RANDOX

EVIDENCE MULTISTAT

Clinical Diagnostics

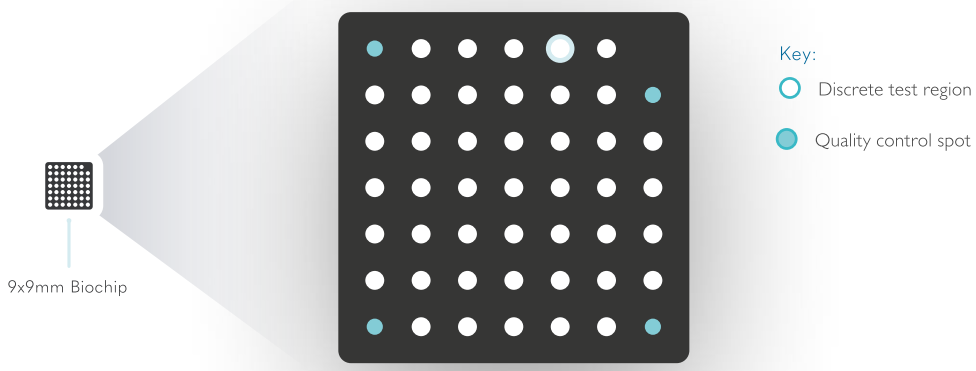
EVIDENCE
MULTISTAT

CONTENTS

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.

Algorithm-Based Testing

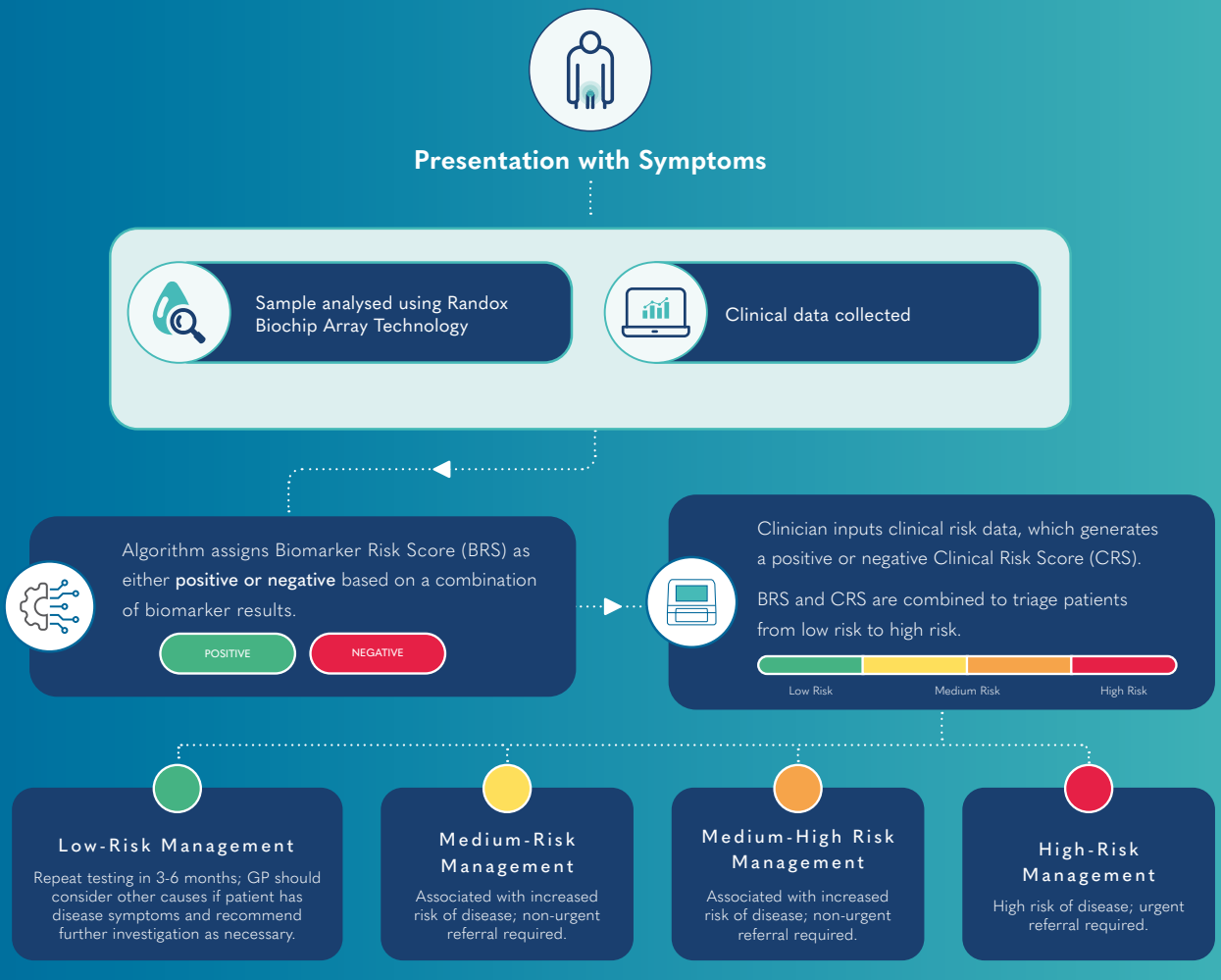
Biomarker algorithms can be applied clinically to some of our Biochip panels to stratify patients from 'low' to 'high' risk of developing certain diseases.

