RANDOX

EVIDENCE MULTISTAT

Emergency and Critical Care Management

EVIDENCE
MULTISTAT

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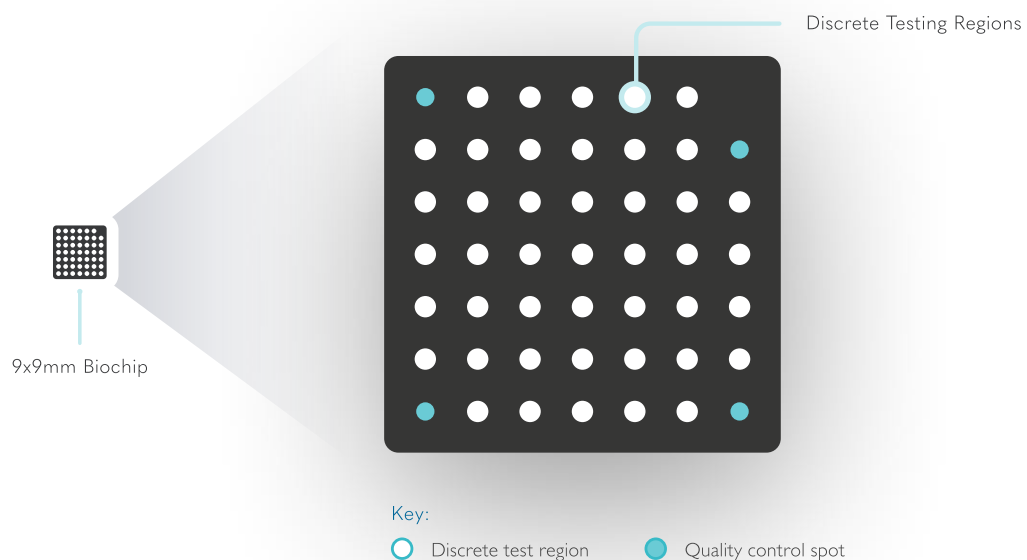
BIOCHIP ARRAY TECHNOLOGY

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.

Discrete Testing Regions

9x9mm Biochip

Key:

○ Discrete test region   ● Quality control spot

Biochip in Numbers

Up to **48** tests per Biochip

4 spots reserved for Quality Control

Critical Care Biochips

Hyperinflammation

Acute Respiratory Distress Syndrome

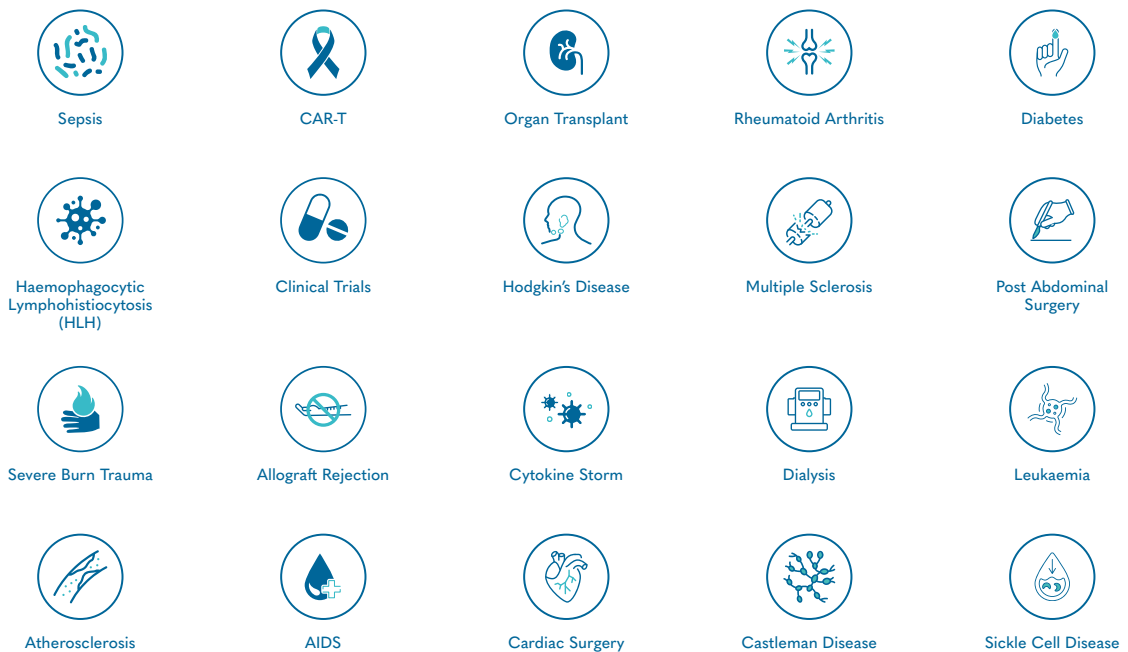Neurovascular Dysfunction

Kidney Dysfunction

Clinical Drug Testing

Hyperinflammation

The Hyperinflammation Biochip can aid intensive and critical care units to monitor the cytokine 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

