

# RANDOX

## EVIDENCE MULTISTAT

Emergency and Critical Care Management



EVIDENCE  
MULTISTAT

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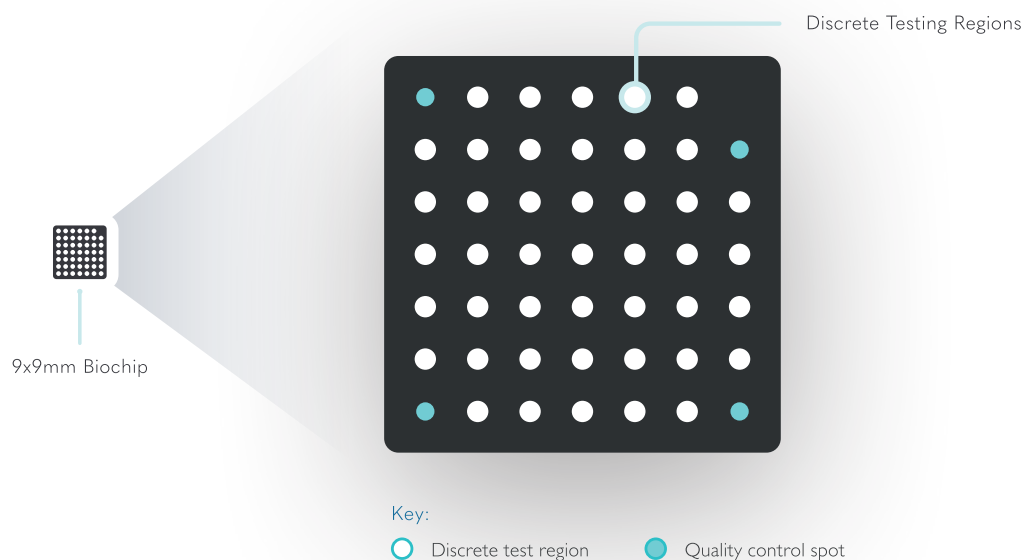
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# BIOCHIP ARRAY TECHNOLOGY

Biochip Array Technology enables rapid and precise detection of multiple analytes from a single patient sample.

The biochip is a solid-state device with discrete testing regions onto which antibodies specific to different analytes are immobilised and stabilised. Competitive or sandwich chemiluminescent immunoassays are then employed, offering a highly sensitive screen.



## Biochip in Numbers



**153 MILLION**

Tests performed globally using Biochip Array Technology.



**£440 MILLION**

Invested into Biochip Array Technology.



**203**

Number of patents across the Biochip product range.



**12,195**

Tests within the Biochip portfolio.

# Biochip Benefits



## Rapid Intervention

Immediately identify, triage and intervene in critically ill patients from just 30 minutes.



## Real-Time Monitoring

Monitoring patient response in real time and rapidly adjusting treatments allows for proactive care.



## Improved Patient Safety

Quicker and more targeted treatment enhances recovery rates and lowers mortality and morbidity.



## Shorter ICU Stays

Drastically decrease time spent in ICU, making more beds available for additional patients.



## Faster Precision Medicine

Improves treatment efficacy and reduces unnecessary exposure to broad-spectrum drugs.



## Resource Optimisation

Precision medicine reduces unnecessary use of supplies, shortens ICU stays and enables better use of staff resources.

# Critical Care Biochips

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## Risk Stratifying Biochips

Our stratifying biochips use AI algorithms to either phenotype illnesses, or triage patients from 'low' to 'high' risk of developing certain diseases.



### InflamiSTRAT

Stratifying patients into hyperinflammatory or hypoinflammatory phenotypes



### Neurovascular Dysfunction

Stratifying patients into stroke or non-stroke categories, and ischemic or haemorrhagic stroke phenotypes



### Kidney Dysfunction

Triaging patients from 'low' to 'high' risk of Acute Kidney Injury (AKI)

## Other Critical Care Biochips

Our other critical care biochips provide a quantitative measure of biomarkers and analytes.



