from the world's first protein biochip array manufacturer

evidence®

biochip array technology

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evidence®
biochip array technology

evidence® combines the latest technological advances with innovative system design to present the world's first Protein Biochip Array Technology system. Setting new standards in clinical analysis, the evidence® has the capacity to perform a test output in excess of 1,400 tests per hour. Dedicated software controls all system operations from onboard maintenance to calibration validation, to patient sample profiling for a variety of tests.

The technology is based on a novel concept using a biochip as a reaction platform, with multiple specific ligands (antibodies or antigens) attached at pre-defined sites on the surface. After addition of a patient sample to the biochip, analytes present in the sample bind to the specific ligands. The degree of binding is determined using a chemiluminescent light source and quantified using a Charge Coupled Device (CCD) camera and imaging system.

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user features of evide

a **cassette loading tower**

Cassettes contain vertically stacked biochip carriers in an easy-load bar-coded cassette. Cassettes are inserted directly and move downward into a storage compartment.

b **refrigerated reagent storage unit**

The refrigerated reagent storage unit comprises two separate internal units for panel-specific reagents and chemiluminescent signal reagents. Bar-coded reagents for the test array enable rapid identification.

c **sample unit**

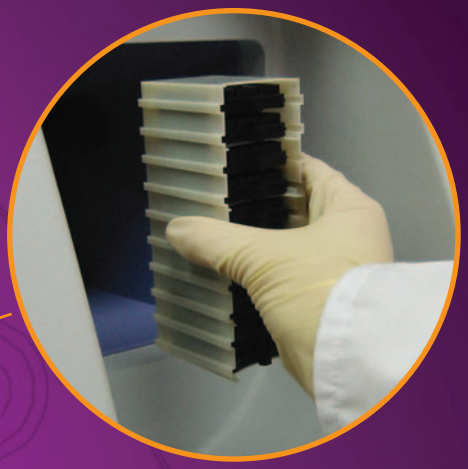
Sample tubes or cups can be continuosly loaded onto two removable sample carousels (180 capacity) each with a barcode reader for rapid sample identification.

ence®

a

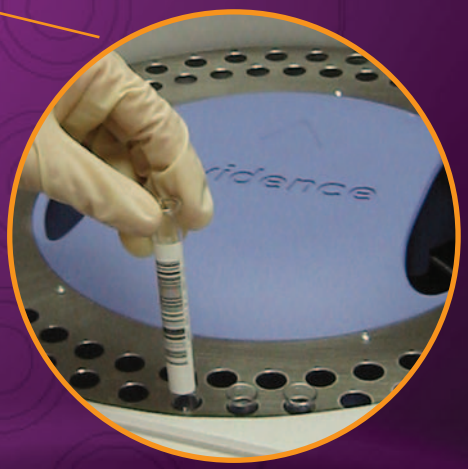
b

f



load biochip cassette

load reagents



load samples

d

bulk solutions unit

Universal wash buffer and displacement fluids are required for routine operation of evidence®.

e

cassette collection unit

Cassettes are released into an onboard collection unit when empty or when the test panel changes.

f

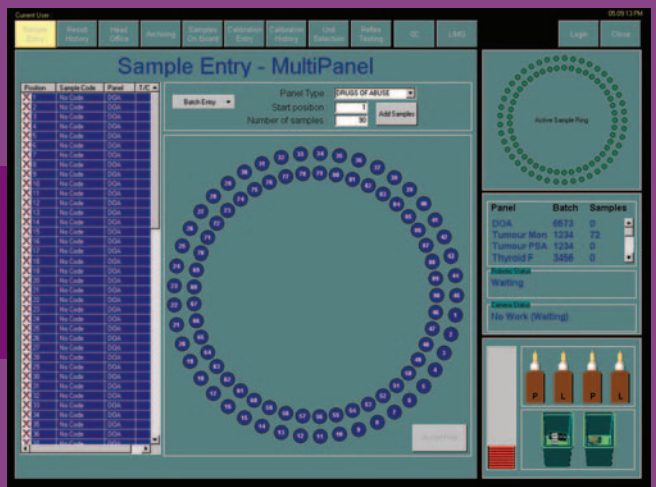
biohazard waste unit

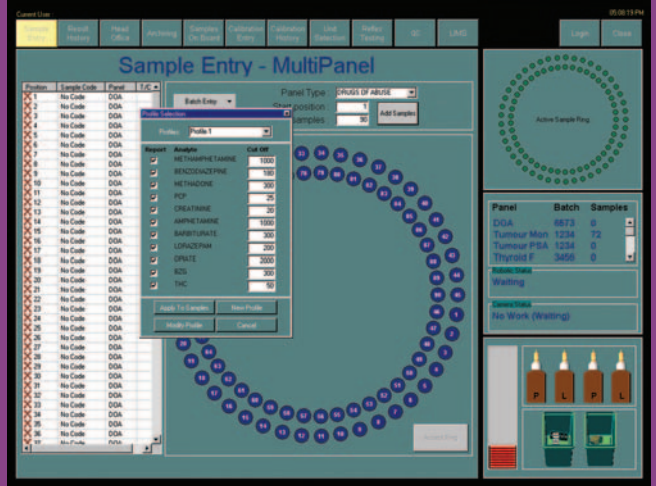
An onboard waste container for used biochip carriers minimises the risk of biological contamination and contains an intelocked door for enhanced safety.