Biomarker Risk Score (BRS)

A BRS is calculated for each patient by applying an algorithm to the quantitative biomarker results. Patients with a score above the cut-off value would be positive, whereas patients below the cut-off would be negative.

Clinical Risk Score (CRS)

A CRS is calculated for each patient; this is a cumulative score utilising clinical and demographic measurements which vary depending on the disease. Patients with a score above the cut-off value would be positive, whereas patients below the cut-off would be negative.



Biochip Benefits

Improve Patient Management

Make better patient management decisions to improve patient outcomes.

Reduce Secondary Care Referrals

Reduce the number of low-risk patients being referred to secondary care, reducing the current healthcare burden.

Monitor Treatment Efficacy and Disease Progression

By measuring biomarkers, Biochip can monitor treatment efficacy and determine if the disease is getting better or worse. This allows for quick adjustments to treatment plans.

Reduce Invasive Procedures

Reduce the need for time consuming scans, as well as risky, invasive and costly biopsies and endoscopies in low-risk patients.

Expedite High-Risk Patients

Expedite those with high-risk scores for urgent investigations, allowing earlier intervention and treatment.

Reduce Costs

Biochip can help utilise healthcare resources more effectively, improve preventative care and reduce associated costs with progressed diseases.

Clinical Diagnostic Biochips

Our risk stratifying biochips use an AI algorithm to triage patients from 'low' to 'high' risk of developing certain diseases, improving patient management at primary care.

Risk Stratifying Biochips

Bladder Cancer Risk

Triaging haematuria patients

Gastrointestinal Diseases

Triaging dyspepsia patients

Prostate Cancer Risk

Triaging patients with prostate cancer-like symptoms

Other Biochips

Ovarian Cancer

Quantifying CA 125 to aid detection of epithelial ovarian cancer

Gastrointestinal Diseases

Quantifying CgA to aid in identification and monitoring patients with gastroenteropancreatic neuroendocrine tumours

Coeliac Disease

Quantifying Anti-tTG IgA and Anti-tTG IgG to identify patients with coeliac disease

Male & Female Hormones

Providing a range of quantitative biochips for fertility, SHBG, Testosterone, AMH, and hCG

Prostate Cancer

Providing a range of quantitative single-plex biochips for Total PSA, [-4, -5, -7] Pro PSA, Nicked PSA, [-2] Pro PSA, and Free PSA

BLADDER CANCER RISK

Biochip provides **risk stratification** to triage female patients presenting with haematuria at primary care from low to high risk of bladder cancer. This could allow low-risk patients to be monitored in primary care, while medium and high-risk patients can be referred urgently for secondary care investigations.