Sepsis	CAR-T	Organ Transplant	Rheumatoid Arthritis	Diabetes
Haemophagocytic Lymphohistiocytosis (HLH)	Clinical Trials	Hodgkin's Disease	Multiple Sclerosis	Post Abdominal Surgery
Severe Burn Trauma	Allograft Rejection	Cytokine Storm	Dialysis	Leukaemia
Atherosclerosis	AIDS	Cardiac Surgery	Castleman Disease	Sickle Cell Disease

Biochip Performance

Biomarker	Measuring Range
Interleukin-1 beta (IL-1β)	0 - 250 pg/mL
Interleukin-2 (IL-2)	0 - 1000 pg/mL
Interleukin-6 (IL-6)	0 - 500 pg/mL
Interferon gamma (IFN-γ)	0 - 500 pg/mL
Tumour Necrosis Factor alpha (TNF-α)	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

ACCURATE MONITORING

OF HOST IMMUNE RESPONSE

Benefits

Point of Need

Monitoring host response at the point of need enables faster clinical intervention for better-tailored treatments.

Real-Time Monitoring

Complete profiling with narrow time windows assists with faster triage, improved emergency department efficiency and patient stratification.

Decision Management

Extensive biomarker testing and monitoring provides clinicians with an invaluable data set to aid when developing a clinical intervention strategy.

Simple Operator Process

Analyser can be used by suitably qualified personnel to quickly analyse patient samples and obtain easily comprehensible results in just three simple steps.

Product Information

Sample Type:
Plasma

Time to Result:
60 minutes

Acute Respiratory Distress Syndrome

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 the hyperinflammatory phenotype quickly so that the clinician can make informed decisions regarding patient management options, which are essential in improving survival. The Evidence MultiSTAT ARDS 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 assay and algorithm

Applications

Stratifies Into:

Hyperinflammatory   or   **Hypo**inflammatory

Biochip Performance

Biomarker	Measuring Range
Soluble Tumour Necrosis Factor Receptor 1 (sTNFR1)	0 - 25 ng/mL
Interleukin-6 (IL-6)	0 - 1600 pg/mL

Benefits

Fast & Accurate Detection

Fast and accurate detection of biomarkers to facilitate stratification of ARDS patients into hypo and hyper-inflammatory phenotypes.

Simple Operator Process

Analyser can be used by suitably qualified personnel to quickly analyse patient samples and obtain easily comprehensible results in just three simple steps.

Rapid Stratification

Rapid stratification compared to other lab-based biomarker testing facilitating a precision medicine approach in ARDS patients.

Results in 36 Minutes

Prompt reporting time to results enables faster treatment plans for patients.

Product Information

Sample Type:
Plasma

Time to Result:
36 minutes

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

Stroke Research

Brain Inflammation

Parkinson's Disease

Alzheimer's Disease

Down Syndrome

Brain Injury

Delirium

Biochip Performance

Biomarker	Measuring 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

Benefits

Unique Solution for Patient Classification

Simultaneous detection of multiple biomarkers from a single sample provides a better understanding of the patients neurovascular condition.

Improves Patient Care

Biochip testing and monitoring ensures appropriate and timely therapeutic intervention where necessary.

Results in 39 Minutes

Prompt reporting time to results enables faster treatment plans for patients.

Accessible Treatment Management

The MultiSTAT is a benchtop analyser with a small footprint making it suitable for areas with limited space.

