



Evidence Investigator

Multiplexing... Proven, Perfected, Evolved The first biochip analyser for protein and molecular arrays



Evidence Investigator

Versatile, efficient and comprehensive testing

The Evidence Investigator offers complete patient profiling with the most comprehensive test menu on the market. Consolidates immunoassay and molecular diagnostics on a single platform with protein and DNA biochips.

Utilising revolutionary Biochip Array Technology, the Evidence Investigator allows simultaneous detection of multiple analytes from a single sample for efficient and cost effective testing.

The Evidence Investigator is a compact, semi-automated bench top platform applicable in a wide range of settings including:

- Pharma and drug development: Pre-clinical and clinical studies
- Private/Public sector research applications
- Environmental laboratories
- Drug Residue testing
- Veterinary laboratories
- Forensic/Drugs of Abuse testing
- Clinical laboratories



Randox biochips can support up to 22 assays per biochip.



Addition of assay reagents and sample to the biochips

Full reagent package provided. No hidden costs or extra consumables needed.

Multiple results can be obtained simultaneously from as little as 25µl of sample. Up to 45 samples and nine calibrators can be analysed per run.



54 biochips placed in custom thermoshaker

The custom thermoshaker provides the optimum heating environment for samples. The heated lid provides faster heatup times, bi-directional heating, increased temperature range and standardisation of assay incubation conditions.

The Evidence Investigator package



Biochip imaging module



PC & imaging software



Thermoshaker



Barcode scanner



Biochip carrier handling tray



Washing of biochips

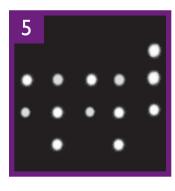
The washing procedure is quick and easy and is performed using a wash bottle.



Biochip carrier loaded into Evidence Investigator

Signal reagent is added to each biochip before imaging.

It only takes 2 minutes for the CCD camera to image each biochip carrier.



Discrete test sites on each biochip for individual analytes

The light signal generated from each of the discrete test regions on the biochip is simultaneously detected.

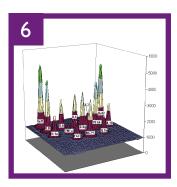


Image processing

The analyser uses unique image processing software to translate the light signal generated from the chemiluminescent reactions into an analyte concentration.

No manual processing of data required.

Why Evidence Investigator?

Industry leading technology for high quality results

Save time - save costs

 Multiplex testing allows multiple tests to be carried out from a single patient sample reducing the amount of time and labour spent on individual tests

Consolidation on one system

- The world's first platform allowing consolidation of immunoassay and molecular diagnostics with protein and DNA based biochips
- Creating cost savings and improving laboratory efficiency

World's most diverse test menu

- More tests available than any other sole supplier
- Routine and novel markers available

Result traceability

- Chain of custody features
- Bar-coded reagents and calibrators



Complete patient profiling

- Multiplex testing with Biochip Array Technology allows clinicians and investigators to consider the complete picture
- Allowing for well informed decisions and accurate diagnosis

Optimum laboratory efficiency

- Multi-analyte controls and calibrators available for accurate and reliable laboratory testing
- Compact bench top system saves valuable laboratory space



Reduced sample volume

- Analyse a complete profile of biomarkers from as little as 25µl of sample
- Ideal for paediatric testing
- · Saves patient distress

High throughput

- The Evidence Investigator has the ability to process 630 tests in 70 minutes using the protein arrays
- It can also detect up to 23 mutations, SNPs or pathogens in as many as 54 samples at once, in as little as three hours for molecular applications

Quality results

- Inter and intra-assay CV's typically less than 10%
- Extensive QC capabilities with multi-analyte controls and calibrators available
- User defined reference ranges
- Quantitative and qualitative results available

Multiple matrices available

 Full analyser package includes biochip imaging module, PC and imaging software, thermoshaker, biochip carrier handling tray and barcode scanner

