



- (51) **International Patent Classification:**  
G01N 33/543 (2006.01)
- (21) **International Application Number:**  
PCT/GB2009/001965
- (22) **International Filing Date:**  
10 August 2009 (10.08.2009)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**  
0814577.3 8 August 2008 (08.08.2008) GB
- (71) **Applicant (for all designated States except US):** INVERNESS MEDICAL SWITZERLAND GMBH [CH/CH]; Bahnhofstrasse 28, CH-6300 Zug (CH).
- (72) **Inventor; and**
- (75) **Inventor/Applicant (for US only):** SMART, David [GB/GB]; 4 Smeaton Park, Moira BT67 0NF (GB).
- (74) **Agents:** CLIFFORD, Emer et al.; Kilburn & Strode LLP, 20 Red Lion Street, London WC1R 4PJ (GB).
- (81) **Designated States (unless otherwise indicated, for every kind of national protection available):** AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ,

CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States (unless otherwise indicated, for every kind of regional protection available):** ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**  
— with international search report (Art. 21(3))  
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

WO 2010/015843 A1

(54) **Title:** ASSAY DEVICE, KIT AND METHOD BASED ON OPTICALLY READABLE ANALYTE SENSITIVE 2D BAR-CODE

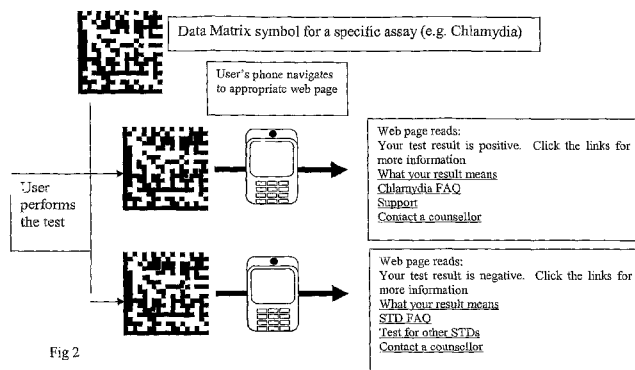


Fig 2

(57) **Abstract:** Optically readable analyte sensitive 2D bar-code encoding information is provided. The analyte sensitive 2D bar-code is capable of undergoing an optically detectable change indicative of the presence and/or amount of said analyte.

## ASSAY DEVICE, KIT AND METHOD BASED ON OPTICALLY READABLE ANALYTE SENSITIVE 2D BAR CODE

### Summary of the invention

The present invention relates to a diagnostic assay device, to a diagnostic assay kit and method of carrying out an assay.

### Background

Cheap disposable assays for measurement of analytes at home or in a point of care setting are widely available. An example is a lateral flow assay for the detection of the pregnancy hormone hCG wherein the presence of a labelled binding reagent at a detection zone is detected either visually or by means of a photodetector. Visual read assay devices have an advantage of being low cost, however a problem associated with such assay devices is that they provide an assay result as a signal of variable strength, which can require a degree of interpretation. This leaves the assay result open to misinterpretation, if the test user has problems with visual acuity and especially where the user or reader of the assay device has a preferred assay result in mind. Furthermore, the amount of labelled binding reagent detected at the detection zone may either increase or decrease depending upon whether the assay is a sandwich assay, or a competition or inhibition type of assay. EP355244 discloses a lateral flow type assay device wherein the detection zone has a "+" shape such that immunobinding of a labelled binding reagent at the detection zone results in a "+" indication. Electronic digital devices have been developed wherein the presence or amount of the labelled reagent is determined by means of a photodetector and the result of the assay displayed on an LCD display. Such digital devices have the advantage in that they provide an unambiguous result such as "YES" or "NO" which does not require interpretation by the user. Such devices may be single use and therefore disposable. They are however expensive to produce as they typically require one or more photodetectors, one or more light sources such as an LED, a power source, an electronic circuit and a digital display. Furthermore the disposal of electronic devices has environmental issues.

As an alternative to a stand alone type of assay device as described above, an assay kit may be provided wherein an assay test is inserted into a test meter in order to read or interpret the

result of the test. Such test-kits are routinely used to measure blood glucose and are described for example by US5989917.