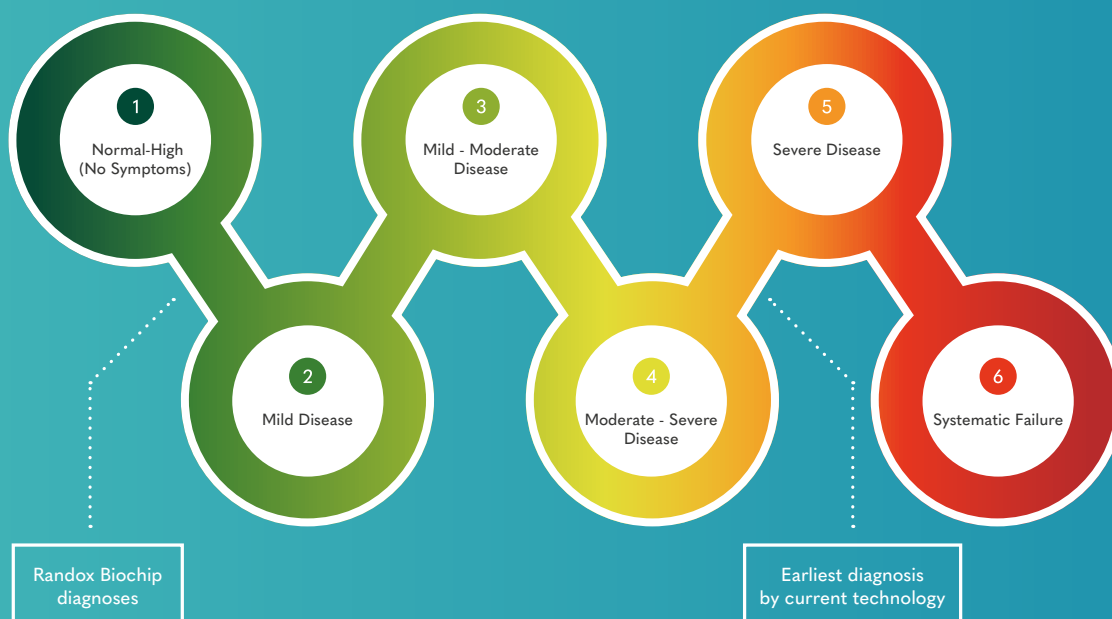## Product Information

Sample Type:
Plasma

Time to Result:
39 minutes

Kidney Dysfunction

During the early stages of kidney dysfunction there are typically no symptoms of kidney disease, and it may only be detected through a blood or urine test done for another reason. Early detection and treatment can help prevent chronic kidney disease 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 diagnosis of kidney dysfunction.

1 Normal-High (No Symptoms)

2 Mild Disease

3 Mild - Moderate Disease

4 Moderate - Severe Disease

5 Severe Disease

6 Systematic Failure

Randox Biochip diagnoses

Earliest diagnosis by current technology

Biochip Markers

Biomarker	
sTNFR1	sTNFR2
H-FABP	Midkine

Benefits

Decision Management

Conducting fast and detailed testing leads to better informed decision-making for developing personalised and accurate treatments, for patients.

Save Hospital Resources

Early detection of kidney dysfunction and patient risk stratification allows for earlier intervention potentially reducing progression of chronic kidney disease and thus avoiding serious complications while reducing the impact on healthcare resources and rising costs.

Simple Operator Process

The MultiSTAT can be used by suitably qualified personnel to quickly analyse patient samples and obtain easily comprehensible results in just three simple steps.

Narrow Time Windows

Time sensitive profiling prevents extended wait times for results.

Product Information

Sample Type:
Serum

Time to Result:
Under 60 Minutes

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 reoccuring prescription management. The preliminary test result will determine recent illicit drug use, facilitating clinical management.

Applications

Overdose

Pregnancy / Neonatal

Psychiatric Management

Prescription Management

Clinical Trials

Analytes Detected

Analytes		
Acetaminophen	Fentanyl	PCP (Phencyclidine)
Amphetamine	Haloperidol	Pregabalin
Barbiturates	Ketamine	Propoxyphene
Benzodiazepines 1 (Oxazepam)	MDMA	Salicylates
Benzodiazepines 2 (Clonazepam)	Meprobamate	TCA (Tricyclic Antidepressants)
Buprenorphine	Methadone	THC (Cannabinoids)
BZG/Cocaine	Methamphetamine	Tramadol
Creatinine (Urine only)	Methaqualone	Zolpidem
Dextromethorphan	Opiate	6-MAM
EtG (Ethyl Glucuronide)	Oxycodone	Xylazine (Blood Only)

Benefits

Simple Operator Use

Cartridges come with pre-filled reagents and a simple interface, enabling suitably qualified personnel to achieve accurate results quickly and interpret them easily.

Comprehensive Testing

Covering a range of drug classes, including common, prescription, and synthetic drugs, the panels use cross-reactivity to accurately differentiate between drugs of the same class.

Rapid Identification of Drug Use

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

Patient Management

Identifies substances to help clinicians evaluate the effectiveness of treatment plans and assesses the current level of care for patients.

Product Information

Sample Type:
Urine, Blood & Oral Fluid

Time to Result:
Under 30 minutes

QC

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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**

30 min

Evidence MultiSTAT **provides results from 30 MINUTES**

QC

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Global Challenges

Around the world, there are
12.2 MILLION
neurovascular complications per year,
ONE EVERY 3 SECONDS

Screening Solutions

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

DOX

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STAT

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	FDA approved, CE marked, Health Canada approved, ANVISA, GIVD, TGA and SFDA MDMA authorised
Sample Loading	Single cartridge loading bay

Also Available

Clinical Diagnostics Biochips

Gastrointestinal Diseases

Bladder Cancer (BCa)

Prostate Cancer (PCa)

Non-Alcoholic Fatty Liver Disease

Female & Male Hormone / Testosterone / SHBG

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