No hidden costs

- Protein arrays: all inclusive kits including reagents, biochips, buffer and multi-analyte calibrators
- Straightforward testing procedure, reducing operator error

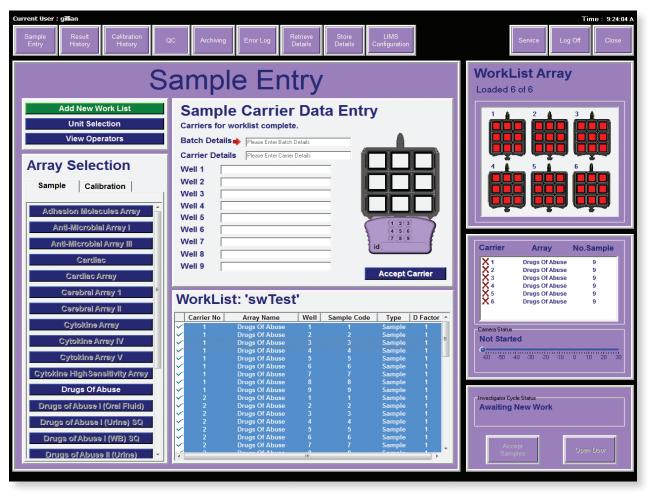
Ease of operation

- Ready to use biochips
- Minimal sample handling

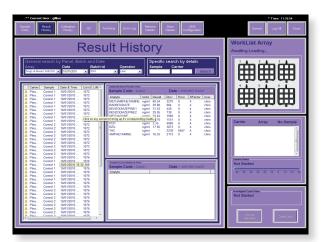
 Protein arrays: serum, plasma, whole blood, urine, tissue, egg, feed, honey, milk, cell culture supernatant, stool, saliva, bronchoalveolar lavage fluid and forensic matrices

Software

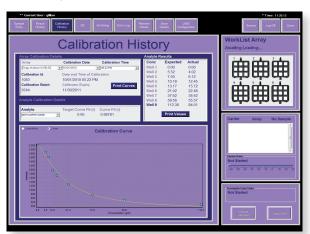
State of the art technology



Sample Entry screen



Results History screen



Calibration screen

On-board data analysis

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

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

Retrospective testing

- Allows the user to retrieve previously unreported tests
- Reduces reagent wastage
- Saves time and labour costs

Highly secure

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

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
- User defined reference ranges
- Fully printable reports

Storage facilities

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

Service

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

Molecular Arrays

providing diagnostic, prognostic and predictive solutions for a range of conditions including sexually transmitted infection, respiratory infection, coronary heart disease (CHD),

Randox Molecular Diagnostics (MDx) offers familial hypercholesterolemia and colorectal a range of molecular arrays and assay formats, cancer with many more applications currently in development. The versatility of the Randox multiplex PCR and proprietary Biochip Array Technology is exemplified by the broad range of array formats available.

Molecular Array Protocol Outline



Benefits of the Respiratory Pathogen Array

- Semi-quantitative testing allowing determination of primary infection
- Comprehensive profile of pathogens identifies secondary or multiple infections which may otherwise remain untreated
- Rapid turnaround time of five hours
- May prevent the spread of infection through early and more appropriate intervention
- May reduce antibiotic misuse
- Reduced sample requirement of particular relevance to young and infirm patients
- Compatible with various sample matrices
- Increased specificity through biochip hybridisation
- Spatial separation on biochips allows clear diagnosis

Benefits of the STI Array

- Simultaneously detect up to 10 STIs from a single patient sample
- Save time and cost associated with single infection detection
- Reduced sample requirements
- Detection of asymptomatic co-infections
- Added specificity due to combination of stringent PCR and array hybridisation
- Rapid turnaround time from sample to result in less than five hours
- Clear and easy results interpretation
- Internal controls for the three critical assay steps
- Ability to test DNA from multiple sample matrices
- Use existing automated extraction methodology
- 54 patient samples can be processed simultaneously, with multiple runs possible in one working day