In further developments of a meter designed to read an assay test, increased functionality has been built into the meter and/or the assay test. For example, US2003/0124738 discloses an assay test strip comprising a machine readable bar-code. WO2006/026741 discloses a wearable sensor comprising a passive RFID tag that stores data. A receiver wirelessly interrogates the sensor with an RF interrogation signal. The RFID tag modulates or otherwise modifies the wireless interrogation signal using the data and the receiver receives back the modulated or otherwise modified interrogation signal. US7061897 discloses a mobile phone comprising a WEB-server and a WEB-browser connected to the WEB server wherein data measured by a glucose measuring sensor are transmitted to a glucose measuring server contained in the mobile telephone, and are stored there. A medical service computer may periodically interrogate the medical measured values via the WEB server. Assay test meters may comprise data out ports such that data relating to the assay test may be downloaded to a computer.

Such functionality is possible for assay devices comprising an electronic means or designed to be used with an assay test meter comprising an electronic means. However provision of electronics in a meter or device is expensive which may limit the adoption of such technologies particularly in the field of consumer diagnostics.

A number of 2D bar-codes currently in use including data matrix, QR code, Aztec code and data glyphs. One of the most widely implemented is Data Matrix, an open standard adopted by a number of large companies including NASA. The data is encoded as a square grid containing a number of black and white squares. Data Matrix is a very efficient, two-dimensional (2D) bar-code symbology that uses a small area of square modules with a unique perimeter pattern, which helps the bar-code scanner determine cell locations and decode the symbol. Characters, numbers, text and actual bytes of data may be encoded, including unicode characters and photos. The encoding and decoding process of Data Matrix is very complex. Several methods have been used for error correction in the past. All current implementations have standardized on the ECC200 error correction method, which is approved by ANSI/AIM BC11 and the ISO/IEC 16022 specification. Certain Data Matrix products all support ECC200 by default. The Reed-Solomon error correction algorithms of

ECC-200 allow the recognition of bar-codes that are up to 60% damaged. The amount of data that can be encoded will vary depending upon the type of data, the encoding mode and what the intended scanner can read. In most implementations, the amount of data that can be encoded is significantly decreased due to mode switching between different types of characters, such as between numbers, upper case, lower case and punctuation.

A number of companies have developed QR and data matrix code readers for use in compatible mobile phones. These readers use the phone's camera to decode the code (mainly QR or data matrix codes). Decoded codes can contain simple text strings or may contain "operation" data which the reader (phone) interprets as an action. For example, decoded code string may contain the string URL:http://xxxxxx.mobi in which case the reader instructs the phone to open its browser and navigate to the particular encoded URL. Other operation data may include commands for sending a specific text message or for setting up an entry into the user's phone contact list.

The Canadian company, Semacode utilise a system using Data Matrix codes where the symbol encodes a URL. Semacode have developed a small Java applet designed to be run on compatible (most modern ones) mobile phones. The applet uses the phone's camera to capture the symbol, decodes the encoded URL, launches the phone's browser and navigates it to the URL encoded by the symbol.

### Figures

Aspects of the invention will now be described with reference to the Figures, of which:

Fig 1 shows an image of a data matrix code which encodes the URL http://google.com. Thus the use of the phone's code reader would navigate the phone's browser to Google.

Figure 2 shows an example for the determination of Chlamydia. The user performs the test and the image of the 2D bar-code is captured by the user's mobile phone. User's phone navigates to the appropriate web page depending upon the result of the test. One web page may correspond to a test-result being positive. The web page may read for example:

Your test result is positive. Click the links for more information

What your result means

Chlamydia FAQSupportContact a counsellor

The other web-page may for example correspond to a test-result being negative. This web-page may for example read: Your test result is negative. Click the links for more information

What your result meansSTD FAQTest for other STDsContact a counsellor

Fig 3a shows the grids after spotting with mouse monoclonal antibody, blocking and drying. While the centre of the black squares is darker than the rest of the square, it clearly shows that the grid pattern scored into the nitrocellulose constrains the spotting solution to the square in which it is applied. Fig 3b shows the grids after incubation with the anti-mouse antibody latex and washing. Blue colouration is just discernible in the squares in which the mouse monoclonal antibody was spotted.

Detailed Description

In a first aspect the invention provides a method for the determination of an analyte, comprising:

- a) contacting the analyte with an optically readable analyte sensitive 2D bar-code encoding information, wherein the presence of analyte results in an optically detectable change in the bar-code and consequently a change in the encoded information;
- b) determining any change in the encoded information, wherein the change in the encoded information is indicative of the presence and/or amount of the analyte.

