



# EVIDENCE MULTISTAT

Fully Automated Drug Testing

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**RANDOX**  
TOXICOLOGY



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Randox Toxicology are world leaders in drug testing solutions with the capability of detecting over 600 drug and drug metabolites using innovative Biochip Array Technology.



## Evidence MultiSTAT

Using our revolutionary Biochip Array Technology (BAT), the Evidence MultiSTAT is an automated analyser that enables on-site, simultaneous detection of up to 29 classical, prescription and synthetic drugs from a single sample. Designed to work across a variety of matrices, our patented multi-analyte testing platform provides a complete toxicology profile within minutes, changing the landscape of drug detection forever.

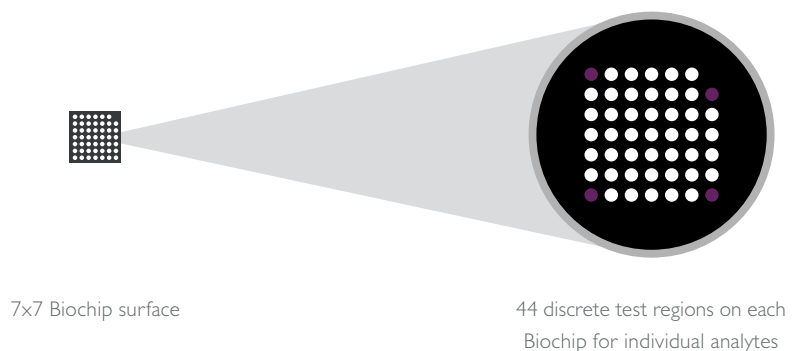
### Multiplex Explained

BAT is an immunoassay testing platform for the simultaneous multi-analyte detection of a panel of related tests. The technology works by combining a panel of up to 44 related tests on a single Biochip with a single set of reagents, controls and calibrators. Competitive chemiluminescent immunoassays are employed for the Biochip Arrays. The light signal generated from each of the test regions on the Biochip is simultaneously detected using digital imaging technology and compared to that from a calibration curve or cut-off material.

#### Key

○ Discrete test region

● Quality control spot





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MULTISTAT

## Benefits

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### Rapid Screening

With minimal sample preparation required, semi-quantitative results can be provided in under 30 minutes, with qualitative results provided in under 20 minutes, offering an efficient and accurate toxicology screen.



### Multiple Matrices

Testing is available across multiple matrices including; blood, urine, and oral fluid to accommodate any testing requirements.



### Simple Process

With prefilled reagent cartridges and a simple interface, non-laboratory trained staff can operate the analyser in any environment and achieve results in minutes.



### Reliable Results

Using chemiluminescence as a measurement principle, the Evidence MultiSTAT consistently delivers accurate results and offers a highly sensitive way to detect drugs of abuse.



### Extensive Test Menu

The Evidence MultiSTAT facilitates on-site simultaneous screening of multiple drug classes, including classical, prescription and synthetic drugs of abuse.

## Matrices

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### Blood

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- Matrix dedicated kit for blood ensures optimum performance
- Sample collection should be carried out in accordance with the collection tube manufacturer's recommendations
- Whole blood samples should be centrifuged and diluted 4-fold prior to analysis
- 200  $\mu$ l sample volume required

### Urine

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- Dedicated kit for urine with the most appropriate cut off
- Detection of both parent and metabolite drug
- 200  $\mu$ l sample volume required
- No sample preparation

### Oral Fluid

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- Matrix dedicated kit for oral fluid ensures optimal assay performance
- Compatible for use with multiple oral fluid collection devices
- Applications for point of collection testing
- 200  $\mu$ l sample volume required
- Sample preparation should be carried out in accordance with the collection device manufacturer's recommendations



## Cartridge & Analyser Overview

1

### Well One

Cut off material is added here (qualitative kits) or adjuster/QC/sample is added here (semi-quantitative kits).

2

### Well Two

Adjuster/QC/sample is added here.

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 44 discrete testing regions.



1

### Touch Screen

A large touch screen interface allows the user to easily navigate through the testing screens of the analyser and view test 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 e.g barcode scanner, printer and export test results via USB.