### Hyperinflammation

Quantitatively measuring inflammation levels in critically ill patients



### Clinical Drug Testing

Quantitatively measuring up to 24 drugs of abuse per patient sample



### Single Analyte Assays

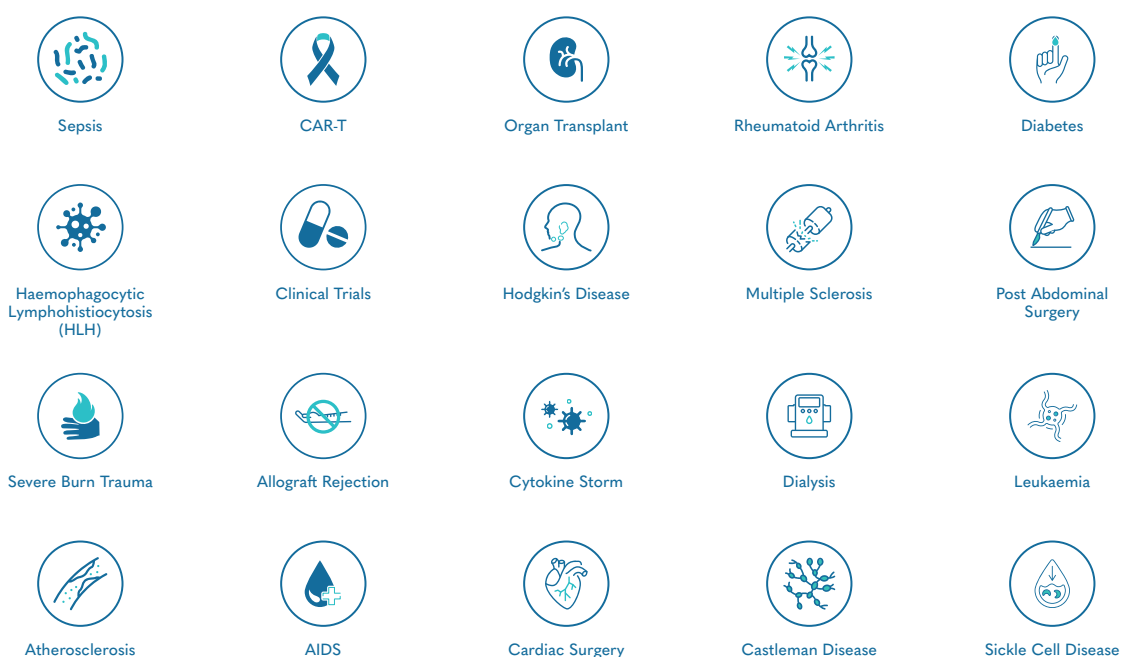
Quantitatively measuring; Midkine, DKK-1, IL-6 IL-18, CXCL9, and RAGE in ICU patients



# Hyperinflammation

The Hyperinflammation Biochip can aid intensive and critical care units to monitor the inflammation levels of critically ill patients. As clinicians apply various anti-inflammatory approaches, the patient's response can be monitored to ensure that the interventions are effective.

## Applications



## Biochip Performance

Biomarkers	Assay Range
Interleukin 1 beta (IL-1 $\beta$ )	0 - 250 pg/mL
Interleukin 2 (IL-2)	0 - 1000 pg/mL
Interleukin 6 (IL-6)	0 - 500 pg/mL
Interferon gamma (IFN- $\gamma$ )	0 - 500 pg/mL
Tumour Necrosis Factor alpha (TNF- $\alpha$ )	0 - 1000 pg/mL
Monocyte Chemoattractant Protein-1 (MCP-1)	0 - 500 pg/mL
Interleukin 15 (IL-15)	0 - 1000 pg/mL
Ferritin	0 - 1000 ng/mL
D-Dimer	0 - 4500 ng/mL

Used in research settings to date



## ACCURATE MONITORING OF IMMUNE RESPONSE

### Benefits



#### Early Detection and Severity Assessment

Increased levels of certain cytokines help in early identification of various illnesses and indicates the severity of hyperinflammation.