A result indicative of, or associated with the presence and/or amount of the analyte may subsequently be provided.

In a second aspect, the invention provides an optically readable analyte sensitive 2D bar-code encoding information wherein said analyte sensitive 2D bar-code is capable of undergoing an optically detectable change indicative of the presence and/or amount of said analyte. The

optically detectable change may also result in a change in the encoded information, wherein a change in the encoded information is indicative of the presence and/or amount of said analyte.

In a third aspect the invention provides for an assay device for the determination of an analyte, comprising the optically readable analyte sensitive 2D bar-code according to the second aspect of the invention.

The 2D bar-code may encode a URL or text (SMS) message.

The 2D bar-code may be chosen from a number that are available such as Data matrix, QR code, Aztec code and data glyphs. A preferred 2D bar-code format is Data Matrix. The data may encoded as a square grid containing a number of black and white squares. However other formats are envisaged such as shapes which may be readily readable other than square, such as rectangular, or combinations of colours other than black and white, such as white and a colour other than black, such as blue, red and green and variations thereof.

The bar-code may be capable of immobilising an optically detectable reagent, wherein the detection of said reagent at said zone is indicative of the presence or absence of analyte. The bar-code may comprise an immobilised binding species capable of immobilising the optically detectable reagent.

The assay device may be used in conjunction with an optical reading means capable of reading the bar-code such as a digital camera or an electronic device such as a mobile phone or PDA comprising a digital camera. The optical reading means may communicate with, or comprise an electronic means to determine the encoded information. The optical reading means may comprise a transmission means to transmit the encoded information to a remote server. The electronic device may be WEB enabled, namely it has the capability to connect to a web-site. The electronic device may comprise stored information and a display means to display information relating to the assay test wherein a change in the bar-code results in a change in the displayed information. The bar-code may for example in the absence of analyte or in the presence of analyte less than a particular threshold value, encode a particular "URL" and in the presence of analyte or the presence of analyte above a particular threshold encode a different "URL" wherein the presence of analyte results in a change in the bar-code.

The electronic device may thus for example connect to different remote web-addresses depending upon the result of the test. The remote web-addresses may for example contain or provide information or advice to the user applicable to the particular test-result.

The 2D bar-code may further comprise encoded information relating to one or more of: the type of test, the expiry date of the test, batch code information, calibration information, a Uniform Resource Locator "URL" which is the global address of documents and other resources on the World Wide Web.

According to a fourth aspect, the invention provides an assay kit comprising the assay device according to the third aspect of the invention and an optical capture means to capture the image of the bar-code.

The assay kit may further comprise an electronic reading means to read the encoded information.

According to a fifth aspect the invention provides a method of conducting an assay test for the determination of an analyte comprising:

- a) contacting the analyte with an analyte sensitive optically readable 2D bar-code according to the second aspect of the invention;
- b) optically capturing in digital form the image of the bar-code;
- c) electronically decoding the encoded information contained by said captured image;
- d) providing an indication or result of the assay test based upon the electronically decoded information

The capture of the image of the bar-code according to step b) of the fifth aspect of the invention may be carried out by means of a digital camera. The digital camera may be provided as part of a mobile phone or PDA. The data contained by the image may then be decoded by means of software. The software may be present in the electronic device. Examples of suitable software provided in a mobile phone are Java<sup>TM</sup>, Symbian<sup>TM</sup>, Brew<sup>TM</sup> and Windows CE<sup>TM</sup>. A result based upon the decoded data may be displayed, for example on a display screen of the device.

Alternatively, a particular command may be generated by the software, the particular command being dependent upon the decoded information, which may subsequently be submitted to a server. The server may be remote from the electronic device, in which case the command may be transmitted wirelessly. Alternatively the server may be physically connectable or connected to the electronic device. The command may be for example a particular URL or an SMS command. Thus dependent upon the result, a particular webpage or SMS text may be generated. A mobile phone comprising a digital camera is ideally suited for carrying out this method as it is able to both capture the image of the bar-code, wirelessly transmit either the image of the bar-code to a server or transmit a command to a server, and receive and display an indication or result indicative of the assay result from the server in the form of an SMS or MMS text message or in the form of a web-page.

In the case where the command is a URL, a web page may be generated by the server, which may subsequently be sent to the user of the electronic device via a browser provided on the electronic device.

Where the command is an SMS command, a text may be generated dependent upon the data submitted and the SMS text may subsequently be sent to the electronic device.