Randox investigated 48 urine and 32 serum biomarkers known to be involved in the pathobiology underlying bladder carcinogenesis in a recent study (Duggan et al., 2022). Four markers were demonstrated to be clinically significant in identifying female patients with bladder cancer.

Applications

- Primary Care GPs
- Urology Departments
- Hospital Labs
- Oncology Departments

Biochip Markers

Biomarkers	
Interleukin-12p70 (IL-12p70)	Interleukin-13 (IL-13)
Midkine	Clusterin

Product Information

Sample Type
Urine

Time to Result
<60 Minutes

Sample Volume
400 µL

Result
Quantitative

Samples per Cartridge
2

49%
Of bladder cancer cases are preventable

$101k
Could be saved per patient with effective screening and early detection

614,298
New bladder cancer cases globally in 2022

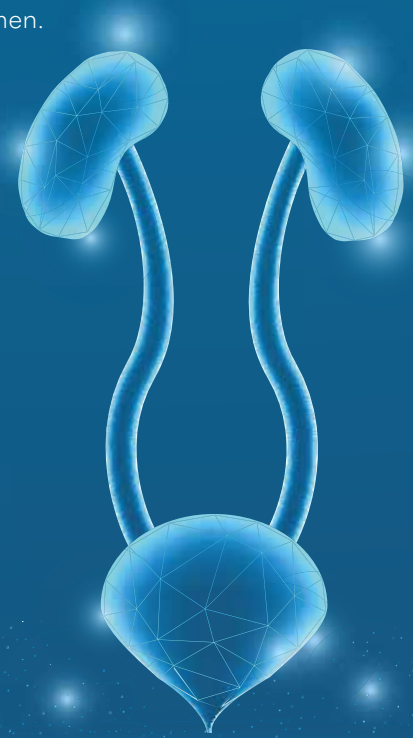
Biochip Benefits

1. **Highly Accurate in Identifying Patients at Risk**
Our biomarker combination showed a sensitivity of 83.7% and specificity of 80.4% for accurate risk-stratification of female haematuria patients.

2. **Reduce Secondary Care Referrals**
Reduces the need for costly, risky, and invasive cystoscopy referrals for low-risk patients, decreasing post-procedure complications.

3. **Reduce Underdiagnosis in Women**
Biochip's novel combination of biomarkers could help clinicians reduce undiagnosed bladder cancer in women, who are often diagnosed at more advanced stages and have poorer survival rates than men.

4. **Reduce Costs**
Biochip can help utilise healthcare resources more effectively, improve preventative care and reduce associated costs with progressed diseases.



Used in research settings to date

GASTROINTESTINAL DISEASES

GastroPanel Biochip

The GastroPanel Biochip provides risk stratification to triage patients presenting with dyspepsia at primary care from 'low-risk' to 'high-risk' probability. This allows for urgent secondary referrals for medium and high-risk patients.

Biochip detects 3 stomach-specific biomarkers to provide clinicians with more information on the function and structure of stomach mucosa.

These biomarkers are secreted by the cells in the gastric mucosa: pepsinogen I (PGI), pepsinogen II (PGII) and gastrin-17 (G-17). This complete panel of all 3 biomarkers provides a more comprehensive profile of the gastric mucosa than could be achieved by using any of these as stand-alone biomarkers.

Applications

- Primary Care GPs
- Gastroenterology Departments
- Hospital Labs
- Oncology Departments

Biochip Markers

Markers	
Gastrin-17 (G-17)	Pepsinogen I (PG I)
Pepsinogen II (PG II)	-

Product Information

Sample Type:
Plasma

Time to Result:
60 Minutes

Sample Volume:
170 µL

Result:
Quantitative

Samples per Cartridge:
2

113M
Gastrointestinal endoscopy procedures in 2024

$2,750
Average cost of endoscopy procedures

80%
Of patients with dyspepsia had a normal endoscopy

Biochip Benefits

1. **Reduce Secondary Care Referrals**
   Biochip non-invasively identifies low-risk gastrointestinal patients, reducing unnecessary referrals, endoscopies, scans, and post-endoscopy complications.