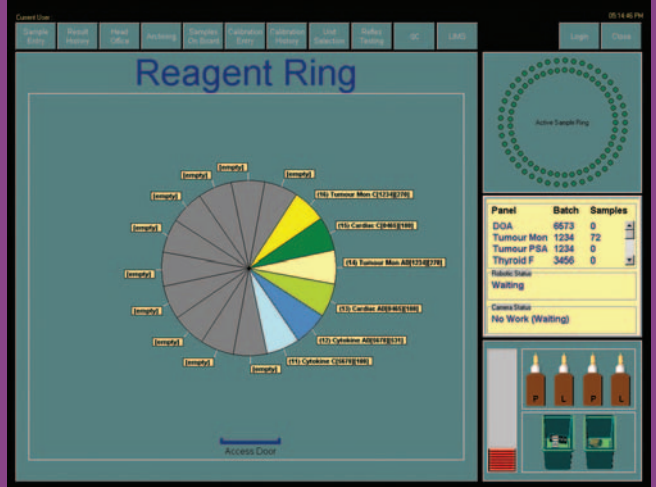
evidence®
management system

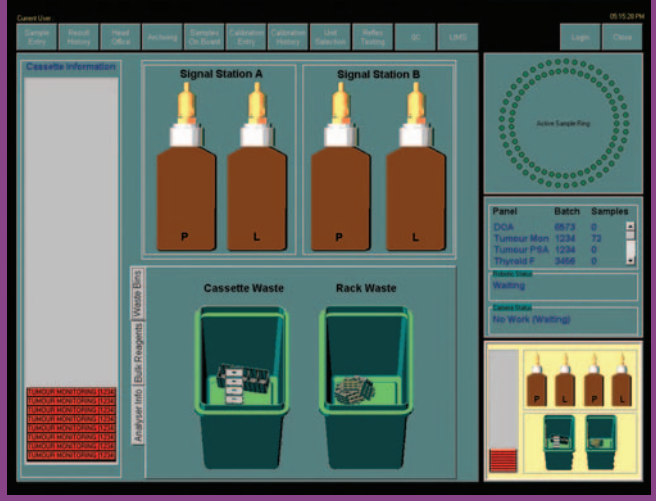
All operational functions of evidence® are managed and controlled by the dedicated Windows® based system software. System sensors enable regular update of onboard inventory details, which are constantly displayed on the user screen.

The Graphic User Interface (GUI) comprises a main access screen, three easiview inventory screens and a menu options section. Easiview screens are used to provide constant on screen information of inventory status. The three screens provide information on the Active Sample Ring, Panel-specific reagents and Waste and Signal reagents.









Software features

- Colour-coded, on screen inventory units for demonstration of component status.
- Automatic system initialisation procedure.
- Retrospective reporting facility to enable the retrieval of previously unreported tests.
- Calibration information supplied on disc for easy upload.
- User-defined cut-off values for semi-quantitative assays without the need to recalibrate.
- Multi-format option for results review e.g. by patient sample, by biochip carrier, etc. This facilitates troubleshooting of results.
- Results archive facility.
- Access to analyser software for remote maintenance and trouble shooting.
- Test selection and reporting option from dedicated assay panels to eliminate test redundancy.
- Automatic onboard inventory check for lot and panel specific biochips and reagents before a test panel is presented for selection.
- To ensure safe operation and handling, software restricts access to onboard units and reagents.
- Audible alarms to alert user
- evidence® can be connected to a laboratory information management system (LIMS)
- QC software with Multi-rule capability

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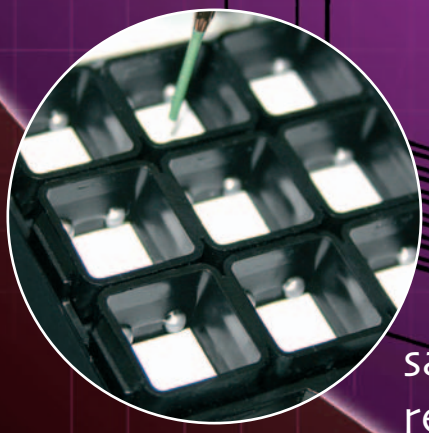
A biochip s journey through evidence® is fully automated