Alternatively, rather than the decoding software being present as part of the electronic device, the image once captured may be transmitted to a server comprising the decoding software. The image data may be decoded and a particular response generated, such as the result of the test, or a particular URL or SMS text which is dependent upon the submitted data. This may then be sent to the electronic device.

The assay test result may be provided by a web-address.

The analyte of interest may be of biological, industrial or environmental in origin. The analyte may be for example a marker of an infectious disease, a drug of abuse, a cardiac marker, a protein, a peptide, a hormone or a carbohydrate. The analyte may be hCG. The analyte may be a gas or a liquid. The analyte may be electromagnetic radiation comprising visible light, UV light or infra red light.



The analyte may be provided in a liquid sample. In particular the liquid sample may be chosen from or comprise a bodily fluid such as blood, urine, serum, saliva, interstitial fluid, semen, vaginal fluid.

The assay device may be an immunoassay device for the detection of an analyte. Alternatively it may be for example a gas monitor or a monitor of electromagnetic radiation.

The assay device may be a flow through or lateral flow type of assay device comprising a flow-path. The flow-path may comprise a porous matrix such as a porous carrier or a microfluidic channel. The 2D bar-code may be provided in the flow-path of the assay device.

The 2D bar-code may be capable of immobilising a labelled binding reagent wherein the presence or absence of labelled binding reagent at the 2D bar-code is indicative of the presence or absence of an analyte. The 2D bar-code may comprise an immobilised species capable of immobilising a labelled binding reagent. The immobilised species may be a binding reagent for the analyte. Alternatively the immobilised species may be an immobilised analyte or analyte analogue capable of immobilising a labelled binding reagent for the analyte. The optically detectable reagent may be a labelled binding reagent for the analyte or a labelled analyte or analyte analogue.

The binding reagent may be chosen from one that is able to specifically bind with the species or analyte of interest to form a specific binding pair. Examples of specific binding pairs include an antibody and antigen where the antigen may be a peptide sequence, complementary nucleotide or peptide sequences, polymeric acids and bases, dyes and protein binders, peptides and specific protein binders, enzymes and cofactors, and effector and receptor molecules, where the term receptor refers to any compound or composition capable of recognising a particular or polar orientation of a molecule, namely an epitopic or determinant site.

Reference to an antibody includes but is not limited to, polyclonal, monoclonal, bispecific, humanised and chimeric antibodies, single chain antibodies, Fab fragments and  $F(ab')_2$  fragments, fragments produced by a Fab expression library, anti-idiotypic (anti-Id) antibodies, and epitope-binding fragments of any of the above.

The assay device may comprise a labelled binding reagent provided upstream from the 2D bar-code such that during running of the assay test, labelled binding reagent becomes immobilised at the detection zone resulting in a change in the bar-code and thus its encoded information.

According to an embodiment, the assay device comprises a 2D bar-code comprising an immobilised binding reagent for the analyte provided downstream from a labelled binding reagent for the analyte.

According to a further embodiment for the determination of a hapten, the assay device comprises a 2D bar-code comprising an immobilised binding reagent for the analyte provided downstream from a labelled analyte or analyte analogue, or alternatively immobilised analyte or analyte analogue provided downstream from a labelled binding reagent for the analyte.

The binding reagent may be labelled with a coloured entity such as a dye or particle, or an enzyme capable of reacting with a substrate to produce a colour. The particle may be a coloured polymer such as coloured polyurethane or a metallic particle such as gold. Such labels are well known in the art.

The porous carrier may comprise one or more porous carrier materials. The labelled binding reagent may be provided on a first porous carrier material such as glass-fibre and the bar-code may be provided on a second porous carrier material such as nitrocellulose.

During use, the user performs the assay test which results at least in specific areas of the bar code being altered as a consequence of immobilisation of an optically detectable species. The user may then image the bar-code. The bar-code may be imaged for example by a camera or other imaging means. The image may then be transmitted to an electronic means which is capable of reading the encoded information. This information may then be transmitted for example to a browser wherein a change in the encoded information will result in the navigation to a particular web-page appropriate for the result of the test. The user can then be provided with the results of the assay and supplied with links to a number of resources for example FAQs, contacts for Support Groups and additional information pages appropriate to the result. If the user subscribes to an online medical information record, the results could be transmitted directly, or with user affirmation, to that record.