2. **Earlier Intervention**
   Allows clinicians to triage 'high-risk' patients for referrals, intervene early to provide treatment for gastric disorders, and monitor treatment efficacy.

3. **Reduced Secondary Care Complications**
   Biochip could reduce hospital admissions from post-endoscopy complications such as infections and damage to organs.

4. **Ease of Use**
   Biochip provides an easy and comprehensive method for assessing gastric health and individuals at risk of gastric disorders.

Used in research settings to date

CgA Biochip

The CgA Biochip aids in detecting and monitoring patients with gastroenteropancreatic neuroendocrine tumours (GEP-NETs). NETs originate from neuroendocrine cells found in neuronal and endocrine tissues throughout the body.

The most common sites of NETs are the lung, stomach, appendix, cecum, duodenum, pancreas, colon and rectum. High levels of CgA can also be found in cases of benign diseases such as gastro-intestinal disorders, kidney failure and cardiovascular disorders.

Applications

- Primary Care GPs
- Gastroenterology Departments
- Hospital Labs
- Oncology Departments
- Nephrology Departments
- Respiratory Medicine Departments
- Cardiology Departments

Biochip Markers

Markers
Chromogranin A (CgA)

Product Information

Sample Type: Serum

Time to Result: <40 Minutes

Sample Volume: 120 µL

Result: Quantitative

Samples per Cartridge: 2

Biochip Benefits

1

Improved Patient Outcomes

60-80% of gastroenteropancreatic neuroendocrine tumor (GEP-NET) cases are metastatic when identified, making early detection critical to improve patient outcomes.

2

Wide-Ranging Applications

Studies have also demonstrated the utility of CgA as a circulating biomarker. Elevated CgA has been found in patients with various neuroendocrine tumours.

3

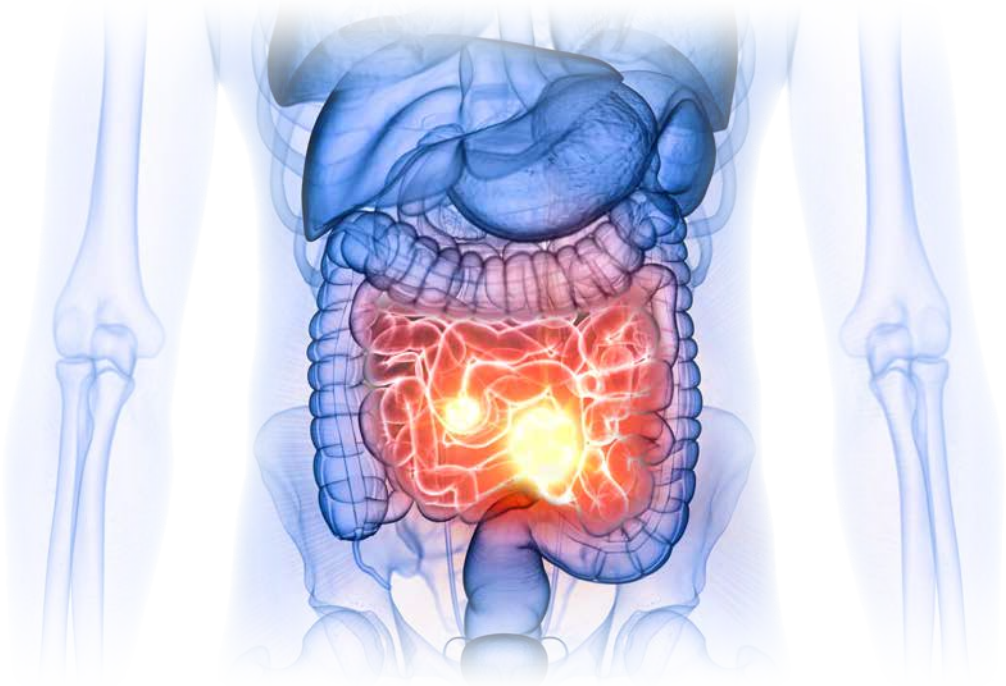
Improved Monitoring

Circulating CgA may also prove useful for predicting recurrences and monitoring during follow-ups.