#### Rapid Intervention

Initiate therapeutic interventions quickly with results in under 60 minutes.



#### Real-time Monitoring

Monitoring patient response in real time and rapidly adjusting treatments allows for proactive care.



#### Shorter ICU Stays

Drastically decrease time spent in ICU, making more beds available for additional patients.

### Product Information



**Sample Type**  
Plasma



**Time to Result**  
<60 Minutes



**Sample Volume**  
400µl



**Result Type**  
Quantitative



**Samples Per Cartridge**  
2

# InflamiSTRAT

Studies have shown that clinicians can improve patient survival rates in acute respiratory distress syndrome (ARDS) by distinguishing between two consistently identified phenotypes.

It is crucial to identify inflammatory phenotypes quickly so that the clinician can make informed decisions regarding patient management options, which are essential in improving survival. The Evidence MultiSTAT InflamiSTRAT Biochip\* allows for fast and accurate detection of Interleukin-6 (IL-6) and Soluble Tumour Necrosis Factor Receptor 1 (sTNFR1), enabling the stratification of the ARDS phenotypes.

\*Used in conjunction with blood gas bicarbonate levels and separate algorithm

## Applications

Stratifies ARDS patients into:



or



Hyperinflammatory

Hypoinflammatory

## Biochip Performance

Biomarkers	Assay Range
Soluble Tumour Necrosis Factor Receptor-1 (sTNFR1)	0.6 – 20.1 ng/mL
Interleukin 6 (IL-6)	39.7 – 1337 pg/mL

# RAPID STRATIFICATION OF ARDS PATIENT PHENOTYPES

## Benefits



### Rapid Phenotype Identification

Stratification in just 36 minutes enables fast intervention and targeted treatment plans.



### Real-time Monitoring

Monitoring patient response to treatments in real time allows for rapid adjustments for proactive care.



### Reduced ICU Stays

A rapid precision medicine approach improves patient outcomes and reduces ICU stays.



### Resource Optimisation

Precision medicine reduces unnecessary use of supplies, shortens ICU stays and enables better use of staff resources.

## Product Information



**Sample Type**  
Plasma



**Time to Result**  
36 Minutes



**Sample Volume**  
250µl



**Result Type**  
Quantitative



**Samples Per Cartridge**  
2

# Neurovascular Dysfunction

The Neurovascular Dysfunction Biochip gives clinicians a greater understanding of conditions involving disruption of the blood-brain barrier and associated vasculature. This biomarker panel is currently useful in the following disease areas as a research tool.

## Applications



Epilepsy



Alzheimer's Disease



Brain Inflammation



Parkinson's Disease



Stroke Research



Down Syndrome



Brain Injury



Delirium

Studies have shown that Biochip can stratify patients into stroke and non-stroke categories, and ischaemic or haemorrhagic phenotypes.

CT scans provide good sensitivity for identifying haemorrhagic strokes (~90%), but poor sensitivity for identifying ischaemic strokes (~20%). The Neurovascular Dysfunction Biochip can be used in conjunction with MRI and CT scans to enhance the phenotype identification accuracy of stroke patients.

## Biochip Performance

Biomarkers	Assay Range
Glutathione S-transferase Pi (GSTPi)	0 - 200 ng/mL
Parkinson Disease Protein 7 (PARK7)	0 - 100 ng/mL
Nucleoside Diphosphate Kinase A (NDKA)	0 - 250 ng/mL
Glial Fibrillary Acidic Protein (GFAP)	0 - 100 ng/mL
Fatty Acid Binding Protein 3 (FABP3)	0 - 150 ng/mL
Interleukin 6 (IL-6)	0 - 500 pg/mL
Soluble Tumour Necrosis Factor Receptor-1 (sTNFR1)	0 - 25 ng/mL
D-Dimer	0 - 5000 ng/mL

# RAPID IDENTIFICATION AND STRATIFICATION OF BRAIN DISRUPTION

## Benefits



### Rapid Stroke Phenotyping

Enables stratification of patients into stroke or non-stroke categories, and ischaemic or haemorrhagic phenotypes.