## Applications

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### Emergency/Hospitals

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Emergency rooms typically screen for many routine drugs of abuse, as patients may be incoherent when providing information.



### Workplace Drug Testing

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With far-reaching implications, up to 20 percent of work-related fatalities test positive for drugs or alcohol. The drugs at the root of this issue include cocaine, heroin, methamphetamine and prescription drugs.



### Rehabilitation Centres

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It is important to have a clear understanding of the drugs in the patient's system before facilitating detox and to monitor abstinence.



### Mining Industry

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The priority for any mine is preventing accidents by keeping workers who are under the influence of drugs and alcohol off site. MultiSTAT can help to reduce costs associated with high false result rates incurred with current test methods.



### Medical Examiners

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It is essential Medical Examiners are able to screen for a wide range of drugs and drug metabolites in order to successfully investigate deaths that occur under unusual or suspicious circumstances.



### Prisons

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Drug testing in prisons is key to ensuring offenders have a better chance of leading a drug free lifestyle after incarceration, as the links between drug use and crime is increasing.



### Doctors Surgeries

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Drug testing patients who are being treated for pain can be tested for opioid misuse and abuse, offering wider options and the ability for doctors caring for pain patients to make informed decisions.



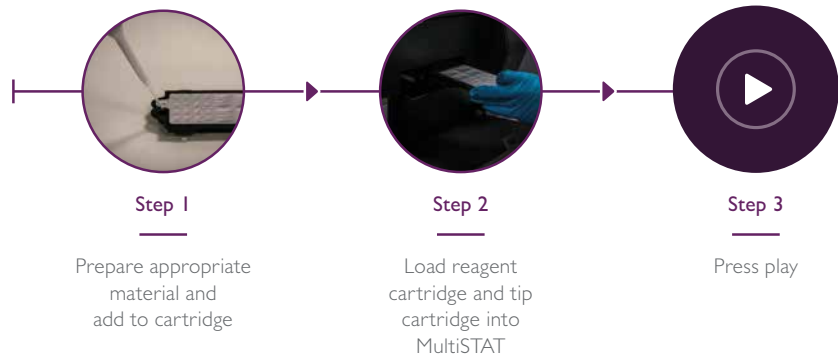
### Airports

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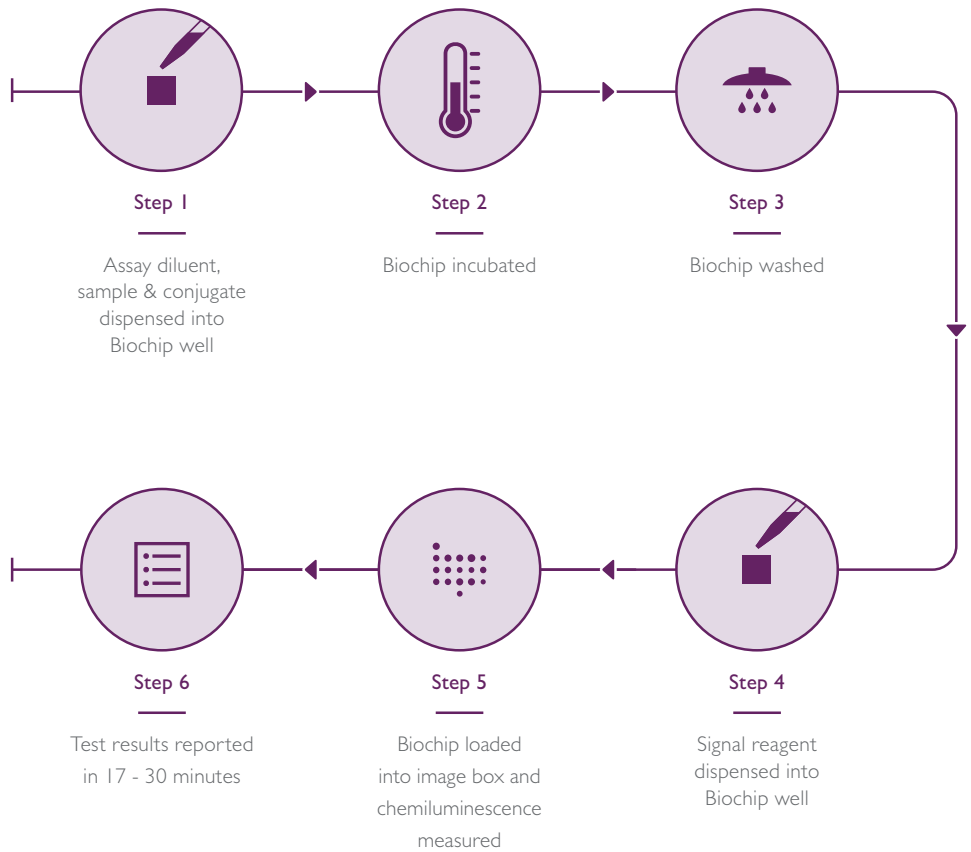
Testing employees for drugs is extremely important. Random tests and tests after an accident or serious incident involving an employee is crucial to passenger safety and airport security.