4

Reduce Costs

Biochip can help utilise healthcare resources more effectively, improve preventative care and reduce associated costs with progressed diseases.



Used in research settings to date

PROSTATE CANCER RISK

Biochip provides **risk stratification** to triage patients presenting with symptoms at primary care from low to high risk of prostate cancer. This could allow low-risk patients to be monitored in primary care, while medium and high-risk patients can be referred urgently for secondary care investigations.

Randox investigated **19 biomarkers** in a recent study (McNally et al., 2022), identifying **4 novel markers** which were demonstrated to be clinically significant in identifying patients with prostate cancer.

Applications

- Primary Care GPs
- Urology Departments
- Hospital Labs
- Oncology Departments

Biochip Markers

Biomarkers	
Epidermal Growth Factor (EGF)	Interleukin-8 (IL-8)
Monocyte Chemoattractant Protein-1 (MCP-1)	Total Prostate-Specific Antigen (tPSA)

Product Information

Sample Type
Serum

Time to Result
<60 Minutes

Sample Volume
250 µL

Result
Quantitative

Samples per Cartridge
2

$28k/year
Is the average cost of early-stage treatment

$74k/year
Is the average cost to treat advanced prostate cancer

1,414,259
New prostate cancer cases globally in 2022

Biochip Benefits

1. **Improved Predictive Potential**
Biochip prostate cancer risk score accuracy for detecting prostate cancer is 86% vs 70% for elevated tPSA alone.

2. **Independent of Body Mass Index (BMI)**
Our prostate cancer risk score is independent of BMI; a high BMI can lower tPSA levels.

3. **Reduces Unnecessary Biopsies**
Reduces unnecessary referrals to secondary care for invasive and costly biopsy investigations - 75% of biopsies from raised tPSA and Digital Rectal Exam referrals are negative.

4. **Reduces Hospital Readmissions**
Reduces hospital admissions from post-biopsy complications such as infections and bacterial prostatitis.

Used in research settings to date

PROSTATE CANCER

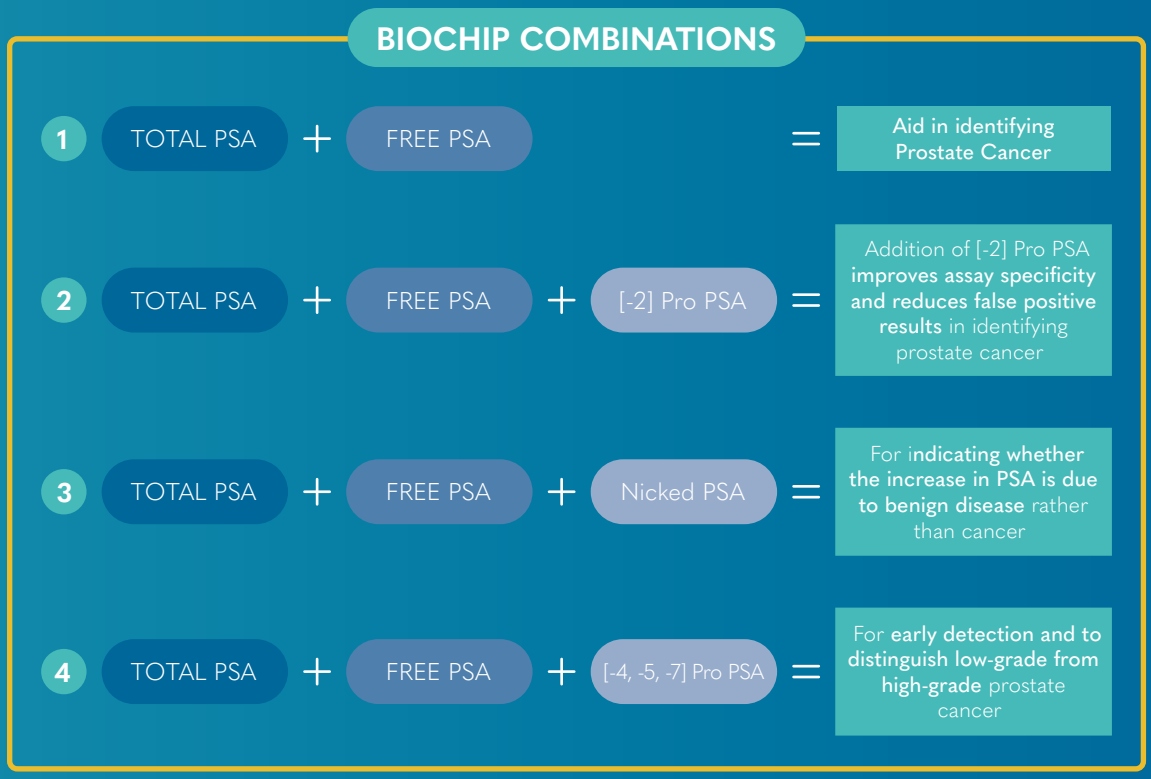
The PSA test is commonly used to screen for prostate cancer. However, due to its limited specificity, a more accurate tool is necessary for detecting prostate cancer.