### Facilitates Accurate Treatment Selection

Treatment pathways differ significantly between ischaemic or haemorrhagic phenotypes.



### Improved Patient Safety

Quicker appropriate treatment enhances recovery rates and lowers mortality and morbidity.



### Shorter ICU Stays

Faster identification, intervention and treatment can prevent complications and promote quicker recovery, shortening ICU stays.

## Product Information



**Sample Type**  
Plasma



**Time to Result**  
39 Minutes



**Sample Volume**  
400µl



**Result Type**  
Quantitative



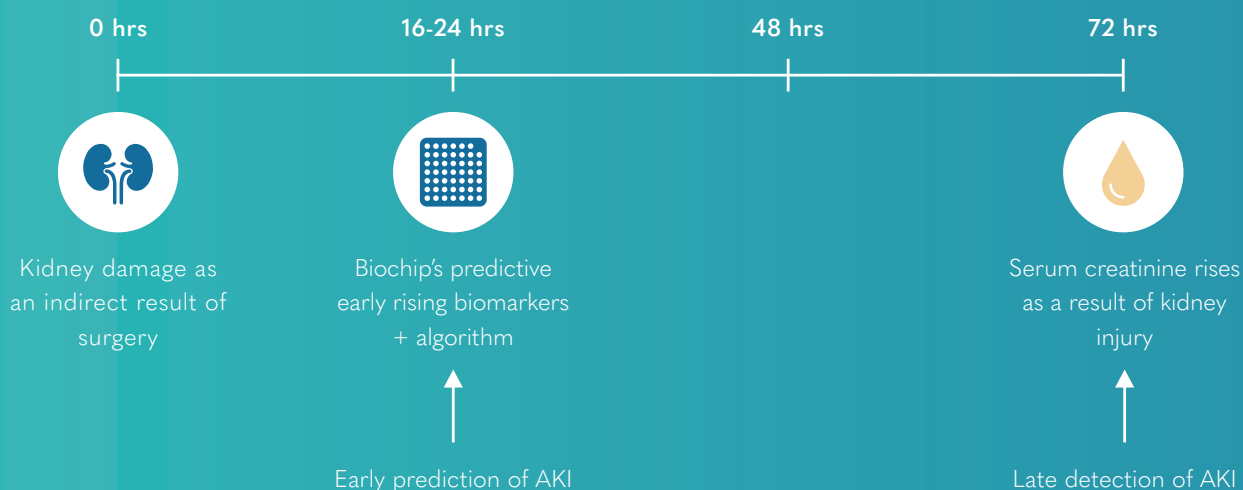
**Samples Per Cartridge**  
2

# Kidney Dysfunction

During the early stages of kidney dysfunction, there are typically no symptoms of kidney injury, and it may only be detected through a blood or urine test done for another reason. Early detection and treatment can help prevent Acute Kidney Injury (AKI) from progressing. If left untreated, it can progress to kidney failure, where dialysis or a kidney transplant may be necessary to maintain life.

## Application

To facilitate the early detection of AKI.



## Biochip Performance

Biomarkers	Assay Range
Soluble Tumour Necrosis Factor Receptor-1 (sTNFR1)	0.08 - 16.22 ng/mL
Soluble Tumour Necrosis Factor Receptor-2 (sTNFR2)	0.04 - 12.41 ng/mL
Heart-Type Fatty Acid-Binding Protein	2.05 - 67.59 ng/mL
Midkine	0.9 - 46.7 ng/mL

# EARLY DETECTION FACILITATING EFFECTIVE CLINICAL TREATMENT

## Benefits



### Improved Triaging

Current triaging is inadequate; in most cases where creatinine is elevated and eGFR is decreased, kidney damage has already started. Biochip provides predictive biomarkers to identify patients who are at risk of AKI, improving triaging.



### Early Intervention

Patients undergoing cardiac or orthopaedic trauma surgery are at risk of developing AKI. Biochip can facilitate early intervention, mitigating the chances of developing AKI and reducing mortality and morbidity rates.



