

EVIDENCE EVOLUTION

An Evidence Series Immunoanalyser

RANDOX

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DEDICATED TO IMPROVING HEALTH WORLDWIDE

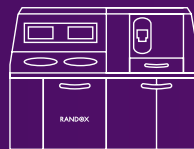
In 2002, Randox invented a world first, Biochip Array Technology, instantly changing the landscape of diagnostic testing forever. Biochip Array Technology is a multi-analyte platform which provides an unrivalled increase in patient information per sample. Instead of a patient sample needing to be subdivided for each test result, or in some cases re-collected, Biochip Array Technology offers a diagnostic patient profile with each patient sample. So now the patient's needs become the focus, as Biochip Array Technology delivers the multiple results needed for improved diagnosis.

With over £250 million invested into Biochip Array Technology research and development, Randox have launched a range of Biochip Array Technology immunoanalysers – The Evidence Series. This includes the Evidence, the Evidence Evolution, the Evidence Investigator and the Evidence MultiSTAT. Each analyser is developed with boundary pushing engineering, designed to make financial, labour and time savings for the end user.

THE EVIDENCE SERIES



Evolution



Evidence



Investigator



MultiSTAT

BIOCHIP ARRAY TECHNOLOGY



Biochip Array Technology is a precision multiplex testing platform allowing for the simultaneous quantitative or qualitative detection of a wide range of analytes from a single sample.

Biochip Array Technology uniquely offers immunoassay diagnostic testing for simultaneous multi-analyte biomarker detection. After the addition of a single patient sample to the biochip, analytes present in the sample bind to the specific biochip bound ligands. The degree of binding is determined using a chemiluminescent light source and quantified using a Charge Coupled Device (CCD) camera and imaging system.

Each biochip has up to 49 Discrete Test Regions (DTR). This means that up to 44 tests can be carried out simultaneously. The additional DTR are reserved for internal quality control and visual reference, a unique Biochip Array Technology feature.

APPLICATIONS

- Clinical Diagnostics
- Drug Development
- Molecular Research and Diagnostics
- Forensic Toxicology
- Food Diagnostics for the presence of veterinary residues
- Academic Research
- Veterinary Testing

MULTIPLEX TECHNOLOGY



Precise Testing

- Biochip Array Technology has a proven high standard of precise test results with CVs <10%
- Multiplex analysis minimises analytical variation between tests



Optimum Efficiency

- Dedicated multi-analyte reagents and quality control material manufactured by Randox provide highly efficient testing whilst minimising wastage
- This ensures Biochip Array Technology is a truly effective end-to-end solution



True Cost Reduction

- Multiplex testing reduces the amount of time and labour spent on individual tests and associated laboratory costs
- Through running tests simultaneously, multiplex testing represents greater value for money as fewer patient samples, consumables and laboratory time are able to deliver more in-depth analysis



Superior Patient Profiling

- Testing for multiple markers simultaneously increases the amount of patient information rapidly available to the clinician, allowing for more informed patient diagnosis from the same sample

FLEXIBILITY



Small Sample Volume

- A smaller sample volume can be used to run more assays due to multiplexing
- Increased patient profiling saves precious sample if further analysis is required



Wide and Varied Test Menu

- Randox's vast Biochip Array Technology test menu allows clinicians to detect routine and novel markers for advanced diagnostic analysis
- Randox has the world's most innovative test development program ensuring that, with Biochip Array Technology, you are able to effortlessly add to your testing program



Adaptability

- Multiple sample types can be used on one analyser including serum, plasma, whole blood, urine and oral fluid - includes all Toxicology matrices
- Allows the clinician to offer flexible patient testing as new tests can be added without additional equipment

SUPERIOR REPORTING



Result Traceability

- RFID tagged biochips and reagents ensure complete and secure traceability of results



Retrospective Reporting

- Retrieve previously unreported results without additional testing, saving time and the need to collect more sample



Reflex Testing

- Based on results, users can set values for each target to prompt automatic testing of another array

JOIN THE EVOLUTION

The Evidence Evolution opens up a new chapter in diagnostic testing. Merging unrivalled versatility, quality and efficiency, the Evidence Evolution guarantees to deliver more results, faster and more economically than its predecessors.