Randox provides a range of single-plex PSA assays which can be used in different combinations to aid in reducing false positives, determining benign disease rather than cancer, and improving early detection and cancer grading.

Applications

- Primary Care GPs
- Urology Departments
- Hospital Labs
- Oncology Departments

Product Information					
Biochip Biomarkers	Sample Type	Samples Per Cartridge	Sample Volume	Result	Time to Result
Total PSA	Serum	2	140 µL	Quantitative	40 Minutes
[-4, -5, -7] Pro-PSA	Serum or Plasma	2	200 µL	Quantitative	<50 Minutes
	Seminal Fluid		5 µL		
Nicked PSA	Serum or Plasma	2	250 µL	Quantitative	<50 Minutes
	Seminal Fluid		5 µL		
[-2] Pro-PSA	Serum or Plasma	2	250 µL	Quantitative	<50 Minutes
	Seminal Fluid		5 µL		
Free PSA	Serum	2	140 µL	Quantitative	40 Minutes



Biochip Benefits

1 **Distinguish Cancer Grade**
Biochip can aid in indicating benign disease or cancer and distinguishing low-grade from high-grade cancer.

2 **Reduce False Positives**
Biochip can reduce false positive results and the number of biopsies associated with a standalone PSA test.

3 **Tailored Treatments**
Biochip can improve patient outcomes through more effective tailoring of treatments.

4 **Rapid Results**
Biochip provides rapid results from 40 minutes, easing patient anxiety.

Used in research settings to date

OVARIAN CANCER

National Institute for Health and Care Excellence (NICE) advises that the best available marker for epithelial ovarian cancer is CA 125 due to the combination of reliability and general availability. Biochip provides the quantitative detection of CA 125 in a serum sample for epithelial ovarian cancer.

Serum CA 125 measurement, an abdominal and pelvic ultrasound, along with the woman's menopausal status, are used to assess whether a referral for histology or cytology is required. CA 125 levels after chemotherapy is one of the strongest available indicators of disease outcome, and the most important application for monitoring patients with epithelial ovarian cancer.

Applications

- Primary Care GPs
- Gynaecology Departments
- Hospital Labs
- Oncology Departments

