system for genomic and proteomic agricultural disease assessment via expression profile comparison of claim 1 wherein the biological information is genomic information.
- 22 4. The system for genomic and proteomic agricultural disease assessment 23 via expression profile comparison of claim 1 wherein the biological 24 information is genomic information and is taken from the group consisting 25 of DNA and RNA.
- The system for genomic and proteomic agricultural disease assessment via expression profile comparison of claim 1 wherein the biological information is information concerning sugars in the biological sample.
 - 6. The system for genomic and proteomic agricultural disease assessment

via expression profile comparison of claim 1 wherein subsequent biological information comprises a subsequent biological sample from the organism deposited on a subsequent analysis device at a date subsequent to the deposit of first biological sample.

The system for genomic and proteomic agricultural disease assessment

- 7. The system for genomic and proteomic agricultural disease assessment via expression profile comparison of claim 1 wherein the analysis device reader is connected to the network via a personal computer.
- 8. The system for genomic and proteomic agricultural disease assessment
 9 via expression profile comparison of claim 1 wherein the analysis device
 10 reader is connected to the network via a wireless device.

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- 11 9. The system for genomic and proteomic agricultural disease assessment 12 via expression profile comparison of claim 8 wherein the wireless device is 13 a genophone.
- 10. The system for genomic and proteomic agricultural disease assessment
 via expression profile comparison of claim 9 wherein the genophone
 comprises an analysis device reader and a wireless transceiver connected
 to a second network for transmitting the biological information in a wireless
 mode to the first network.
 - 11. The system for genomic and proteomic agricultural disease assessment via expression profile comparison of claim 1 wherein the first network is a wireless network.
- The system for genomic and proteomic agricultural disease assessment via expression profile comparison of claim 1 wherein the analysis device reader is located in a kiosk and wherein the kiosk is connected to a credit facility for processing credit request for use of the analysis device reader.
- The system for genomic and proteomic agricultural disease assessment via expression profile comparison of claim 12 wherein access to the kiosk is made via a token associated with a particular user.
- 29 14. The system for genomic and proteomic agricultural disease assessment

1 via expression profile comparison of claim 13 wherein the token is a smart 2 card. 3 15. The system for genomic and proteomic agricultural disease assessment 4 via expression profile comparison of claim 13 wherein the token is a credit 5 card. 6 16. The system for genomic and proteomic agricultural disease assessment 7 via expression profile comparison of claim 13 wherein the token is a stored 8 value card. 17. 9 The system for genomic and proteomic agricultural disease assessment 10 via expression profile comparison of claim 1 wherein instructions stored in 11 the analysis processor further comprise instructions for creating a first expression profile from the biological information. 12 13 18. The system for genomic and proteomic agricultural disease assessment 14 via expression profile comparison of claim 17 wherein instructions stored in the analysis processor further comprise instructions for creating a 15 subsequent expression profile from the subsequent biological information 16 and for comparing the first expression profile to the subsequent expression 17 18 profile to detect disease and genetic conditions. 19 19. A method of genomic and proteomic agricultural disease assessment via 20 expression profile comparison comprising: 21 establishing a baseline expression profile at a first date; 22 storing the expression profile in an analysis center; 23 creating a subsequent expression profile at a date later than that of the 24 baseline expression profile: 25 comparing the subsequent expression profile to the baseline expression 26 profile; and 27 assessing physiological conditions based upon the comparison.

via expression profile comparison of claim 19 wherein establishing a

The method of genomic and proteomic agricultural disease assessment

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1		baseline expression profile comprises depositing a biological sample on a
2		first analysis device;
3		reading the analysis device in an analysis device reader; and
4		transmitting the analysis device reader results over a network to an
5		analysis center.
6	21.	The method of genomic and proteomic agricultural disease assessment
7		via expression profile comparison of claim 20 wherein the network is the
8		Internet.
9	22.	The method of genomic and proteomic agricultural disease assessment
10		via expression profile comparison of claim 20 wherein the network is a
11		wireless network.
12	23.	The method of genomic and proteomic agricultural disease assessment
13		via expression profile comparison of claim 20 wherein the analysis device
14		reader is connect to a personal computer; and wherein the personal
15		computer is connected to the network.
16	24.	The method of genomic and proteomic agricultural disease assessment
17		via expression profile comparison of claim 20 wherein the analysis device
18		reader is a wireless device for reading the analysis device and for
19		transmitting the analysis device reader results in a wireless mode to the
20		analysis center.
21	25.	The method of genomic and proteomic agricultural disease assessment
22		via expression profile comparison of claim 20 wherein the biological
23		sample is taken from the group consisting of secretion, metabolites, juices
24		and fluids.
25	26.	The method of genomic and proteomic agricultural disease assessment
26		via expression profile comparison of claim 19 wherein the analysis device
27		reader results comprise genomic information.
28	27.	The method of genomic and proteomic agricultural disease assessment
29		via expression profile comparison of claim 19 wherein the analysis device