Utilising the same multiplex technology as the fully automated Evidence, Evidence MultiSTAT and semi-automated Evidence Investigator, the Evidence Evolution is capable of processing up to 44 results from a single sample. To achieve this volume of results, you do not have to compromise on time, with the first set of results produced in less than 36 minutes with a new set of results every minute after. This rapid, but thorough testing is only possible through progressive engineering and a culture of constant innovation.

It is this culture that led to the Evidence Evolution being the most versatile analyser Randox has ever produced. Offering Biochip Array Technology batch analysis, STAT samples, true random access and reflex testing, the Evidence Evolution empowers users to build a more in-depth patient profile.

The Evidence Evolution offers a true walkaway time of 2 hours. We understand time in a laboratory setting is a precious commodity and the Evidence Evolution impacts upon this positively. The Evidence Evolution delivers this impressive walkaway time through combining continuous sample and reagent loading, as well as automated on-board sample dilution.

Other advantages include; testing across multiple matrices, state of the art intuitive software and advanced precision bio-drive robotics. The Evidence Evolution meets the needs of a modern, high throughput laboratory.



| | |
|------------|--------------------------------|
| Dimensions | 132 (H) x 120 (D) x 168 (W) cm |
| Weight | 720 kg, 1567 lbs |
| Throughput | Up to 2640 tests per hour |



RANDOX



WHY JOIN THE EVOLUTION?



ANY TEST, ANY TIME



The Evidence Evolution is a highly versatile immunoanalyser which can process any required workflow including routine laboratory testing, STAT samples and true random access. Capable of achieving 2640 test results per hour with first sample reported in <36 minutes and up to 44 results reported each minute after.

How it works:

A.

New biochips can be easily introduced at any stage

B.

Tests are queued using intuitive software

C.

Ability to run STAT samples as needed



TRUE WALKAWAY TIME OF 2 HOURS



Innovative engineering reduces the amount of human interaction needed and is designed to be as labour saving as possible. Once the system is fully loaded it can be left unsupervised for 2 hours. This true walkaway time frees up operators and allows the laboratory to run more efficiently.

How it works:

A.

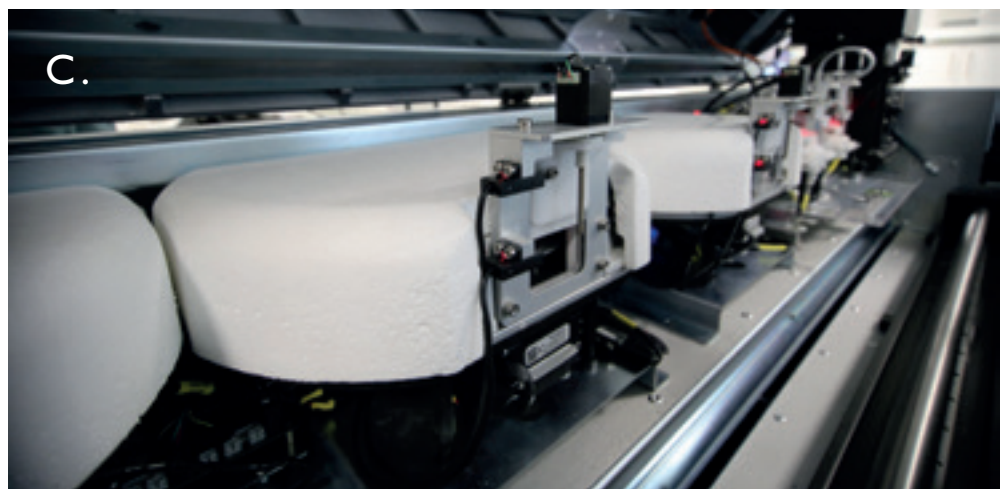
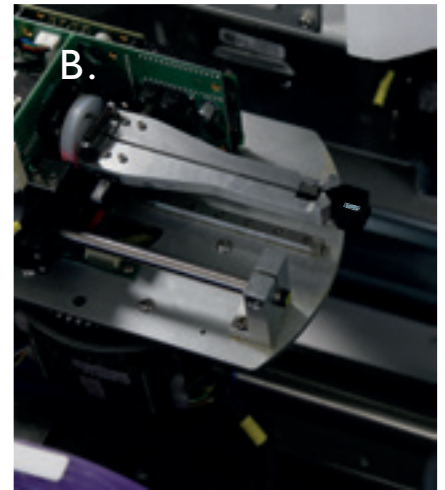
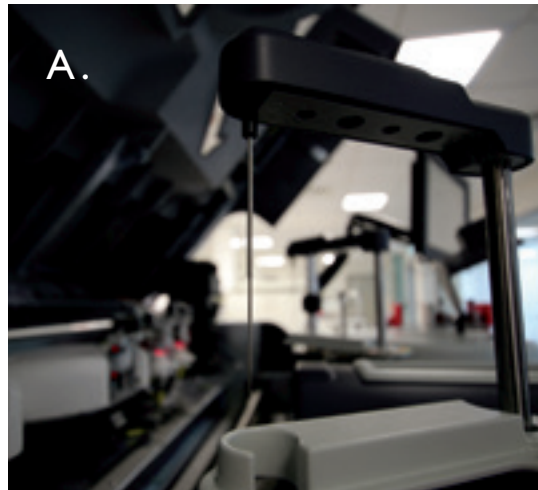
Precision probe places sample on to biochip