Benefits of the KRAS, BRAF, PIK3CA Array

- Streamlined workflow protocol and reagents are optimised for the molecular laboratory
- \bullet Compatible with a broad range of genomic DNA input and type:
- Formalin fixed paraffin embedded (FFPE) tissue
- Fresh/frozen tissue
- Detection of 1% mutant in a background of wildtype genomic DNA
- Single DNA sample required
- Single reaction multiplex PCR coupled to a biochip provides greater mutation coverage of the three most important genes (KRAS, BRAF and PIK3CA) implicated in metastatic colorectal cancer therapy response
- Turnaround time of three hours

Benefits of the Familial Hypercholesterolemia Array

- The FH array is a rapid simple method for determining mutational status
- Samples can be assessed in small batches (as low as three samples)
- Easy to interpret results using the Evidence Investigator dedicated software
- Turnaround time of three hours
- Streamlined workflow protocol and reagents optimised for the molecular laboratory
- System can be used to detect single base changes, insertions and deletions, within the same multiplex PCR
- Only 20ng of genomic DNA required

Benefits of the Cardiac Risk Prediction Array

To the patient

- Randox Cardiac Risk Prediction Array is a rapid simple method for reliable genetic risk assessment of CHD
- Combined with common risk factors, the array allows more accurate classification and preventative actions to be taken
- Identifies patients genetically predisposed to statin-induced myopathy

To the laboratory

- Simple and rapid protocol allows a patient sample to be genotyped in one day
- Streamlined workflow protocol and reagents optimised for the molecular laboratory
- 36 patient samples can be processed per kit
- Easy to interpret results using Randox Evidence Investigator dedicated software
- All 19 SNPs can be genotyped simultaneously

Immunoassay Arrays

Highly accurate testing

- BAT has a proven high standard of accurate test results with CV's <10%
- Multiplex analysis minimises analytical variation between tests

Better patient diagnosis

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

Optimum efficiency

 Multi-analyte reagents and quality control material, provides highly efficient testing while eliminating any wastage

Assay formats

Protein / Antibody assay formats

Competitive immunoassay

In a competitive immunoassay, the more analyte present in a sample, the less labelled conjugate that will bind to the immunoreaction site. Therefore the signal produced will be low. If there is little analyte in the sample, more labelled conjugate will bind to the capture antibody resulting in a higher signal.

Sandwich immunoassay

In a sandwich immunoassay, the more analyte present in a sample, the more conjugate will bind to the capture antibody. As a result, the signal will be high. Conversely, lower signal is produced when the concentration of analyte in the sample is low.

Antibody Capture

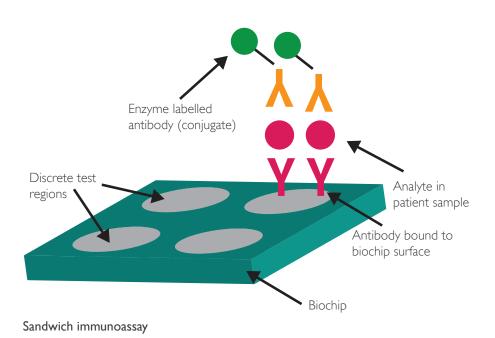
In this methodology antigens are prefabricated onto the surface of the biochip and antibodies in the sample are then bound.