1		reader results comprise proteomic information.
2	28.	The method of genomic and proteomic agricultural disease assessment
3		via expression profile comparison of claim 19 wherein the analysis device
4		reader results comprise sugars in the biological sample.
5	29.	The method of genomic and proteomic agricultural disease assessment
6		via expression profile comparison of claim 19 wherein creating a
7		subsequent expression profile comprises depositing a biological sample on
8		a subsequent analysis device;
9		reading the subsequent analysis device in an analysis device reader; and
10		transmitting the analysis device reader results for the subsequent analysis
11		device over a network to the analysis center.
12	30.	The method of genomic and proteomic agricultural disease assessment
13		via expression profile comparison of claim 20 wherein the analysis
14		comprises instructions stored in memory for comparing the subsequent
15		expression profile to the baseline expression profile.
16	31.	The method of genomic and proteomic agricultural disease assessment
17		via expression profile comparison of claim 20 wherein the analysis device
18		reader is located in a kiosk and wherein the kiosk is connected to a credit
19		facility for processing credit request for use of the analysis device reader.
20	32.	The method of genomic and proteomic agricultural disease assessment
21		via expression profile comparison of claim 20 wherein the kiosk is made
22		available via a token associated with a particular user.
23	33.	The method of genomic and proteomic agricultural disease assessment
24		via expression profile comparison of claim 20 wherein the token is a smart
25		card.
26	34.	The method of genomic and proteomic agricultural disease assessment
27		via expression profile comparison of claim 20 wherein the token is a credit
28		card.
29	35.	The method of genomic and proteomic agricultural disease assessment 25

1 via expression profile comparison of claim 20 wherein the token is a stored 2 value card. 3 36. The method of genomic and proteomic agricultural disease assessment 4 via expression profile comparison of claim 20 wherein the biological 5 information is genomic information and is taken from the group consisting 6 of DNA and mRNA. 7 37. The method of genomic and proteomic agricultural disease assessment 8 via expression profile comparison of claim 19 wherein the analysis device 9 reader results comprise homones. 10 38. The method of genomic and proteomic agricultural disease assessment 11 via expression profile comparison of claim 19 wherein the analysis device 12 reader results comprise peptides. 39. The method of genomic and proteomic agricultural disease assessment 13 14 via expression profile comparison of claim 19 wherein the analysis device 15 reader results comprise metabolites. The method of genomic and proteomic agricultural disease assessment 16 40. 17 via expression profile comparison of claim 19 wherein the analysis device 18 reader results comprise enzymes. 19 41. The method of genomic and proteomic agricultural disease assessment 20 via expression profile comparison of claim 19 wherein the analysis device 21 reader results comprise antibodies. 22 42. The method of genomic and proteomic agricultural disease assessment 23 via expression profile comparison of claim 20 wherein the analysis device 24 is a microarray. 25 43. The method of genomic and proteomic agricultural disease assessment 26 via expression profile comparison of claim 20 wherein the analysis device 27 is a fiber optic probe comprising a plurality of sensors. 28 44. The method of genomic and proteomic agricultural disease assessment 29 via expression profile comparison of claim 20 wherein the analysis device

1	is a	semiconductor	microchip.
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The method of genomic and proteomic agricultural disease assessment via expression profile comparison of claim 20 wherein the analysis device is a cartridge comprising a semiconductor microchip.