B.

Robotic arm carries biochip to each station automatically

C.

Three incubators enable constant biochip preparation



AUTOMATED REFLEX TESTING



Users can set values for each target, prompting testing of another array automatically, saving valuable time and allowing for follow up tests to be conducted immediately.

This feature enables clinicians to gather a more in-depth knowledge of patients from the same sample, without having to analyse the initial result. Complete result profiles provide the thorough information required to treat patients, reducing delays by eliminating the need to manually order additional tests. This method reshapes the way diagnostic testing is carried out.

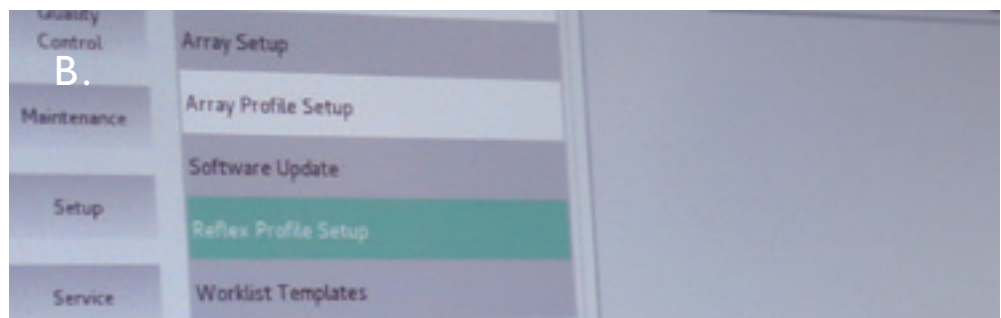
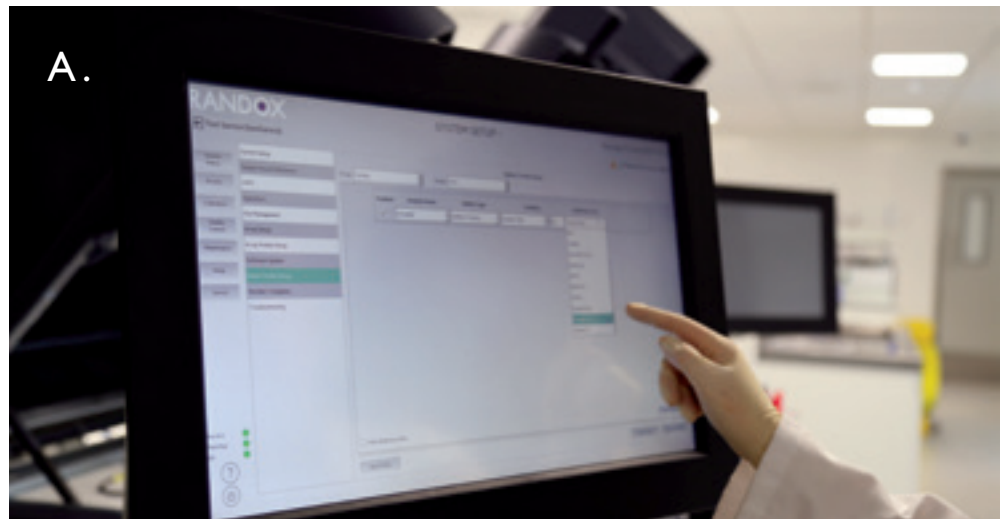
How it works:

A.

