

## EVIDENCE INVESTIGATOR

An Evidence Series Analyser

RANDOX

Adaptable, Efficient & Comprehensive

## CONTENTS

	Randox
	Dedicated To Improving Health Worldwide • p.04
01	Biochip Array Technology
	Introduction • p.05
	Benefits • p.06
02	Evidence Investigator
	Adaptable, Efficient & Comprehensive • p.08
	Key Benefits • p.12
03	Technical Information
	Evidence Investigator Package • p.14
	Immunoassay Testing Process • p.15
	Software • p.16
	Specifications • p.18
04	Molecular
	Molecular Testing • p.20
	Molecular Testing Process • p.21
05	Test Menu
	Immunoassay, Toxicology, Molecular, Food Diagnostics • p.22
06	Supporting You
	Customer Support Network • p.28

Why Buy Evidence Investigator? • p.30

## DEDICATED TO IMPROVING HEALTH WORLDWIDE

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

With over  $\pounds$ 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 offers unique immunoassay-based diagnostic testing for simultaneous multi-analyte biomarker detection. After the addition of a 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 can have up to 49 Discrete Test Regions (DTR). This means that up to 44 tests can be carried out simultaneously. The additional DTRs are reserved for internal quality control and visual reference, a unique Biochip Array Technology feature.



## APPLICATIONS

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

## MULTIPLEX TECHNOLOGY

#### **Precise Testing**

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



### **Optimum Efficiency**

- Dedicated multi-analyte reagents and quality control material are manufactured by Randox providing reliable and controlled testing
- 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 as well as associated laboratory costs
- Through running tests simultaneously, multiplex testing represents greater value for money as fewer samples and consumables are able to deliver more in-depth analysis



#### Superior Patient Profiling

• Testing for multiple markers simultaneously increases the amount of information rapidly available to the clinician, allowing for more informed diagnosis

## FLEXIBILITY

#### Small Sample Volume

- A smaller sample volume required due to multiplexing
- Increased profiling saves precious sample if further reflex analysis is required



#### Wide and Varied Test Menu

- Randox's vast Biochip Array Technology test menu allows users to detect routine and novel markers for advanced diagnostic and research analysis
- Randox has the world's most innovative test development program. With 400 assays in development, Biochip Array Technology ensures you are able to effortlessly add to your testing program



#### Adaptability

- Multiple sample types can be used on one analyser including serum, plasma, cerebrospinal fluid, whole blood, urine, oral fluid and food diagnostics for veterinary drug residues
- Allows the user to easily extend testing as new tests can be added without additional equipment

## SUPERIOR REPORTING



#### **Retrospective Reporting**

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

## ADAPTABLE, EFFICIENT & COMPREHENSIVE

The Evidence Investigator is a compact, semi-automated benchtop analyser that offers efficient and comprehensive testing across a range of applications including clinical diagnostics, molecular, research, toxicology and food diagnostics.

Renowned for its versatility, robustness and effective reporting methods, the Evidence Investigator has been used in a wide range of laboratory settings for over 15 years. This highly advanced yet simple to use analyser has only one moving part, giving the user peace of mind. The Evidence Investigator contains a host of innovative on-board data analysis features ensuring manual processes are kept to a minimum.

Offering efficiency without compromising on accuracy, the Evidence Investigator is the perfect fit for medium throughput laboratories seeking maximum use of benchspace.









## ACCURATE AND ROBUST

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Results are generated using a Charge Coupled Device (CCD) camera, which quantifies chemiluminescent light. This light measures the degree of binding between the sample and specific biochip bound ligands.

The Evidence Investigator is extremely well equipped to provide reliable results, while simultaneously robust enough to withstand frequent, heavy use.



## UNIQUE CONSOLIDATION



The Evidence Investigator is the world's first platform allowing consolidation of immunoassay and molecular diagnostics. This is achieved through utilising protein and DNA based biochips. By giving the user the ability to consolidate tests, the Evidence Investigator improves laboratory efficiency and reduces costs.



## ADVANCED ANALYSIS AND REPORTING METHODS



The Evidence Investigator image processing software translates light signal generated from chemiluminescent reactions into analyte concentration. This removes the need for any manual processing of data.

The Evidence Investigator also has the ability to retrieve previously unreported tests so they can be tested retrospectively. This saves time, labour costs and reduces any reagents wastage. All data is then analysed on-board, removing issues related to human error and result manipulation.



## EVIDENCE INVESTIGATOR PACKAGE



The Evidence Investigator comes supplied as part of a package, with all essential components provided. These components are approved for use with the Evidence Investigator and make it easier for the user to conduct testing.