The 2D bar-code may be sensitive to electromagnetic radiation, namely a change in the encoded information occurs in the presence of light. According to an embodiment, the assay device may function as a sunlight meter to indicate the intensity or strength of the sun. The 2D bar code may comprise for example one or more photochromic elements in the form of optically readable squares or the like that change in colour as a consequence of a change in the intensity of light which results in a change in the encoded information. The one or more photochromic elements may be differentially responsive to different light intensities. For example, a filter may be provided in front of a photochromic element or a plurality of photochromic elements may be provided of differing light sensitivity.

Alternatively the 2D bar code may be sensitive to particular gas, namely it may function as a part of gas monitor, wherein the one or more elements of the 2D bar code undergo a colour change in the presence of a particular gas resulting in a change in the encoded information.

Types of gases that might be detected include carbon monoxide, air, components of exhaled breath and gaseous components of vehicle-exhaust.

The assay may further comprise a calibrated colour scale, such as a grey scale which is typically provided adjacent to the 2D bar code. The colour scale will typically be provided in the form of a number of readable squares of a particular colour ranging from dark to light. In the case of a grey scale, number of readable squares may be provided ranging from black to white with shades of grey inbetween. In this way the squares of the 2D bar code may be compared to that of the colour scale and used to compensate for changes in the ambient light conditions in which 2D bar code is viewed or variations in the angle in which for example the digital camera is placed in front of the bar code or the distance from the bar code. The colour scale squares are separated from the 2D bar code such that the reader is able to differentiate the colour scale from the 2D bar code itself.

There is a certain degree of redundancy in the Data Matrix code (i.e. the change in URL is not encoded by a change in a single code element). This could increase the specificity of the test.

The advantages of such a system are that the symbol based system uses a reader to interpret the test result. The user is not required to determine the test result. The user is not given the result in isolation. He or she is provided with a result which can be placed in a healthcare context and where a number of appropriate resources can be delivered at the same time. For example, for certain diseases (e.g. STDs) the user can receive a test result and a variety of context-sensitive information and counselling. The result may be automatically transcribed into an electronic format suitable for data transmission. No transcription of the result is required.

The system could be used for example in a POC environment where the results are transmitted by clinic/hospital intranet direct to a patient's record. If a healthcare professional has performed the test, the results and the patient's record could be retrieved directly back to a mobile phone/camera PDA.

A further advantage is that a webpage may be transmitted to the user along with further links to other web-pages containing advice relating to the diagnosed condition, or other products or special offers associated with the diagnosed condition.

A further advantage is that the assay device itself does not require any electronic components such as an optical reading means, a computation means or any means to transmit the result of the assay or other information relating to the assay test.

Further advantages are that the reading means can be a digital camera provided as part of a mobile phone which are widely available and relatively cheap compared to most analyte test system readers, and that the digital camera may be used as a generic device to capture images from different test devices.

The assay device may be capable of measuring more than one analyte, wherein the presence or amount of each analyte results in a different change in the bar-code.

The aspects as described above may be further understood with respect to an illustrative example, below.

### Example

#### Production of assay device comprising IgG Detecting 2D analyte sensitive bar-codes.

Nitrocellulose was scored with a pattern of vertical and horizontal lines using a Graphtec cutter to make 5x5 grids of 4mm squares.



Squares were coloured black according the pattern above by spotting with 1.25ul of a suspension of black microspheres (Duke Scientific 250nm polymer microspheres, resuspended at 0.8% solids in PBS + 5mg/ml BSA (Intergen)). This emulates the registration and alignment encoding used by the DataMatrix system of encoding. In some cases, the black spots were applied before the nitrocellulose grids were blocked, in others they were applied after the grids were blocked. This made no difference to the final result.

Grids were also spotted with a monoclonal antibody to the alpha subunit of human chorionic gonadotropin (3299.4 in PBS, 1.25ul) according to the patterns given below.

After drying in air at room temperature for 90min, the grids were blocked for 5min in 1ml each (sufficient to cover the grid) 1% PVA (Sigma, P8136, 30-70kD, >80% hydrolysed) in PBS and then dried overnight at room temperature. Grids were then incubated with blue polymer latex coated with anti-mouse IgG diluted in 1%PVA in PBS, (1ml for 10 min) and then washed extensively with PBS 1%PVA to remove background binding (i.e. until the gaps between the black squares were free of blue colour).