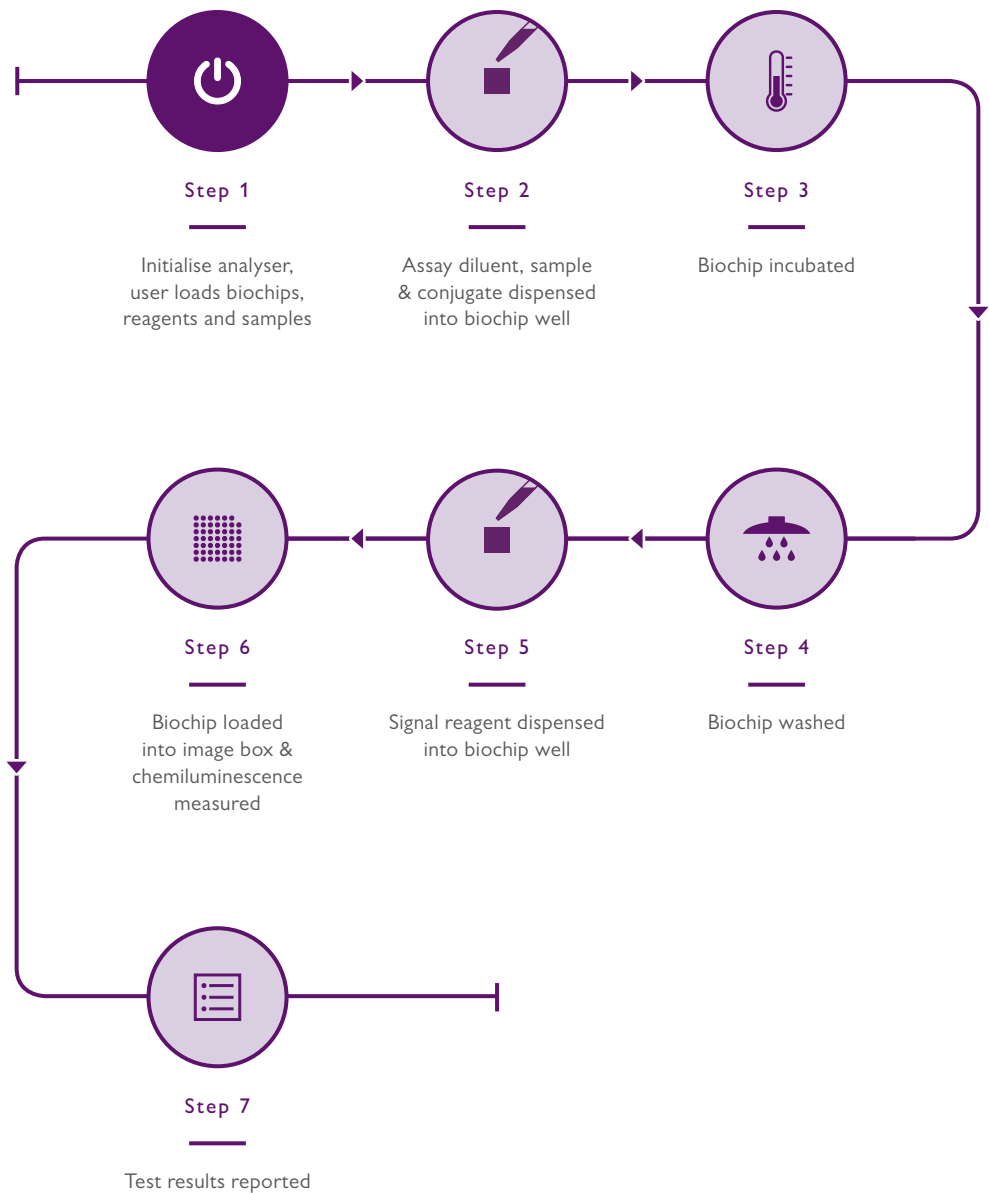
Easily set up Reflex criteria via software

B.