- 5 46. The method of genomic and proteomic agricultural disease assessment 6 via expression profile comparison of claim 20 wherein the analysis device 7 utilizes electron concentration and hybridization technology.
- The method of genomic and proteomic agricultural disease assessment via expression profile comparison of claim 20 wherein the analysis device comprises a microfabricated capillary electrophoresis chip.
- 11 48. The method of genomic and proteomic agricultural disease assessment 12 via expression profile comparison of claim 20 wherein the analysis device 13 comprises a centripetal acceleration microsystem platform.
- 14 49. The system for genomic and proteomic agricultural disease assessment 15 via expression profile comparison of claim 1 wherein the biological 16 information is hormonal information.
- The system for genomic and proteomic agricultural disease assessment via expression profile comparison of claim 1 wherein the biological information is peptide information.
- The system for genomic and proteomic agricultural disease assessment via expression profile comparison of claim 1 wherein the biological information is metabolite information.
- The system for genomic and proteomic agricultural disease assessment via expression profile comparison of claim 1 wherein the biological information is enzyme information.
- The system for genomic and proteomic agricultural disease assessment
 via expression profile comparison of claim 1 wherein the biological
 information is antibody information.
- 29 54. The system for genomic and proteomic agricultural disease assessment

1		via expression profile comparison of claim 1 wherein the analysis device is
2		a microarray.
3	55.	The system for genomic and proteomic agricultural disease assessment
4		via expression profile comparison of claim 1 wherein the analysis device is
5		a fiberoptic probe comprising a plurality of sensors.
6	56.	The system for genomic and proteomic agricultural disease assessment
7		via expression profile comparison of claim 1 wherein the analysis device is
8		a semiconductor chip.
9	57.	The system for genomic and proteomic agricultural disease assessment
10		via expression profile comparison of claim 1 wherein the analysis device is
11		a cartridge comprising a semiconductor chip.
12	58.	The system for genomic and proteomic agricultural disease assessment
13		via expression profile comparison of claim 1 wherein the analysis device
14		comprises electronic concentration and hybridization technology.
15	59.	The system for genomic and proteomic agricultural disease assessment
16		via expression profile comparison of claim 1 wherein the analysis device is
17		a microfabricated capillary electrophoresis chip.
18	60.	The system for genomic and proteomic agricultural disease assessment
19		via expression profile comparison of claim 1 wherein the analysis device
20		comprises a centripetal acceleration microsystem platform.
21	61.	A system for genomic and proteomic agricultural disease assessment via
22		expression profile determination comprising:
23		an analysis device for collecting a biological sample;
24		an analysis device reader adapted to create a reading from the analysis
25		device, the analysis device reader comprising;
26		an analysis device receptacle for receiving and creating the analysis
27		device reading from the contents of the analysis device;
28		a power supply connected to the analysis device receptacle for providing
29		power to the receptacle;

1		a processor comprising analysis logic for receiving the results of the
2		reading from the analysis device and for creating a record of the results;
3		memory connected to the analysis processor for receiving the record of the
4		results; and
5		a display connected to the processor for displaying the record of results.
6	62.	The system for genomic and proteomic agricultural disease assessment
7		via expression profile determination of claim 61 wherein the record of
8		results comprises a first expression profile.
9	63.	The system for genomic and proteomic agricultural disease assessment
10		via expression profile determination of claim 62 wherein the processor
11		further comprises logic for comparing the first expression profile to a
12		second expression profile and for alerting a user via the display of the
13		presence of any differences between the expression profile and the
14		subsequent expression profile.
15	64.	The system for genomic and proteomic agricultural disease assessment
16		via expression profile determination of claim 61 further comprising a
17		communications port for transmitting the record of results over a network.
18	65.	The system for genomic and proteomic agricultural disease assessment
19		via expression profile determination of claim 64 where the network is
20		selected from the group consisting of wireless networks, the Internet, an
21		intranet, and wireless local loop network.
22	66.	The system for genomic and proteomic agricultural disease assessment
23		via expression profile determination of claim 61 wherein the analysis
24		device is adapted to detect hormones and the record of results is hormonal
25		information.
26	67.	The system for genomic and proteomic agricultural disease assessment
27		via expression profile determination of claim 61 wherein the analysis
28		device is adapted to detect peptides and the record of results is peptide
29		information.