While the results as shown in Figure 3b are faint, they demonstrate that it is possible to emulate a 2D bar-code through immunological detection of bound antibody. By extension, it is therefore possible to produce blue colour on the square by using the bound antibody to capture an analyte (e.g. hCG) and to then detect that analyte using a second anti-analyte antibody bound to a coloured latex.

It will be appreciated that the present invention is not limited to the specific aspects and examples described herein. Any suitable method for contacting an analyte with optically readable analyte sensitive including information may be employed. Furthermore, the determination of a change in such encoded information can be carried out in any suitable manner as will be known to the skilled person.

Claims

1. An optically readable analyte sensitive 2D bar-code encoding information wherein said analyte sensitive 2D bar-code is capable of undergoing an optically detectable change indicative of the presence and/or amount of said analyte.
2. The optically readable analyte sensitive 2D bar-code according to claim 1 wherein the optically detectable change is capable of resulting in a change in the encoded information, wherein a change in the encoded information is indicative of the presence and/or amount of said analyte.
3. The optically readable analyte sensitive 2D bar-code according to claim 1 or claim 2 comprising an immobilised binding reagent capable of immobilising a labelled binding reagent for the analyte, or a labelled analyte or labelled analyte analogue.
4. An assay device for the determination of an analyte in a liquid sample, comprising the optically readable analyte sensitive 2D bar-code according to any of claims 1 to 3.
5. The assay device according to claim 4 further comprising a flow-path, wherein the analyte sensitive 2D bar-code is provided within the flow-path.
6. The assay device according to claim 5 wherein the flow-path comprises a porous carrier.
7. The assay device according to claim 5 or claim 6 comprising a labelled binding reagent for the analyte or for a binding reagent for the analyte, provided upstream from the 2D bar-code.
8. An assay kit comprising the assay device according to any of claims 3 to 7 and an optical capture means to capture the image of the 2D bar-code in a digital form.
9. The assay kit according to claim 8 further comprising a decoding means to decode the encoded information contained by said 2D bar-code.

10. The assay kit according to claim 9 comprising a wireless transmission means to wirelessly transmit the decoded information or a command dependent upon the decoded information.
11. A method of conducting an assay test for the determination of an analyte comprising:
  - a) contacting the analyte with an analyte sensitive optically readable 2D bar-code according to any of claims 1 to 3;
  - b) optically capturing in digital form the image of the barcode;
  - c) electronically decoding the encoded information contained by said captured image;
  - d) providing an indication or result of the assay test based upon the electronically decoded information.
12. The method according to claim 11 wherein the indication or result is provided by a web-address.
13. A method for the determination of an analyte, comprising:
  - a) contacting the analyte with an optically readable analyte sensitive 2D bar-code encoding information, wherein the presence of analyte results in an optically detectable change in the bar-code and consequently a change in the encoded information;
  - b) determining any change in the encoded information, wherein the change in the encoded information is indicative of the presence and/or amount of the analyte.
14. The method according to any of claims 11 to 13 wherein the analyte is provided in a liquid sample.
15. The assay device, kit, 2D bar-code or method according to any of claims 1 to 14 or, substantially as hereinbefore described and with reference to the accompanying drawings.