Dedicated Reflex Testing user interface

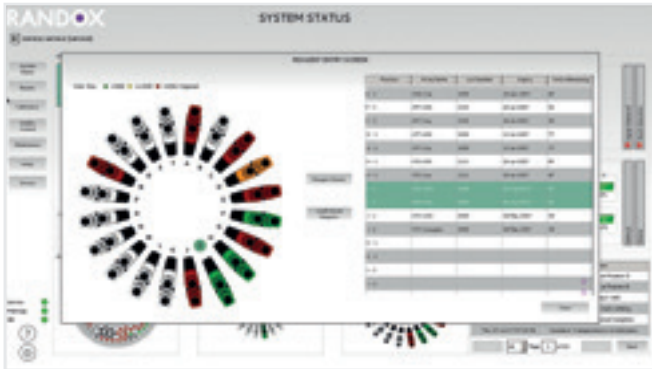


EVOLUTION PROCESS



-
- User Step
 - Analyser Step

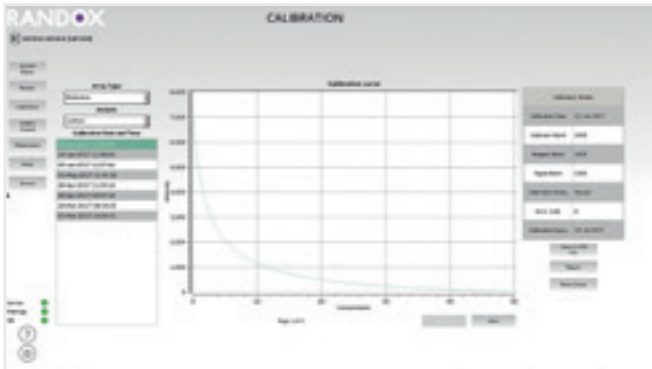
SOFTWARE



Home

Our built in software provides users a wide range of testing options.

The Evidence Evolution has the ability to run tests at a high throughput whilst also allowing for future scheduling of tests, meaning your lab efforts are more streamlined and more efficient.



Calibration

Dedicated onboard software provides detailed calibration offerings through a range of selections.

By selecting a relevant criterion, a graph showing the calibration curve will be displayed. Each array being tested has either a 9-point or 10-point calibration.

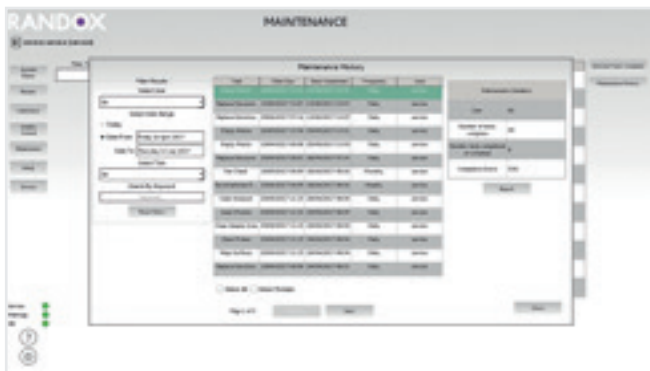
Calibration frequency will be array dependent, but will be required with each new kit batch and signal batch.



QC

The Evidence Evolution provides a specific screen with Quality Control reporting, and allows the selection of Array, Analyte and the time period of when QC testing was performed.

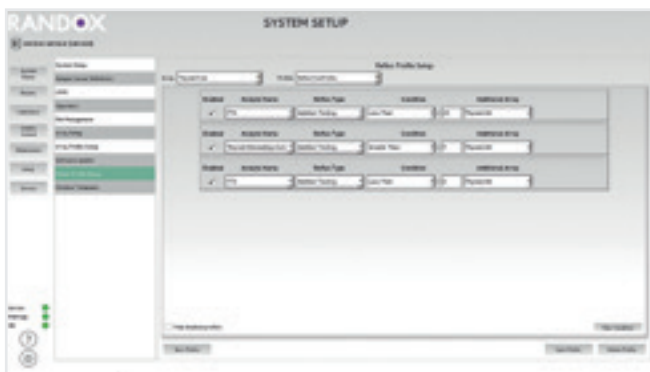
Specific functionality provides tabbed pages when multiple analytes are present for a selected array so you can move through pages to view each QC result.



Maintenance

It is vital that your analyser stays in top condition at all times. In order for this to happen our maintenance function ensures the system will run efficiently and effectively. When in operation, maintenance tasks will be alerted to the operator by an on-screen message displayed at the top right corner of the screen.