Small sample volume

- Reduced sample volume requirements puts the patient at ease
- Patient profiling saves precious sample if further analysis is required

Cost consolidation

 Multiplex testing reduces the amount of time spent on individual tests and associated laboratory costs



Multiple sample types

- Multiple sample types can be used on one analyser including serum, plasma, whole blood, urine, oral fluid and alternative matrices
- This allows the clinician to offer flexible patient testing

Result traceability

 Bar-coded biochips and patient samples ensure complete traceability of results

Retrospective reporting

• Retrieve previously unreported results without additional testing, saving time

Wide and varied test menu

• Randox's vast biochip test menu allows clinicians to detect routine and novel markers for advanced diagnostic analysis

Extensive Quality Control features

- Internal quality control markers on every biochip ensure optimum assay performance
- Comprehensive Quality control data is automatically created and displayed with every patient result

Biochip test menu

The world's largest and most diverse test menu

Clinical Arrays

Cardiac Array

Creatine-Kinase Muscle Brain (CK-MB) Heart Type Fatty Acid Binding Protein (H-FABP) Myoglobin (Myo) Troponin I (cTnI)

Thyroid Total Array

Thyroid Stimulating Hormone (TSH) Total Thyroxine (TT4) Total Tri-iodothyronine (TT3) Estradiol (EST)

Follicle Stimulating Hormone (FSH) Luteinising Hormone (LH) Progesterone (PROG) Prolactin (PRL) Testosterone (TEST) Free Thyroxine (FT4)
Free Tri-iodothyronine (FT3)
Thyroid Stimulating Hormone (TSH)

Tumour PSA Array

Carcinoembryonic Antigen (CEA) Free Prostate Specific Antigen (fPSA) Total Prostate Specific Antigen (tPSA)

Applications available for serum and/or plasma

Fertility Hormone Array Additional Tests

Anti-Tg Anti-TPO Beta Crosslaps B-HCG CA 125 CA 15-3 CA 19-9 Carbamazepine Digitoxin Folate Gentamicin Growth hormone Intact PTH Methotrexate Osteocalcin Phenobarbital Phenytoin

Thyroid Free Array

Sex Hormone-Binding Globulin (SHBG)
Thyroglobulin (Tg)

Theophylline Tobramycin Valproic Acid Vancomycin Vitamin B12 Vitamin D CAIII GPBB

Research Arrays

Adhesion Molecules Array

E-Selectin L-Selectin P-Selectin

Digoxin

Intercellular Adhesion Molecule-I (ICAM-I) Vascular Cell Adhesion Molecule-I (VCAM-I)

Cerebral Array I

Brain-Derived Neurotrophic Factor (BDNF) Glial Fibrillary Acidic Protein (GFAP) Heart Type Fatty Acid Binding Protein (H-FABP) Interleukin-6 (IL-6)

Cerebral Array II

C-Reactive Protein (CRP)

D-dimer

Neuron Specific Enolase (NSE)

Neutrophil Gelatinase-Associated Lipocalin (NGAL) Soluble Tumour Necrosis Factor Receptor I (sTNFRI)

Cytokine Array I

Epidermal Growth Factor (EGF)

Interferon- γ (IFN- γ)

Interleukin- $I\alpha$ (IL- $I\alpha$) Interleukin- $I\beta$ (IL- $I\beta$)

Interleukin-2 (IL-2)

Interleukin-4 (IL-4)

Interleukin-6 (IL-6)

Interleukin-8 (IL-8)

Interleukin-10 (IL-10)

Monocyte Chemotactic Protein-I (MCP-I) Tumour Necrosis Factor- α (TNF- α)

Vascular Endothelial Growth Factor (VEGF)

 $(High\ sensitivity\ Array\ on\ Evidence\ Investigator\ only)$

Cytokine Array II

Eotaxin

Insulin like Growth Factor I, Free (IGF-I (free) Interleukin-I Receptor Antagonist (IL-IRa) Interleukin-I2/23-p40 (ILI2/23-p40) Interferon-y-Inducible Protein I0 (IP-I0) Platelet Derived Growth Factor BB (PDGF-BB) Regulated on Activation, Normal T Expressed and Secreted (RANTES)

Cytokine Array III

Granulocyte Macrophage Colony Stimulating Factor (GM-CSF)

Interleukin-5 (IL-5)
Interleukin-15 (IL-15)