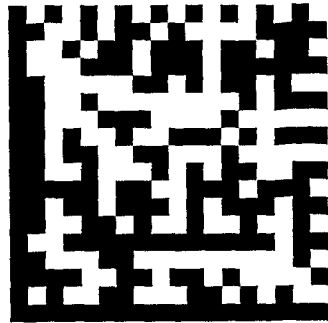


Fig 1

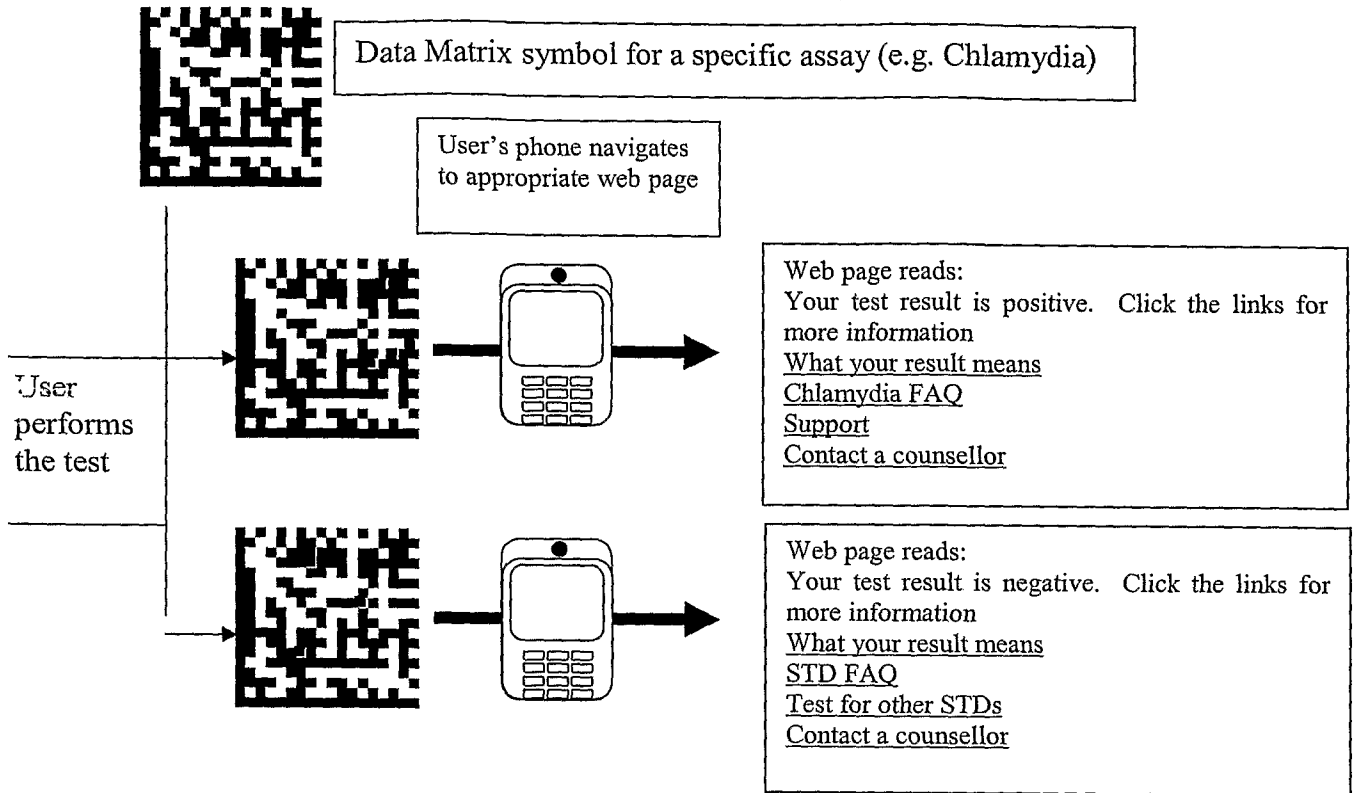


Fig 2

Fig 3a

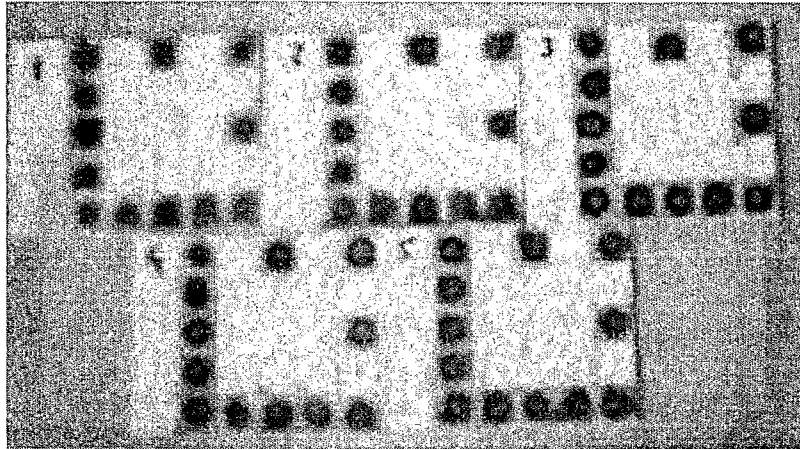
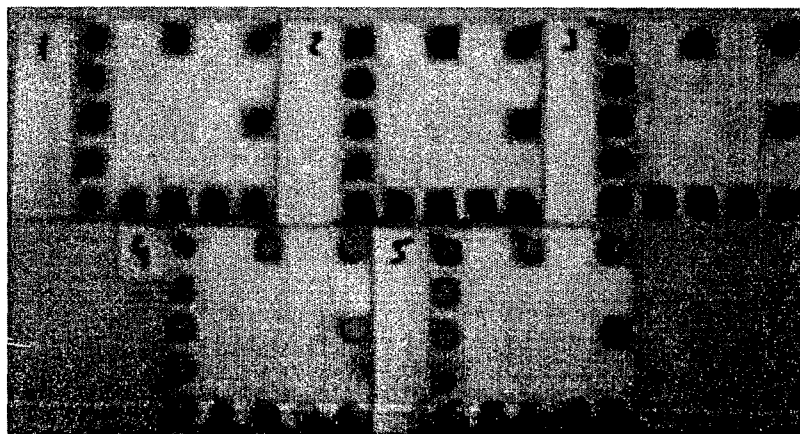