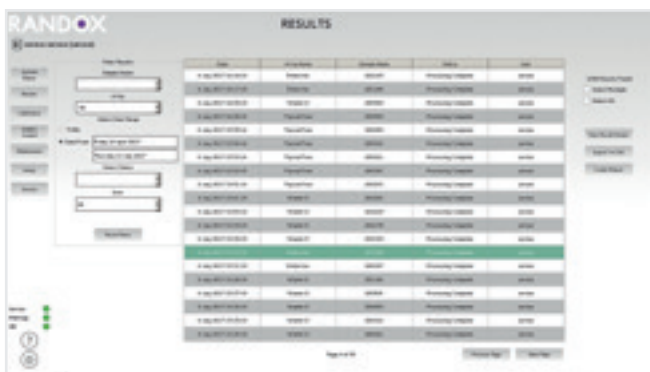
A comprehensive maintenance history function allows detailed reporting on any tasks that have been carried out and is available in report format via PDF export.



Reflex Testing

Reflex profiling is a method of initiating additional automated test analyses, as a 'reflex action' to the result(s) of a previous test. This advanced system allows you to test more specifically and in greater detail depending on the result.

Furthermore, multi-levelled Reflex Profiles provide even greater reporting opportunities, as the result of one Reflex Test can trigger other Reflex Tests, until the requirements of all parties are met.



Results

With the ability to run such a high volume of tests, reporting is a critical element of the software offering of the Evidence Evolution.

The user can create a report at any time. The standard report display is either daily or a 90-day period. However, the user can select a FROM and TO date period for specific periods outside of standard options.

SPECIFICATIONS

| | |
|-----------------------|--|
| Biochip Capacity | 10 biochips per cartridge. Can store up to 20 cartridges. 200 biochips total |
| Measurement Principal | Chemiluminescence |
| Operational Modes | Random and continuous access, priority STAT loading, batch mode |
| Sample Capacity | 120 Samples |
| Time to First Result | Approximately 36 minutes, with 1 result every minute after (array specific) |

| | |
|-------------------------|---|
| Access Loading | Continuous sample, reagent and biochip input and output |
| Aspiration Capability | Precision pump with liquid level and clot detection |
| Biochip Format | Cartridge format with 10 x single biochip, individually sealed wells |
| Calibration Principal | 6 Point Master Curve Generation, individual point re-run |
| Connectivity | 6 x USB ports, 1 x Ethernet, 1 x RS232, WiFi |
| Data Backup Methods | Via writable DVD, CD, USB Mass-storage or Network Folder |
| Data Storage Capacity | Up to 12 million test results with complete raw data. RAID 1 data mirroring |
| Environmental | Ambient Environment 18 - 30°C, < 2°C temperature variation per hour, 20 – 85% relative humidity |
| Incubation Temperatures | 3 x chambers at temperatures of 25°C, 32°C and 37°C |
| Liquid Waste | Liquid waste output for collection or plumbed directly to drainage system |
| LIS Connectivity | Bi-directional: ASTM Standard (RS232 Connection) |
| Maximum Throughput | When processing 44 analytes per biochip, 2640 tests can be run per hour |
| Network Services | Highly secure Remote Diagnostics, automated software update and array updates |
| On-board Refrigeration | Available to store biochips and reagents at optimal temperature |

“ THE EVIDENCE EVOLUTION IS OUR MOST ADVANCED IMMUNOANALYSER TO DATE. ”

| | |
|---------------------------|---|
| Operator Interface | 22" Touch-screen monitor, highly intuitive software |
| Peripherals | A4 Laser Printer |
| Quality Control | Interactive Levey-Jennings, user definable multipoint rules with system alarm |
| Reagent Capacity | 20 twin vessel reagent bottles (50ml per vessel) |
| Sample Bar-code | Code 39, Codabar, Code 128, I 2 of 5, Code 93, UPC/EAN, Pharmacode, PDF417 (option), MicroPDF(option) |
| Sample Capacity | 120 Samples |
| Sample Dilution | Automatic, on-board dilution, continuously variable between 1:1 and 1:82, array dependent |
| Sample Tube Compatibility | 2ml Paediatric Cups, Standard Sample Tubes (D. 10-16mm x H. 75-100mm), Cobas Cups (using optional adaptors) |
| Sample Volume | Array dependent |
| Sample Wedges | 10 Independent wedges holding 12 samples each. Each wedge can hold any combination of sample tubes |
| System Fluids | On-board dilution of bulk reagents, refrigerated storage, continuous level monitoring |
| True walkaway time | 2 hours |
| Water Consumption | Less than 3 litres per hour |