### Shorter ICU Stays

Drastically decrease time spent in ICU, making more beds available for additional patients.



### Resource Optimisation

Precision medicine reduces unnecessary use of supplies, shortens ICU stays and enables better use of staff resources.

## Product Information



**Sample Type**  
Serum



**Time to Result**  
<60 Minutes



**Sample Volume**  
250µl



**Result Type**  
Quantitative



**Samples Per Cartridge**  
2

Used in research settings to date

# Clinical Drug Testing

The multiplex Clinical Drug Testing Biochip provides clinicians with a semi-quantitative comprehensive drug screen in patients for various medical reasons including but not limited to; those presenting acute overdose symptoms, screening for clinical trial eligibility and recurring prescription management. The preliminary test result can assist clinicians in identifying recent illicit drug use, as part of their clinical management workflow.

## Applications



Overdose



Pregnancy /  
Neonatal



Psychiatric  
Management



Prescription  
Management



Clinical Trials

## Analytes Detected

Analytes		
Acetaminophen	Ethyl Glucuronide (EtG)	Phencyclidine (PCP)
Amphetamine	Fentanyl	Pregabalin
Barbiturates	Ketamine	Salicylates
Benzodiazepines (Oxazepam)	MDMA	Tricyclic Antidepressants (TCA)
Benzodiazepines (Clonazepam)	Methadone	THC (Cannabinoids)
Benzoylcegonine (BZG) / Cocaine	Methamphetamine	Tramadol
Buprenorphine	Opiate	Zolpidem
Adulterant Check	Noroxycodone	6-Monoacetylmorphine (6-MAM)



## ACCURATE AND RELIABLE CLINICAL DRUG SCREENING

### Benefits



#### Improved Patient Safety

Quicker and more targeted treatment enhances recovery rates and lowers mortality and morbidity.



#### Comprehensive Testing

Covering a range of drug classes including common, prescription, and synthetic drugs, Biochip delivers multi-analyte detection, while eliminating the constraints of batch testing.



#### Rapid Identification of Drug Use

The process requires minimal sample preparation, with results in less than 30 minutes. Biochip is reliable for drug screening as it provides semi-quantitative concentrations of substances and metabolites.



#### Improved Patient Management

Biochip simultaneously screens for multiple substances to rapidly direct clinicians to the next steps and efficiently progress an effective treatment plan.

### Product Information



Sample Type  
Urine



Time to Result  
<30 minutes



Sample Volume  
170µl



Result Type  
Semi-Quantitative



Samples Per Cartridge  
2



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# Single Analyte Assays

Randox also provides a range of single-analyte assays for the critical care environment, eliminating the need for lengthy batching periods and reducing wastage, a common issue with larger throughput analysers that require placement in hospital labs and highly specialised training.

## DKK-1 Biochip

Quantitative measurement of DKK-1 provides clinicians with insight into bone health, various cancers and pancreatic health. DKK-1 is centrally involved in the regulation of bone remodelling, and its dysregulation is associated with bone pathologies. DKK-1 has emerged as a biomarker of cancer progression and prognosis as well as a potential therapeutic target in various types of malignancies.

DKK-1 is also found to be increased in Pancreatic ductal adenocarcinoma (PDAC) patients. DKK-1 can be a promising biomarker specific to PDAC, which has the potential to increase PDAC survival rates through improving early-stage detection and monitoring progression compared to current biomarker gold standards.

## Biochip Performance

Biomarker	Assay Range
Dickkopf-1 (DKK-1)	0.11 - 27.21 ng/mL

## Product Information

  
**Sample Type**  
Serum

  
**Time to Result**  
<40 Minutes

  
**Sample Volume**  
270µl

  
**Result Type**  
Quantitative

  
**Samples Per Cartridge**  
2

## IL-6 Biochip

IL-6 serves as an early marker of inflammation due to illness or injury, with quantitative measurement of IL-6 providing clinicians with greater insight into a patient's immune system and its response to both pathogens and treatments.