Biochip Markers

Biomarker
CA 125

Product Information

Sample Type
Serum

Time to Result
<40 Minutes

Sample Volume
250 µL

Result
Quantitative

Range
Up to 4,000 U/mL

Samples per Cartridge
2

90%
Epithelial ovarian cancer accounts for 90% of primary ovarian cancers

8th
Ovarian cancer is the 8th common cancer in women

94%
Five year survival rate when detected at an early stage

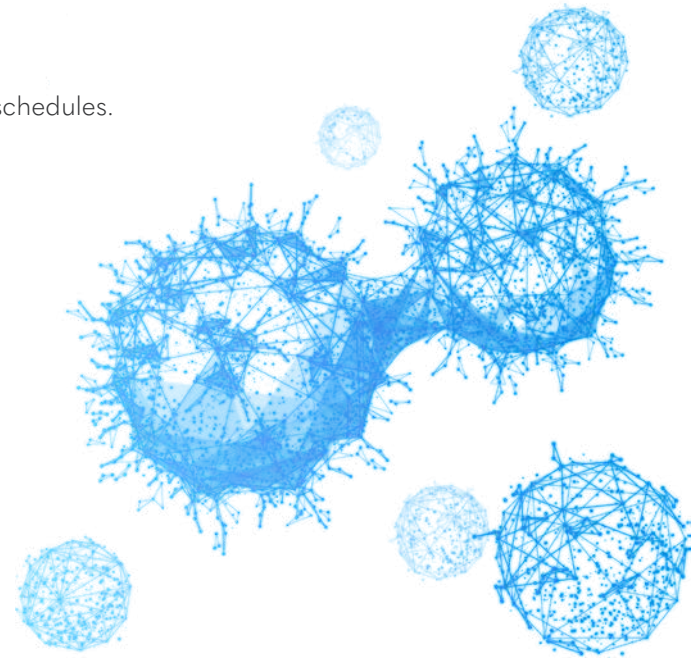
Biochip Benefits

1 **Wide Measuring Range**
With a measuring range of up to 4,000 U/mL, treatment effectiveness can be monitored. Decreasing biomarker levels indicate efficacy, while stable or increasing levels signal for treatment adjustment.

2 **Rapid Detection**
Receiving results in <40 minutes aids clinicians in making fast decisions about whether to refer a patient for urgent investigations.

3 **Ease of Use**
Allowing samples to be processed in primary care, reducing turnaround times, transport issues, and administrative tasks.

4 **No Sample Batching**
Providing flexibility in testing schedules.



Used in research settings to date

COELIAC DISEASE

Screening for IgA antibodies to tissue transglutaminase (Anti-tTG IgA) and IgG antibodies to tissue transglutaminase (Anti-tTG IgG) can provide insight into a patient's response to foods like gluten, often checked when identifying food sensitivities or autoimmune conditions, such as coeliac disease.

Applications

- Primary Care GPs
- Gastroenterology Departments
- Hospital Labs

Anti-tTG IgA Biochip

Anti-tTG IgA are used as the preferred test for screening of coeliac disease and dermatitis herpetiformis, being highly (>90%) sensitive and specific.

There is a good correlation between anti-tTG antibody and disease activity. Relapse or poor compliance with a gluten-free diet is often associated with the return of antibody positivity.

Biochip Marker

Biomarker
IgA antibodies to tissue transglutaminase (Anti-tTG IgA)

Product Information

Sample Type
Serum

Time to Result
40 Minutes

Sample Volume
230 µL

Result
Quantitative

Samples per Cartridge
2

Used in research settings to date

Anti-tTG IgG Biochip

Coeliac disease is often associated with IgA deficiency, a common immunodeficiency found in around 1 in 500 of our population. IgA levels are estimated in all patients with suspected coeliac disease. As such, IgA-deficient individuals with suspected coeliac disease are tested for Anti-tTG IgG to aid in diagnosis.

Biochip Marker

Biomarker
IgG antibodies to tissue transglutaminase (Anti-tTG IgG)

Product Information

Sample Type
Serum

Time to Result
40 Minutes

Sample Volume
230 µL

Result
Quantitative

Samples per Cartridge
2

Biochip Benefits

1. **Improved Patient Management**
   Make better patient management decisions to improve patient outcomes.

2. **Monitor Patient Compliance**
   Biochip can ensure patients are sticking to their prescribed diet, through monitoring the return of antibody positivity.

3. **Ease of Use**
   Biochip provides an easy and comprehensive method for assessing coeliac disease.

Used in research settings to date

MALE & FEMALE HORMONES

Screening male and female hormones is vital for early detection of health issues. This allows healthcare providers to tailor treatments effectively, improving outcomes for conditions such as infertility, hormonal imbalances and menopause.