Fig 3b



**INTERNATIONAL SEARCH REPORT**

International application No  
PCT/GB2009/001965

**A. CLASSIFICATION OF SUBJECT MATTER**  
INV. G01N33/543

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

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
G01N

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

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

EPO-Internal, BIOSIS, COMPENDEX, EMBASE, FSTA, INSPEC, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/124738 A1 (CROSBY PETER A [US]) 3 July 2003 (2003-07-03) cited in the application paragraphs [0007] - [0011], [0018], [0021] - [0023], [0025], [0027], [0030], [0032], [0033] claims 1,4,11,12,15,26	1-5,8-15
X	EP 0 421 294 A2 (ABBOTT LAB [US]) 10 April 1991 (1991-04-10) column 6, line 12 - column 7, line 17 column 9, line 29 - line 47 column 10, line 42 - column 11, line 24 claims 1,4,10,11 figures 5-7	1-7, 13-15.

Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the international search

17 November 2009

Date of mailing of the international search report

30/11/2009

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel: (+31-70) 340-2040,  
Fax: (+31-70) 340-3016

Authorized officer

Adida, Anne

## INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2009/001965

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DATABASE WPI Week 200733 Thomson Scientific, London, GB; AN 2007-347762 XP002555622 &amp; JP 2007 046933 A (TOKYO INST TECHNOLOGY NAT UNIV CORP) 22 February 2007 (2007-02-22) abstract</p> <p>-----</p>	1-4,8-9, 13,15
A	<p>US 2003/076792 A1 (THEIMER WOLFGANG [DE]) 24 April 2003 (2003-04-24) the whole document</p> <p>-----</p>	1-15
A	<p>WO 2007/110486 A1 (AVANTONE OY [FI]; NYBERGH KJELL [FI]; AHOLA TOM [FI]; SALMINEN JUKKA [ ] 4 October 2007 (2007-10-04) the whole document</p> <p>-----</p>	1-15
A	<p>Vermeulen, J. et al.: "Making Bits and Atoms talk Today" Design and Integration Principles for Smart Objects (DIPSO 2007). p. 331-336.</p> <p>2007, XP002555623 ISBN: 978-3-00-022599-4 Retrieved from the Internet: URL:https://doclib.uhasselt.be/dspace/bits tream/1942/8034/1/VermeulenThysLuytenConin x_dipso2007.pdf&gt; [retrieved on 2009-11-16] the whole document</p> <p>-----</p>	1-15

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/GB2009/001965
---------------------------------------------------

Patent document cited in search report	Publication date	Publication date	Patent family member(s)	Publication date
US 2003124738	A1	03-07-2003	CA 2446329 A1	07-11-2002
			DE 02766865 T1	15-07-2004
			EP 1390752 A1	25-02-2004
			JP 2004527755 T	09-09-2004
			WO 02088739 A1	07-11-2002
EP 0421294	A2	10-04-1991	AT 128235 T	15-10-1995
			AU 637830 B2	10-06-1993
			AU 6385590 A	11-04-1991
			CA 2026843 A1	06-04-1991
			DE 69022521 D1	26-10-1995
			DE 69022521 T2	25-04-1996
			DE 421294 T1	14-08-1991
			ES 2027215 T1	01-06-1992
			GR 91300086 T1	10-12-1991
			JP 2999238 B2	17-01-2000
			JP 3176659 A	31-07-1991
			US 5075078 A	24-12-1991
			JP 2007046933	A
US 2003076792	A1	24-04-2003	NONE	
WO 2007110486	A1	04-10-2007	GB 2436636 A	03-10-2007