Belonging to the cytokine family, IL-6 triggers both pro-inflammatory and anti-inflammatory reactions. IL-6 provides general health and inflammation profiling, and has a wide range of applications such as cancers, neuroinflammation, sepsis, ARDS, lymphoma, and rheumatoid arthritis.

## Biochip Performance

Biomarker	Assay Range
Interleukin 6 (IL-6)	5.9 - 1477.8 (pg/mL)

## Product Information



**Sample Type**  
Plasma



**Time to Result**  
35 Minutes



**Sample Volume**  
250µl



**Result Type**  
Quantitative



**Samples Per Cartridge**  
2

## IL-18 Biochip

IL-18 is a pro-inflammatory cytokine that plays a significant role in the immune system, and its measurement as a biomarker is increasingly used in clinical settings to assess and monitor various inflammatory and immune-mediated conditions.

### Biomarker for Inflammatory Diseases

Elevated levels of IL-18 are highly specific for certain autoinflammatory conditions like macrophage activation syndrome (MAS) and PSTPIP1-associated diseases.

### Disease Monitoring

IL-18 levels can help monitor disease activity in conditions such as systemic juvenile idiopathic arthritis, adult-onset Still's disease, and hemophagocytic lymphohistiocytosis (HLH).

### Cancer Immunotherapy

IL-18 is being explored as an immune booster in CAR T-cell therapy and other cancer treatments. It enhances cytotoxic T cell and NK cell activity, potentially improving outcomes in solid tumours. However, its pro-inflammatory nature poses risks of hyperinflammation, making its use a "double-edged sword."

## Biochip Performance

Biomarkers	Assay Range
IL-18	62.5 – 15879.9 (pg/mL)

## Product Information



**Sample Type**  
Serum



**Time to Result**  
35 Minutes



**Sample Volume**  
190µl



**Result Type**  
Quantitative



**Samples Per Cartridge**  
2

## CXCL9 Biochip

CXCL9 (C-X-C motif chemokine ligand 9), also known as monokine induced by gamma interferon (MIG), is a small cytokine that plays a key role in immune system signalling. It is part of the CXC chemokine family and is primarily induced by interferon-gamma (IFN- $\gamma$ ).

CXCL9 has emerged as a valuable biomarker and potential therapeutic target in several clinical contexts:

### Autoimmune Disease: Lupus Nephritis

Elevated serum CXCL9 levels correlate with disease activity in systemic lupus erythematosus (SLE) patients with lupus nephritis.

### Organ Transplant: Acute Cellular Rejection (ACR)

Research has shown that increased levels of CXCL9 can distinguish between patients with transplant rejection, and those without. Typically if organ rejection is suspected, a biopsy is required. CXCL9 may be useful as a non-invasive alternative.

### Inflammatory Bowel Disease: Ulcerative Colitis

Serum CXCL9 is significantly elevated in UC patients and may serve as a marker of disease activity and a therapeutic target.

## Biochip Performance

Biomarker	Assay Range
CXCL9	21.8 - 8449.8 (pg/mL)

## Product Information



**Sample Type**  
Serum



**Time to Result**  
36 Minutes



**Sample Volume**  
190 $\mu$ l



**Result Type**  
Quantitative



**Samples Per Cartridge**  
2

## RAGE Biochip

Quantitative measurement of Receptor for Advanced Glycation End product (RAGE) provides clinicians with insight into inflammation and cellular signalling.

RAGE is expressed in various cell types, including immune cells, endothelial cells, and neurons. AGE is formed during ageing and is accelerated in pathophysiological states such as diabetes, Alzheimer's disease, kidney failure, and immune/inflammatory diseases.

## Biochip Performance

Biomarker	Assay Range
Receptor for Advanced Glycation End product (RAGE)	445.5 - 134960.9 pg/mL

## Product Information



**Sample Type**  
Serum



**Time to Result**  
35 Minutes



**Sample Volume**  
150µl



**Result Type**  
Quantitative



**Samples Per Cartridge**  
2



## Midkine Biochip

Quantitative measurement of Midkine provides clinicians with insight into a wide range of illnesses such as cancers, autoimmune diseases, heart failure and kidney dysfunction.