CLINICAL AND TOXICOLOGY IMMUNOASSAY TEST MENU

Adhesion Molecules

E-Selectin
Intercellular Adhesion Molecule-I – ICAM-I
L-Selectin
P-Selectin
Vascular Cell Adhesion Molecule-I – VCAM-I

Alzheimer's

Apolipoprotein E4 – ApoE4
Pan Apolipoprotein E – Apo E

Anaemia

Ferritin
Folate
Vitamin B12

Bone Disease

Vitamin D

Cancer

Carcinoembryonic Antigen – CEA
Free Prostate Specific Antigen – FPSA
Total Prostate Specific Antigen – TPSA

Cardiac

Cardiac Troponin I – cTnI
Creatine Kinase MB – CKMB
Heart-Type Fatty Acid-Binding Protein – FABP3
Myoglobin

Cytokines

Epidermal Growth Factor – EGF
Granulocyte Macrophage Colony Stimulating Factor – GM-CSF
Interferon- γ – IFN- γ
Interleukin-1 alpha – IL-1 α
Interleukin-1 beta – IL-1 β
Interleukin-2 – IL-2
Interleukin-3 – IL-3
Interleukin-4 – IL-4
Interleukin-5 – IL 5
Interleukin-6 – IL-6
Interleukin-7 – IL-7
Interleukin-8 – IL-8
Interleukin-10 – IL-10
Interleukin-12p70 – IL-12p70
Interleukin-13 – IL-13
Interleukin-15 – IL 15
Interleukin-23 – IL-23
Macrophage Inflammatory Protein-1 α – MIP-1 α
Matrix Metalloproteinase 9 – MMP 9
Monocyte Chemotactic Protein-1 – MCP-1
Soluble IL-2 Receptor Alpha – sIL-2R α
Soluble IL-6 Receptor – sIL-6R
Soluble Tumour Necrosis Factor Receptor 1 – sTNFR1
Soluble Tumour Necrosis Factor Receptor 2 – sTNFR2
Tumour Necrosis Factor- α – TNF- α
Vascular Endothelial Growth Factor – VEGF