Macrophage Inflammatory Protein - $I\alpha$ (MIP- $I\alpha$)

Cytokine Array IV

Matrix Metalloproteinase-9 (MMP-9) Soluble IL-2 Receptor α (sIL-2R α) Soluble IL-6 Receptor (sIL-6R) Soluble Tumour Necrosis Factor Receptor I (sTNFRI) Soluble Tumour Necrosis Factor Receptor II (sTNFRI)

Cytokine Array V (On Evidence Investigator only)

Interleukin-3 (IL-3) Interleukin-7 (IL-7) Interleukin-13 (IL-13) Interleukin-12p70 (IL-12p70) Interleukin-23 (IL-23)

Endocrine Array

Cortisol

Dehydroepiandrosterone Sulphate (DHEAs)

 17α Hydroxyprogesterone

Metabolic Syndrome Array I

C-peptide Ferritin

Interleukin-1 α (IL-1 α)
Interleukin-6 (IL-6)

Leptin

Plasminogen Activator Inhibitor-1 (PAI-1)

Tumour Necrosis Factor- α (TNF α)

Metabolic Syndrome Array II

Adiponectin

C-Reactive Protein (CRP)

Cystatin C

Molecular Arrays available on Evidence Investigator only

Respiratory Multiplex Array

Influenza A

Influenza B

Human adenovirus A/B/C/D/E Human bocavirus 1/2/3 Human coronavirus 229E/NL63 Human coronavirus OC43/HKU1 Human enterovirus A/B/C Human metapneumovirus Human parainfluenza virus I Human parainfluenza virus 2

Human respiratory syncytial virus A Human respiratory syncytial virus B Human rhinovirus A/B

Chlamydophila pneumoniae Haemophilus influenza Legionella pneumophila Moraxella catarrhalis Mycoplasma pneumoniae Staphylococcus aureus Streptococcus pneumoniae

STI Multiplex Array

Chlamydia trachomatis Neisseria gonorrhoea Herpes simplex I Herpes simplex II

Treponema pallidum (Syphilis) Trichomonas vaginalis Mycoplasma hominis Mycoplasma genitalium Ureaplasma urealyticum Haemophilus ducreyi

K-RAS/BRAF/PIK3CA Array

K-RAS BRAF PIK3CA

Cardiac Risk Prediction Array

Familial Hypercholesterolemia Array

Human parainfluenza virus 4 Toxicology Arrays

Human parainfluenza virus 3

Drugs of Abuse Array I Plus

Amphetamine Barbiturates Benzodiazepine I Benzodiazepine 2 Buprenorphine Cannabinoids

Cocaine metabolite (Benzoylecgonine)

MDMA Methadone Methamphetamine **Opiates** Phencyclidine

Tricyclic Antidepressants (TCAs Generic)

Drugs of Abuse Array II

Buprenorphine Fentanyl Generic Opioids Ketamine LSD Methaqualone MDMA

Oxycodone I Oxycodone 2 Propoxyphene Drugs of Abuse Array III

Chloral Hydrate Metabolite

Ethyl Glucuronide Fentanyl Ketamine Metabolite Meperidine Meprobamate Zaleplon Zolpidem Zopiclone

Flunitrazepam

Drugs of Abuse Array IV

Acetaminophen Dextromethorphan Escitalopram Ethyl Glucuronide Fluoxetine Haloperidol Ibuprofen Methylphenidate Salicylate Sertraline Tramadol

Trazodone Tricyclic Antidepressants (TCAs Generic) Drugs of Abuse Array V

Bath Salts I (Methcathinone + Mephedrone)

Bath Salts II (MDPV) Benzylpiperazines Mescaline Phenylpiperazines I Phenylpiperazines II Salvinorin

Synthetic Cannabinoids I Synthetic Cannabinoids II Synthetic Cannabinoids III Synthetic Cannabinoids IV

Applications available for urine, whole blood, oral fluid and a wide

range of forensic matrices.