A soluble secreted protein, Midkine is highly elevated in various illnesses and could serve as a valuable disease biomarker. In many types of cancer, it has been shown to be overexpressed, especially during tumour progression into more advanced stages.

## Biochip Performance

Biomarker	Assay Range
Midkine	0 - 109.41 ng/mL

### Product Information



**Sample Type**  
Urine



**Time to Result**  
60 Minutes



**Sample Volume**  
400µl



**Result Type**  
Quantitative



**Samples Per Cartridge**  
2



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## Evidence MultiSTAT

Using our revolutionary Biochip Array Technology, the Evidence MultiSTAT is a fully automated analyser that enables the detection of up to 48 targets simultaneously from a single patient's sample.



# Analyser Overview

## The Cartridge



- 1 Well One**  
Cut-off material is added (qualitative kits) or adjuster/QC/sample is added (quantitative kits).
- 2 Well Two**  
Adjuster/QC/sample is added.
- 3 Foil Cover & Fluid Reservoirs**  
All additional fluids required are stored here.
- 4 Biochip Wells**  
Two biochips are located here. Each biochip has up to 48 discrete testing regions.

## Three Step Process



Prepare sample &  
add to cartridge



Load reagent & tip  
cartridge to MultiSTAT



Press Play



### Rapid Screening

Minimal sample preparation is required and results for samples can be provided from under 30 minutes, allowing for quicker clinical decisions and timely patient management.

## The Analyser



### 1 Touch Screen

A large touchscreen interface allows the user to easily navigate through the analyser and view results.

### 2 Tip Cartridge Drawer

The user will insert the prefilled tip cartridge here prior to testing.

### 3 Reagent Cartridge Drawer

The user will insert the reagent cartridge here prior to testing.

### 4 2 x USB Ports

USB Ports allow the user to add accessories. For example, barcode scanner, printer or USB to export test results.

## Benefits



### No-Fuss Procedure

Pre-filled reagent cartridges and a simple user interface mean that minimal laboratory training is required. This versatile benchtop analyser can achieve accurate, quantitative results in minutes.



### Multi-Panel

The Evidence MultiSTAT can run a variety of panels, and test for multiple markers, facilitating comprehensive point of need testing.

# Why MultiSTAT?



## Growing Awareness

Since **2000**, **cytokine storms** have been frequently reported with hyperinflammatory conditions and diseases



## Expanding Need

Among ICUs in 50 countries  
**the prevalence of ARDS**  
was **10.4%** of all  
**ICU admissions**



Evidence MultiSTAT  
provides results from  
**30 MINUTES**





## Global Challenges

Around the world, there are  
**12.2 MILLION**  
strokes per year,  
**ONE EVERY 3 SECONDS**



## Screening Solutions

Drug-related problems contribute to  
**MORE THAN 15%**  
of hospital admissions



# Technical Overview

Dimensions	585 (H) x 535 (D) x 570 (W) mm
Weight	48 kg, 106 lbs
Analyser Description	Fully automated touchscreen biochip analyser
Biochip Format	Cartridge based system – assay reagents sealed in a pre-filled cartridge
Data Back-up Methods	Data export functionality via USB
Measurement Principal	Competitive and sandwich techniques with chemiluminescent reaction
Accreditation	United States (FDA), EU (CE certified), United Kingdom (UKCA), Canada (Health Canada), Brazil (ANVISA), Australia (TGA) and Saudi Arabia (SFDA)
Sample Loading	Single cartridge loading bay





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## Also Available

### Clinical Diagnostics Biochips



Bladder Cancer Risk



Prostate Cancer Risk



Male and Female Hormones



Ovarian Cancer



Gastrointestinal Diseases



Coeliac Disease

EVIDENCE  
MULTISTAT

# EVIDENCE SERIES



[marketing@randox.com](mailto:marketing@randox.com) | [randox.com](https://randox.com)

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