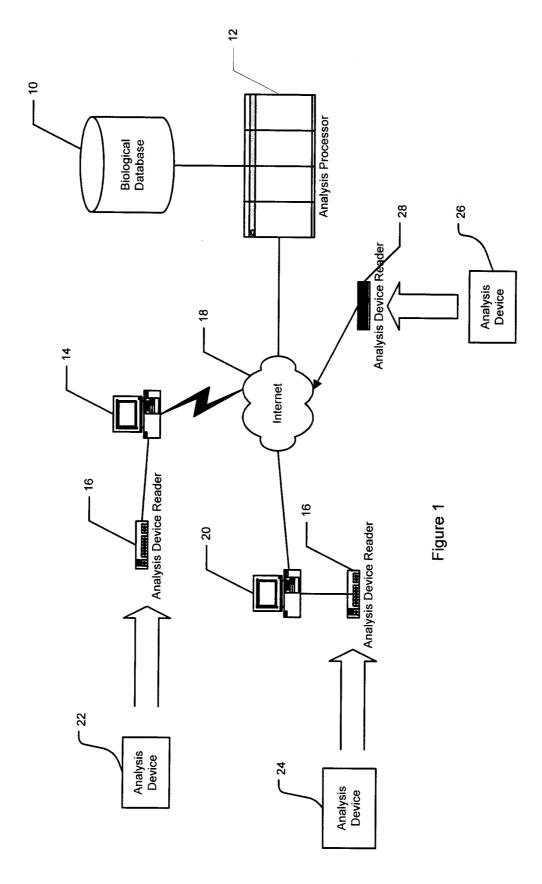
The system for genomic and proteomic agricultural disease assessment

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2		via expression profile determination of claim 61 wherein the analysis
3		device is adapted to detect metabolites and the record of results is
4		metabolite information.
5	69.	The system for genomic and proteomic agricultural disease assessment
6		via expression profile determination claim 61 wherein the analysis device
7		is adapted to detect enzymes and the record of results is enzyme
8		information.
9	70.	The system for genomic and proteomic agricultural disease assessment
10		via expression profile determination of claim 61 wherein the analysis
11		device is adapted to detect antibodies and the record of results is antibody
12		information.
13	71.	The system for genomic and proteomic agricultural disease assessment
14		via expression profile determination of claim 61 wherein the analysis
15		device is selected from the group consisting of a microarrays, a fiberoptic
16		probe comprising a plurality of sensors, a semiconductor chip, a cartridge
17		comprising a semiconductor chip, an electronic concentration and
18		hybridization technology device, and a microfabricated capillary
19		electrophoresis chip.
20	72.	A method of genomic and proteomic agricultural disease assessment via
21		expression profile determination comprising:
22		establishing a first expression profile at a first date by depositing a
23		biological sample on an analysis device;
24		reading the analysis device in an analysis device reader, the analysis
25		device reader comprising an analysis device receptacle for receiving the
26		analysis device, and analysis processor and associated memory, and
27		interconnected power supply, and display;
28		analyzing the reading from the analysis device in the analysis processor;
29		displaying the analysis results on the display;

1		storing the analysis results in a memory associated with
2		reading the analysis device processor.
3	73.	The method of genomic and proteomic agricultural disease assessment
4		via expression profile determination of claim 72 wherein the biological
5		sample is taken from the group consisting of hormones, peptides,
6		metabolites, enzymes, antibodies, genes proteins sugars, DNA and RNA
7	74.	The method of genomic and proteomic agricultural disease assessment
8		via expression profile determination of claim 72 wherein the analysis
9		device is taken fro the group consisting of a microarrays, fiberoptic probe
10		comprising a plurality of sensors, semiconductor chips, cartridges
11		comprising a semiconductor chip, electronic concentration and
12		hybridization technology devices, centripetal acceleration microsystem
13		platforms, and microfabricated capillary electrophoresis chips.
14	75.	The method of genomic and proteomic agricultural disease assessment
15		via expression profile determination of claim 74 wherein the analysis
16		device is adapted to provide readings from biological samples from the
17		group consisting of hormones, peptides, metabolites, enzymes, antibodies
18		genes proteins sugars, DNA and RNA.
19		



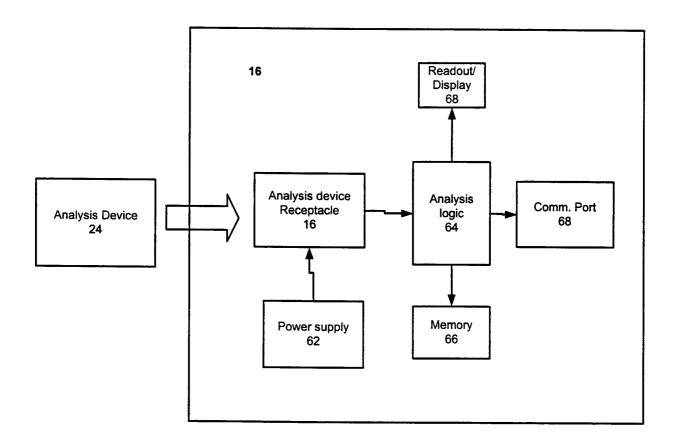


Figure 1A