(for urine applications creatinine is included as a dilution marker)

Food Diagnostics Arrays

Anthelmintics Array

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

Anti-Microbial Array I Plus

Sulphachlorpyridazine Sulphadiazine Sulphadimethoxine Sulphadoxine Sulphamerazine Sulphamethazine Sulphamethizole Sulphamethoxazole Sulphamethoxypyridazine Sulphamonomethoxine Sulphapyridine Sulphaguinoxaline Sulphathiazole Sulphisoxazole Trimethoprim

Anti-Microbial Array II

Ceftiofur

Quinolones (generic) Florfenicol/Thiamphenicol Streptomycin/Dihydrostreptomycin Tetracyclines (generic) Tylosin/Tilmicosin

Anti-Microbial Array III

AMOZ AO7

Chloramphenicol

SFM

Anti-Microbial Array III (Chloramphenicol only) Chloramphenicol

Chloramphenicol Glucuronide

Anti-Microbial Array IV

Amikacin Apramycin Bacitracin Clindamycin Desmycosin Erythromycin Gentamicin Hygromycin losamycin Kanamycin Lincomycin Neomycin Paromomycin Pirlimycin Roxithromycin Spectinomycin Spiramycin

Streptomycin/Dihydrostreptomycin

Tobramycin Tylosin/Tilmicosin Virginiamycin

Coccidostats Array

Amprolium Clopidol Decoquinate Diclazuril Halofuginone Imidocarb Lasalocid Maduramicin Monensin Nicarbazin Nifursol Robenidine Salinomycin/Narasin Semduramicin Toltrazuril

Growth Promoter Multiple Matrix Screen Array

β-agonists Boldenone Corticosteroids Nandrolone Ractopamine Stanozolol Stilbenes Trenbolone Zeranol

Growth Promoter Rapid Urine

Screen Array β-agonists Boldenone Corticosteroids Ractopamine Stanozolol Trenbolone Zeranol

Synthetic Steroids Array

Ethinylestradiol Gestagens Methlytestosterone 17β - Clostebol

Beta Lactam Array

Ampicillin Amoxicillin Cloxacillin Dicloxacillin Nafcillin Oxacillin Penicillin G Penicillin V Cefacetril Cefazolin Cefoperazone Cefquinome Ceftiofur Cephalexin Cephalonium Cephapirin

Unrivalled customer service

Our global network, ensuring local support

Local support

At Randox, we realise the importance of local support. Our global team of expert technical and applications staff ensure unbeatable customer service wherever you are in the world.

Time is critical in any laboratory, therefore you are our top priority. Dedicated specialists answer all your queries in a quick and thorough manner. With our field engineers on hand at any time, you can be sure of a fast response anywhere in the world.