Applications

Primary Care GPs

Fertility Health Clinics

Hospital Labs

Fertility Biochip

The Fertility Biochip is an advanced tool that provides a detailed understanding of baseline hormone levels and any imbalances that may be causing adverse effects on a person's overall health or fertility, enabling the tracking of changes over time.

Our Fertility Biochip can provide a full diagnostic hormone profile which can indicate various conditions such as polycystic ovary syndrome (PCOS), menopause, hormone imbalances affecting ovulation and ovulation indication. For patients going through in vitro fertilisation (IVF), the Fertility Biochip can determine the menstrual cycle stage and response to fertility treatment.

Biochip Markers

Biomarkers	
Prolactin	Estradiol
Follicle Stimulating Hormone (FSH)	Progesterone
Luteinizing Hormone (LH)	-

Product Information

Sample Type
Serum

Time to Result
31 Minutes

Sample Volume
285 µL

Result
Quantitative

Samples per Cartridge
2

PCOS
Is the most common endocrine disorder in women

1 in 6
People experience infertility worldwide

40%
Of men over 45 have low testosterone levels

Sex Hormone-Binding Globulin (SHBG) Biochip

The SHBG Biochip is primarily measured alongside a total testosterone test to estimate the amount of free testosterone in the patient's blood. In men it is used to look for testosterone deficiency, whereas in women the primary function for a SHBG test would be to investigate excess production of testosterone.

Biochip Marker

Biomarker
Sex Hormone-Binding-Globulin (SHBG)

Product Information

Sample Type
Serum

Time to Result
34 Minutes

Sample Volume
110 µL

Result
Quantitative

Samples per Cartridge
2

Testosterone Biochip

The Testosterone Biochip can be used to aid diagnosis and treatment of conditions such as infertility, primary and secondary hypogonadism, testicular failure, androgen resistance and PCOS.

Biochip Markers

Biomarker
Total Testosterone

Product Information

Sample Type
Serum

Time to Result
31 Minutes

Sample Volume
275 µL

Result
Quantitative

Samples per Cartridge
2

Anti-Müllerian Hormone (AMH) Biochip

Anti-Müllerian Hormone (AMH) testing offers critical insights into a woman's ovarian reserve and egg count. Biochip quantifies the concentration of AMH, a hormone produced by ovarian follicles. Elevated AMH levels indicate a higher ovarian reserve, whereas diminished levels indicate a reduced level. AMH testing can aid clinicians in assessing the body's responsiveness to ovarian stimulation protocols.

Biochip Marker

Biomarker
Anti-Müllerian Hormone (AMH)

Product Information

Sample Type
Serum

Time to Result
60 Minutes

Sample Volume
275 µL

Result
Quantitative

Samples per Cartridge
2

Human Chorionic Gonadotropin (hCG) Biochip

Human Chorionic Gonadotropin (hCG) testing measures the levels of hCG, a hormone produced by the placenta during pregnancy. This hormone is crucial for maintaining pregnancy as it supports the uterine lining and prevents menstruation. Testing for hCG can be used to confirm pregnancy, estimate age of the foetus, identify abnormal pregnancies, and screen for potential miscarriages. Biochip uses serum samples as blood tests are more precise and can detect hCG levels at an early stage after conception.

Biochip Marker

Biomarker
Human Chorionic Gonadotropin (hCG)

Product Information

Sample Type
Serum

Time to Result
37 Minutes

Sample Volume
275 µL

Result
Quantitative

Samples per Cartridge
2


QC
RANDOX
—evidence—
MULTISTAT

Evidence MultiSTAT

In the Non-Critical Care Setting

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 2 samples can be provided in under 30 minutes, allowing for quicker clinical decision 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 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 near-patient testing

TECHNICAL SNAPSHOT

Dimensions	585 (H) x 535 (D) x 570 (W) mm
Weight	48 kg, 106 lbs
Analyser Description	Fully automated touchscreen biochip array 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

Also Available

Critical Care Biochips

- Hyperinflammation
- InflamiSTRAT
- Neurovascular Dysfunction
- Kidney Dysfunction
- Clinical Drug Testing
- Single Analyte Assays

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