Biochip carrier handling tray







Thermoshaker



PCR (Molecular Only)



Barcode scanner

## IMMUNOASSAY TESTING PROCESS



03 • Technical Information

## SOFTWARE







#### On-board data analysis

- No manipulation of results required
- Reduces the risk of operator error
- Rapid results improves workflow

#### Simplicity

- Minimal training required
- Highly intuitive operating system
- Colour-coded sample addition

#### Flexibility

- Multi-format option for results review e.g. by array, by users, by date or sample code
- Fully printable reports

#### Retrospective testing

- Retrieve previously unreported tests
- Reduces reagent wastage
- Saves time and labour costs

#### Storage facilities

- Store up to 20,000 sample results
- Store up to 500,000 sample test results

#### Highly secure

- Password protected for various user levels
- Full traceability of data

#### Extensive QC capabilities

• Internal QC software included with Levey-Jennings charts multi-point QC rules and auto flagging of outliers

#### Connectivity

• LIMS integrated for convenient reporting

#### Service

- Easy troubleshooting process
- Regular system checks to continually assure the operator of optimum system performance

## SPECIFICATIONS

Accreditation	Internally accredited to full CE and UL certification
Analyser description	Semi-automated Biochip Array Analyser
Biochip capacity	9 biochips on Evidence Investigator, 54 biochips on Thermoshaker
Calibration method	9 point calibration
Connectivity	LIMS integration

Data back-up methods	Via writable DVD, CD, USB Mass-storage or Network folder
Environment	Operating temperature 16 to 25°C Relative Humidity < 80% Altitude < 2000m Pollution degree 2 (IEC 664)
Fuses	Mains Inlet Fuse (FI) T 2 A H 250V (20mm x 5mm) Motor Control Board (FI) T I A L 250V (20mm x 5mm)
Incubation time	Array-specific, 30–90 minutes
Installation requirements	Evidence Investigator must be connected to a single-phase power supply
Measurement principal	Chemiluminescent
Network services	Highly Secure Remote Diagnostics, automated software and array updates
Peripherals	Printer, barcode scanner, carrier handling tray, thermoshaker and thermocycler (molecular only)
Quality control	Levey-Jennings, user definable multipoint rules
Reagent volume	Array specific, details supplied in kits

03 • Technical Information

## EQUIPPED TO PROVIDE RELIABLE RESULTS AND ROBUST ENOUGH TO WITHSTAND FREQUENT, HEAVY USE

Sample loading	Single carrier loading bay
Sample throughput	Array specific
Sample type	Array specific including serum, plasma, whole blood, urine, tissue, feed, honey, milk, egg, cell culture supernatant, cerebrospinal fluid, oral fluid, bronchoalveolar lavage fluid, forensic matrices
Sample volume	Array specific; 25–150µl
Start up / shut down time	On command
Time to first result	Array specific
Input voltage	Supply Voltage 100–120Vac, 60Hz, 22VA 200–240Vac, 50Hz, 30VA Installation category II Camera Power Supply 100–240Vac, 47–63Hz, 1.35A
UPS	Recommended
Water quality	CLSI Type II or better

## MOLECULAR TESTING

Our molecular product range offers diagnostic, prognostic and predictive solutions across a variety of disease areas including sexually transmitted infection (STI), respiratory tract infection, colorectal cancer, familial hypercholesterolemia (FH) and cardiovascular disease (CVD). Additionally, we can provide a wide range of assay formats including single nucleotide polymorphisms (SNP) genotyping, pathogen detection and mutation detection.



#### Pathogen Detection

#### STI and Respiratory Multiplex Arrays

Both arrays detect the most common and frequently requested infections in sexual and respiratory health. These comprehensive, highly sensitive and specific tests enable identification of co-infections simultaneously, often in asymptomatic patients and enable antibiotic stewardship.



#### Mutation Detection

#### KRAS, BRAF, PIK3CA Array and Familial Hypercholesterolemia Arrays I & II

These unique biochip assays permit high discrimination between multiple targets in a number of genes with a rapid turnaround time (3 hours). The arrays enable detection of the most frequently occurring mutations known to cause disease (FH) and adversely affect patient treatment (KRAS, BRAF, PIK3CA). A unique primer set is designed for each target which will hybridise to a complementary oligo-nucleotide probe spotted on a biochip discrete test region (DTR).