ready to use, 9
patient biochip carrier



sample &
reagent addition

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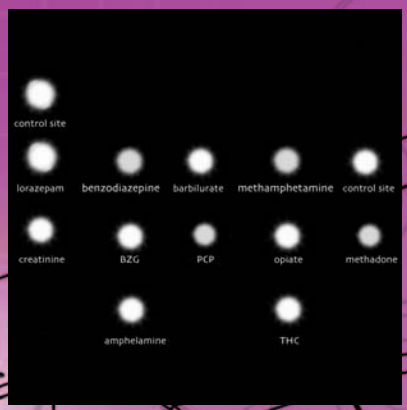

discrete sites on each biochip quantify individual analytes

CCD image capture of 9 biochips in carrier

signal reagent addition

multiple washes to remove excess reagent

incubation at 37°C

multiple test biochips comprising up to 25 discrete test regions on each biochip

Fertility Array

Tumour PSA Array

Free Thyroid Array

Cytokine Array 1

Tumour Monitoring Array

Drugs of Abuse Array I

Total Thyroid Array

Cardiac Array

Maternal screen Array*

Future Developments

Further Cytokine Array*

Drugs of Abuse Array II*

Adhesion Molecules Array

Cerebral Arrays*

* under development

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Consolidation of Tests

evidence® utilises biochips as platforms for immunoassay measurement. Specific and simultaneous profiling of biological markers is the biggest advantage of protein biochip array technology for many applications.

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2001

ISO 13485 SYSTEM CERTIFICATION SGS

UKAS QUALITY MANAGEMENT 005

ROYAL ACADEMY of ENGINEERING

MacRobert Award 2003

evidence®

Panels of tests, allowing the simultaneous detection of analytes from a single sample. Array of tests currently available and in development.

Clinical Arrays

Free Thyroid Array
- ☐ Thyroid stimulating hormone (TSH)
- ☐ Free tri-iodothyronine (FT_3)
- ☐ Free thyroxine (FT_4)

Total Thyroid Array
- ☐ Thyroid stimulating hormone (TSH)
- ☐ Total tri-iodothyronine (TT_3)
- ☐ Total thyroxine (TT_4)

Fertility Array
- ☐ Follicle stimulating hormone (FSH)
- ☐ Prolactin (PRL)
- ☐ Lutenising Hormone (LH)
- ☐ Estradiol
- ☐ Progesterone
- ☐ Testosterone

Tumour Monitoring Array
- ☐ Carcinoembryonic antigen (CEA)
- ☐ α- Fetoprotein (AFP)
- ☐ Human chorionic gonadotrophin (hCG)
- ☐ Gastrointestinal tumour antigen (CA 19-9)
- ☐ Ovarian tumour antigen (CA 125)
- ☐ Breast cancer antigen (CA 15-3)

Tumour PSA Array
- ☐ Total prostate specific antigen (tPSA)
- ☐ Free prostate specific antigen (fPSA)
- ☐ Carcinoembryonic antigen (CEA)

Adhesion Molecules Array
- ☐ I CAM - 1
- ☐ V CAM - 1
- ☐ E - Selectin
- ☐ P - Selectin
- ☐ L - Selectin

Cytokines & Growth Factors Array
- ☐ Interleukin-1 alpha (IL-1 α)
- ☐ Interleukin-1 beta (IL-1 β)
- ☐ Interleukin-2 (IL-2)
- ☐ Interleukin-4 (IL-4)
- ☐ Interleukin-6 (IL-6)
- ☐ Interleukin-8 (IL-8)
- ☐ Interleukin-10 (IL-10)
- ☐ Vascular Endothelial Growth Factor (VEGF)
- ☐ Tumour Necrosis Factor-alpha (TNF-α)
- ☐ Interferon-gamma (IFN-γ)
- ☐ Epidermal Growth Factor (EGF)
- ☐ Monocyte Chemotactic Protein-1 (MCP-1)

Cardiac Array
- ☐ Troponin I
- ☐ Myoglobin
- ☐ CK-MB
- ☐ Carbonic Anhydrase III (CA III)
- ☐ Glycogen Phosphorylase BB (GPBB)
- ☐ Fatty Acid Binding Protein (FABP)

Drugs of Abuse Array I
- ☐ Amphetamine
- ☐ Methamphetamine
- ☐ Cocaine
- ☐ Barbiturates
- ☐ Cannabinoids
- ☐ Opiates
- ☐ Methadone
- ☐ Benzodiazepine I
- ☐ Benzodiazepam II
- ☐ Phencyclidine
- ☐ Creatinine

Multi-analyte Quality Controls
- ☐ Drugs of Abuse
- ☐ Cardiac
- ☐ Cytokine
- ☐ Immunoassay
- ☐ Customised quality controls
- ☐ Adhesion Molecules

Future Developments

- ☐ Allergen Array (IgE)
- ☐ Cerebral Arrays
- ☐ Cytokine Arrays
- ☐ Maternal Screen Array
- ☐ Breast Cancer Diagnosis and Classification
- ☐ Bone Marker
- ☐ Drugs of Abuse Array II

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