Remote Access diagnostics

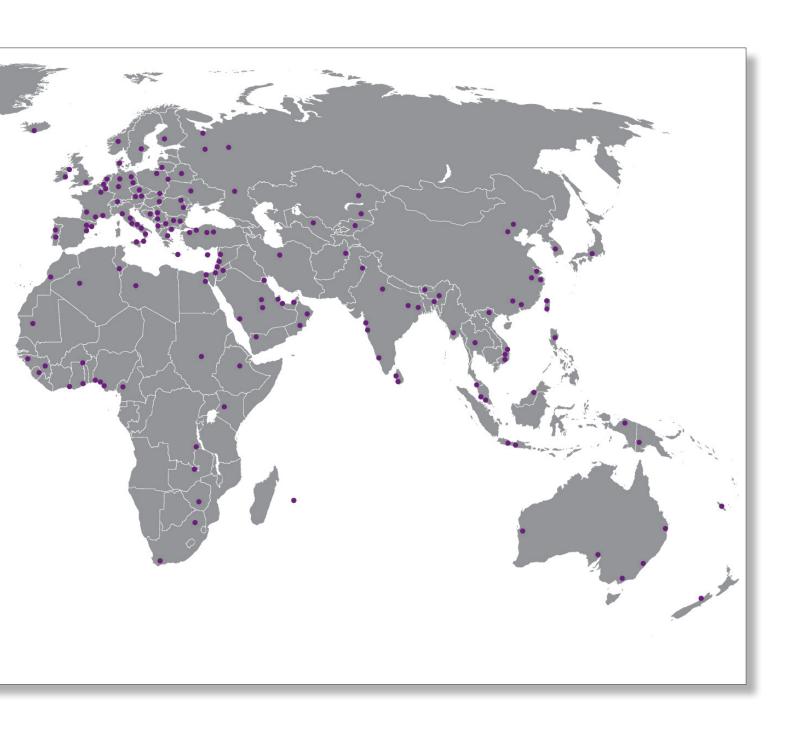
Our ground-breaking 'Remote Access' diagnostics allows immediate support of your system wherever, whenever, reducing downtime and ensuring you are operational as soon as possible.

Randox is committed to the smooth running of your laboratory, from the provision of quality products to unequalled customer support. We can access, diagnose and resolve many queries without the time and costs associated with call outs.





email: investigator.support@randox.com



Evolution of Evidence

A proven technology has evolved

The Evidence Investigator, one system for multiple applications in research, clinical, forensic and veterinary testing.

Biochip Array Technology, itself a revolution in immunoassay technology, has evolved continuously over the years, giving the world accurate, high quality results faster and more efficiently than any previous method. It enables clinicians and investigators to see the full picture with complete test profiles, whilst reducing labour, time and costs. Together,



Evidence Investigator

The Evidence Investigator brought Biochip Array Technology within reach of the smaller laboratory and extended the test menu to include molecular arrays.

Evidence

The original high throughput Evidence analyser still brings unrivalled benefits for batch analysis in the larger laboratory.

the technology and the analysers have evolved to allow application in fields as varied as clinical diagnostics, forensic toxicology, veterinary, drug residues, research and many more. Randox is committed to constant research and development, ensuring that you remain at the cutting edge of laboratory medicine.



Evidence Evolution

The Evidence Evolution is the world's first Random Access biochip testing platform, with advanced STAT testing capabilities.

Specifications

Physical Dimensions

 Height
 750mm, 29.5 in

 Depth
 480mm, 18.9 in

 Width
 420mm, 16.5 in

 Weight (TBC)
 24Kg, 52.9lbs

Performance Characteristics

Accreditation Internally accredited to full CE and UL certification

Analyser description Semi-automated Biochip Array Analyser

Biochip capacity Nine biochips on Evidence Investigator, 54 biochips on Thermoshaker

Biochip format Biochip Carrier holds nine individual biochips

Calibration method Nine 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 (F1) T 2 A H 250V (20mm x 5mm)

Motor Control Board (FI) T I A L 250V (20mm x 5mm)

Incubation time Array-specific, 30-60 minutes

Installation requirements Evidence Investigator must be connected to a single-phase power supply

Measurement principal Competitive, Sandwich and Antibody Capture techniques with Chemiluminescent reaction

Network services Highly Secure Remote Diagnostics, automated software and array updates

Peripherals Printer, barcode scanner, carrier handling rack, thermoshaker, PC and imaging software

Quality control Levey-Jennings, user definable multipoint rules

Reagent volume Array specific, supplied in kits
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, stool, oral fluid, bronchoalveolar lavage fluid, forensic matrices

Sample volume Array specific; 25-150µl

Start up / shut down time Fully automated procedure; 420 seconds to cool down to operating temperature and 150

seconds warm up

Time to first result Array specific

Power Requirements

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 Requirements

Water quality CLSI Type II or better

Catalogue No. / Ordering details

Evidence Investigator analyser EV3602

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