## SNP Genotyping

#### Cardiovascular Risk Prediction Array

This array identifies individuals with a genetic predisposition to coronary heart disease (CHD). The innovative multiplex primers are designed to discriminate DNA sequences which differ only at one base.

## MOLECULAR TESTING PROCESS



## IMMUNOASSAY TEST MENU

#### Adhesion Molecules

E-Selectin Intercellular Adhesion Molecule-I – ICAM-I L-Selectin P-Selectin <u>Vascular Cell Adhesion</u> Molecule-I – VCAM-I

#### Alzheimer's

Apolipoprotein E4 – ApoE4 Pan Apolipoprotein E – Apo E

#### Anaemia

Ferritin Folate Vitamin Bl2

#### Bone Disease

Vitamin D

#### Cancer

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

#### Cardiac

Cardiac Troponin I – cTnl 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- $\gamma$  – IFN- $\gamma$ Interleukin-I alpha – IL-1 $\alpha$ Interleukin-I beta – IL-1 $\beta$ Interleukin-2 – IL-2 Interleukin-3 – IL-3

#### Cytokines Continued

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-Ia - MIP-Ia Matrix Metalloproteinase 9 - MMP 9 Monocyte Chemotactic Protein-I - MCP-I Soluble IL-2 Receptor Alpha - sIL-2Ra Soluble IL-6 Receptor - sIL-6R Soluble Tumour Necrosis Factor Receptor I - sTNFRI Soluble Tumour Necrosis Factor Receptor 2 - sTNFR2 Tumour Necrosis Factor-a - TNF-a 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-I Resistin

#### Renal

#### Adiponectin

Complement C3a des Arginine – C3a des Arg C-Reactive Protein – CRP Cystatin C D-Dimer Epidermal Growth Factor – EGF Liver Fatty Acid Binding Protein-I – FABPI Interleukin-8 – IL-8 Macrophage Inflammatory Protein-Iα – MIP-Iα Neutrophil Gelatinase – Associated Lipocalin – NGAL Soluble Tumour Necrosis Factor Receptor I – sTNFRI 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 I – sTNFRI

#### 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

#### Tissue Damage

Liver Fatty Acid Binding Protein-I – FABPI 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 TEST MENU

#### Analgesics

#### Acetaminophen Buprenorphine Dextromethorphan Fentanyl Generic opioids Ibuprofen Meperidine Methadone Opiates Oxycodone Oxycodone I Oxycodone II Phencyclidine (PCP) Pregabalin Propoxyphene Salicylate Tramadol

#### Antidepressants

Escitalopram Fluoxetine Haloperidol Methylphenidate / Ritalinic acid Sertraline Trazodone Tricyclic Antidepressant

#### New Psychoactive Substances

AB-PINACA AB-CHMINACA Acetyl Fentanyl AH-7921 Alpha-PVP Carfentanil Furanyl Fentanyl JWH- 018 Mephedrone Mescaline Mitragynine MT-45

## New Psychoactive Substances Continued

Naloxone	
Ocfentanyl	
Phenylpiperazine I	
Phenylpiperazine II	
Salvinorin	
Sufentanil	
U-47700	
UR-144	
W-19	
Stimulants	

6-MAM		
Amphetamine		
Benzoylecgonine (Cocaine Metabolite)		
Benzylpiperazine		
Cannabinoids (THC)		
LSD		
MDMA		
Methamphetamine		

#### Sedative Hypnotics

Barbiturates
Benzodiazepines I
Benzodiazepines II
Chloral Hydrate Metabolite
Clonazepam
Etizolam
 Flunitrazepam
Ketamine
Meprobamate
Methaqualone
Zaleplon
Zolpidem
Zopiclone

#### Other

Creatinine EtG Gabapentin Methotrexate

## MOLECULAR TEST MENU

#### Cardiac Risk Prediction Array

#### 20 SNPs

#### Familial Hypercholesterolemia (FH) Arrays

LDLR – 38 mutations APOB – I mutation <u>PCSK</u>9 – I mutation

#### KRAS, BRAF, PIK3CA Array

KRAS – 16 mutations BRAF – 1 mutation PIK3CA – 3 mutations

#### **Respiratory Pathogens Array**

Adenovirus A Adenovirus B Adenovirus C Adenovirus D Adenovirus E Coronavirus 229E/NL63 Coronavirus OC43/HKUI Enterovirus A Enterovirus B Enterovirus C Human Bocavirus I Human Bocavirus 2 Human Bocavirus 3 Human Metapneumovirus – hMPV Influenza A Influenza B Parainfluenza Virus I Parainfluenza Virus 2 Parainfluenza Virus 3 Parainfluenza Virus 4 Respiratory Syncytial Virus a – RSVa Respiratory Syncytial Virus b - RSVb