Diabetes

Insulin

Endocrine

Cortisol
Dehydroepiandrosterone-Sulphate – DHEAS

Fibrinolysis

D-Dimer

Fertility

Estradiol

Follicle Stimulating Hormone – FSH

Luteinizing Hormone – LH

Progesterone

Prolactin

Sex Hormone Binding Globulin – SHBG

Testosterone

Gastrointestinal

Gastrin 17 – GI7

Helicobacter pylori – H. pylori

Pepsinogen I – PGI

Pepsinogen II – PGII

Metabolic

Adiponectin

Ferritin

Insulin

Leptin

Plasminogen Activator Inhibitor – PAI-1

Resistin

Renal

Adiponectin

Complement C3a des Arginine – C3a des Arg

C-Reactive Protein – CRP

Cystatin C

Renal Continued

D-Dimer

Epidermal Growth Factor – EGF

Liver Fatty Acid Binding Protein-I – FABPI

Interleukin-8 – IL-8

Macrophage Inflammatory Protein-I α – MIP-I α

Neutrophil Gelatinase – Associated Lipocalin – NGAL

Soluble Tumour Necrosis Factor Receptor 1 – sTNFR1

Soluble Tumour Necrosis Factor Receptor 2 – sTNFR2

Stroke

Brain-Derived Neurotrophic Factor – BDNF

D-Dimer

Glial Fibrillary Acidic Protein – GFAP

Glutathione S – Transferase Pi – GSTPi

Heart-Type Fatty Acid-Binding Protein – FABP3

Interleukin-6 – IL-6

Nucleoside Diphosphate Kinase – NDKA

Neuron Specific Enolase – NSE

Parkinson Protein 7 – PARK-7

Soluble Tumour Necrosis Factor Receptor 1 – sTNFR1

Thyroid

Anti-Thyroglobulin – Anti-Tg

Anti-Thyroid Peroxidase – Anti-TPO

Free Tri-iodothyronine – FT3

Free Thyroxine – FT4

Thyroid Stimulating Hormone – TSH

Thyroxine Binding Globulin – TBG

Total Tri-iodothyronine – TT3

Total Thyroxine – TT4

CLINICAL AND TOXICOLOGY IMMUNOASSAY TEST MENU

Tissue Damage

Liver Fatty Acid Binding Protein-I – FABP1
 Heart-Type Fatty Acid-Binding Protein – FABP3
 Adipose Fatty Acid Binding Protein – FABP4
 Epidermal Fatty Acid Binding Protein – FABP5
 Ileal Fatty Acid Binding Protein – FABP6
 Brain Fatty Acid Binding Protein – FABP7
 Testis Fatty Acid Binding Protein – FABP9

Toxicology

6-MAM
 AB-CHMINACA
 AB-PINACA
 Acetaminophen
 Acetyl Fentanyl
 AH-7921
 Amphetamine
 Barbiturate
 Barbiturates
 Benzodiazepines I (Oxazepam)
 Benzodiazepines II (Lorazepam)
 BGZ/Cocaine
 Buprenorphine
 BZP
 Cannabinoids (THC)
 Carfentanil/Remifentanil
 Chloral Hydrate Metabolite
 Clonazepam
 Creatinine
 Dextromethorphan
 Escitalopram
 EtG
 Etizolam
 Fentanyl
 Flunitrazepam
 Fluoxetine
 Furanyl Fentanyl
 Generic Opioids
 Haloperidol

Toxicology Continued

Ibuprofen
 JWH - 018
 Ketamine
 LSD
 MDMA
 Meperidine
 Mephedrone
 Meprobamate
 Mescaline
 Methadone
 Methamphetamine
 Methaqualone
 Methylphenidate / Ritalinic Acid
 Mitragynine
 MT-45
 Naloxone
 Ocfentanyl
 Opiate
 Oxycodone
 Oxycodone I
 Oxycodone II
 PCP
 Phenylpiperazine I
 Phenylpiperazine II
 Pregabalin
 Propoxyphene
 Salicylate
 Salvinorin
 Sertraline
 Sufentanil
 Tramadol
 Trazodone
 Tricyclic Antidepressant
 U-47700
 UR-144
 W-18/W-19/W-15
 Zaleplon
 Zolpidem
 Zopiclone
 α -PVP (Flakka)

SYSTEM STATUS -

Sample Data

Sample Data

| Number | Name | Address |
|--------|----------|-------------|
| 1 | John Doe | 123 Main St |

SUPPORTING YOU



Enter Barcode

2785



LOCAL ENGINEERS. GLOBAL COVERAGE.

Randox Laboratories provide customers with an unrivalled support service. Our international team of fully qualified engineering and technical support specialists deliver on-site Evidence Series immunoanalyser installation, training and validation. We also offer a range of bespoke service and extended warranty packages that can be tailored to your budget.

We place extreme importance on customer service and so it is our top priority to provide the best quality support. Our global network of local specialists are here to help you and respond rapidly to any query.



21
Randox offices
distributed across the globe

At Randox we are always ready to provide any support needed to ensure you enjoy the advantages of our unique Biochip Array Technology fully. We understand the importance of up time and how that affects outcomes for the laboratory and the patient.

Through working alongside you, we can ensure your laboratory is working to an optimal level - helping achieve our mission of improving health worldwide.

145
countries covered
by our distributor network

47
technical support specialists

39
trained service engineers

350
scientists placed
around the world

WHY BUY EVOLUTION?



Throughput

Rapid automated diagnostics with a throughput of up to 2640 tests per hour



Automation

Once the system is fully loaded it can be left unsupervised for 2 hours



Versatile

STAT, Random Access and Reflex testing capabilities



Speed

Faster sample processing time than leading competitors



Test Menu

Most unique test menu with all routine immunoassays and new tests under development



Matrices

Applicable for a range of matrices: whole blood, serum, plasma, urine, CSF, oral fluid, hair, vitreous humor, meconium and tissue

JOIN THE EVOLUTION



Randox Evolution

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