#### Respiratory Pathogens Array Continued

Rhinovirus A Rhinovirus B Bordetella pertussis Chlamydophila pneumoniae Mycoplasma pneumoniae Legionella pneumophila Moraxella catarrhalis Streptococcus pneumoniae Haemophilus influenzae

#### Sexually Transmitted Infection (STI) Array

Chlamydia trachomatis – (CT) Haemophilus ducreyi – (HD) Mycoplasma genitalium – (MG) Mycoplasma hominis – (MH) Neisseria gonorrhoea – (NG) Treponema pallidum – (TP) Trichomonas vaginalis – (TV) Ureaplasma urealyticum – (UU) Herpes simplex Virus I – (HSV-1) Herpes simplex Virus 2 – (HSV-2)

## FOOD DIAGNOSTICS TEST MENU

#### Antimicrobial Array I Ultra

#### Antimicrobial Array IV (Continued)

Sulphadimethoxine Tobramycin Sulphadiazine Sulphadoxine Spectinomycin Sulphachlorpyridazine Lincosamides Sulphamethoxypyridazine Sulphamerazine Erythromycin Sulphisoxazole Sulphathiazole Virginiamycin Sulphamethazine Sulphaquinoxaline Sulphapyridine Nitroimidazoles Sulphamethoxazole Chloramphenicol Sulphamonomethoxine Trimethoprim Dapsone

#### Antimicrobial Array II Plus

Quinolones Ceftiofur Thiamphenicol Streptomycin Tylosin Tetracyclines

#### Antimicrobial Array III

AOZ AMOZ AHD SEM

#### Antimicrobial Array III (CAP Only)

Chloramphenicol

#### Antimicrobial Array IV

Spiramycin/Josamycin Apramycin Bacitracin Neomycin/Paramomycin

# Tylosin B/Tilmicosin Amikacin/Kanamycin Streptomycin/Dihydrostreptomycin

#### Antimicrobial Array V

#### Anthelmintics Array

**Benzimidazoles** Amino Benzimidazoles Thiabendazole Triclabendazole Levamisole Moxidectin Avermectins

#### Avermectins Only Array

Avermectins

#### Beta Lactams Array Plus

Beta Lactam Cephalexin Cefuroxime

#### **Coccidiostats Array**

Clopidol Decoquinate Diclazuril Halofuginone Imidocarb Lasalocid Maduramicin

#### Coccidiostats Array (Continued)

Monensin Nicarbazin Robenidine Salinomycin

Toltrazuril

#### **Growth Promoter**

Beta-Agonists Boldenone Corticosteroids Nandrolone Ractopamine Stanozolol Stilbenes Trenbolone Zeranol

#### InfiniPlex for Milk

Quinolones Beta-Lactams Cephalexin Erythromycin Spiramycin Tylosin Lincomycin Pirlimycin Neomycin Streptomycin Gentamicin Kanamycin Spectinomycin Amphenicols Trimethroprim Baquiloprim Rifaximin Apramycin Virginiamycin Tobramycin Tetracyclines Polymixins

#### InfiniPlex for Milk (Continued)

Bacitracin Cefuroxime 5-hydroxy Flunixin Meloxicam Metamizole Tolfenamic Acid Phenylbutazone Chlormadinone Methylprednisolone Sulphapyridine Dapsone Melamine Nitroxynil Aflatoxin MI Sulphonamides Novobiocin Ractopamine Dexamethasone Hygromycin B Sulfaguanidine Sulphamethazine

#### Myco 10 Array

Aflatoxin BI Aflatoxin GI Deoxynivalenol Diacetoxyscirpenol Ergot Alkaloids Fumonisins Ochratoxin A Paxilline T2 Toxin Zearalenone

#### Synthetic Steroids Array

Methyltestosterone 17β-Clostebol Gestagens Ethinylestradiol

## 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

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



## WHY BUY EVIDENCE INVESTIGATOR?



Test Menu

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

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Consolidation

Multiplex testing allows multiple tests to be carried out from a single undivided sample



Speed

Faster sample processing time than leading competitors



Serum, plasma, whole blood, urine, tissue, egg, feed, honey, milk, cerebrospinal fluid, saliva and forensic matrices



Adaptability

Suitable for clinical, molecular, food and toxicology testing



Throughput of up to 2376 tests per hour

## ADAPTABLE, EFFICIENT & COMPREHENSIVE



Randox Investigator

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