## Evidence MultiSTAT Process

### User Steps



### Analyser Steps





## Test Menu

### ToxPlex

Cat. No. EV4455

Time to Result: Under 30 minutes

Matrix: Urine\*

Sample Input: Dual Sample

Results Type: Semi-Quantitative

\*ToxPlex Blood Coming Soon

Assay	Min Cut-Off	Max Cut-Off	Assay	Min Cut-Off	Max Cut-Off
6-MAM	10ng/mL	N/A	Meprobamate	500ng/mL	N/A
Acetaminophen	50µg/mL	N/A	Methadone	200ng/mL	500ng/mL
Amphetamine	200ng/mL	1000ng/mL	Methamphetamine	200ng/mL	1000ng/mL
Barbiturates	200ng/mL	300ng/mL	Methaqualone	200ng/mL	300ng/mL
Benzodiazepines 1	100ng/mL	300ng/mL	Opiate	200ng/mL	2000ng/mL
Benzodiazepines 2	100ng/mL	N/A	Oxycodone	100ng/mL	500 ng/mL
Buprenorphine	1ng/mL	10ng/mL	PCP	25ng/mL	N/A
BZG/Cocaine	100ng/mL	300ng/mL	Pregabalin	1000ng/mL	2000ng/mL
Creatinine (Urine Only)	20mg/dL	N/A	Propoxyphene	300ng/mL	N/A
Dextromethorphan	20ng/mL	N/A	Salicylates	50µg/mL	N/A
EtG	1000ng/mL	N/A	TCA	150ng/mL	1000ng/mL
Fentanyl	1ng/mL	10 ng/mL	THC	20ng/mL	50ng/mL
Haloperidol	50ng/mL	N/A	Tramadol	100ng/mL	300 ng/mL
Ketamine	100ng/mL	300ng/mL	Zolpidem	20ng/mL	-
MDMA	100ng/mL	500ng/mL	-	-	-

### Blood

Cat. No. EV4195

Time to Result: 23 minutes

Assay	Cut-Off	Assay	Cut-Off
6-MAM	10 ng/ml	Methadone	10 ng/ml
AB-CHMINACA	5 ng/ml	Methamphetamine	50 ng/ml
AB-PINACA	2 ng/ml	Opiates	80 ng/ml
Amphetamine	50 ng/ml	Oxycodone	10 ng/ml
BZG (Cocaine Metabolite)	25 ng/ml	PCP (Phencyclidine)	5 ng/ml
Barbiturates	50 ng/ml	Pregabalin	1000 ng/ml
Benzodiazepines	20 ng/ml	TCA (Tricyclic Anti-depressants)	60 ng/ml
Buprenorphine	2 ng/ml	THC (Cannabinoids)	10 ng/ml
EtG (Ethyl Glucuronide)	500 ng/ml	Tramadol	5 ng/ml
Fentanyl	1 ng/ml	α-PVP	5 ng/ml

## Urine I

Cat. No. EV4193

Time to Result: 19 minutes

Assay	Cut-Off	Assay	Cut-Off
6-MAM	10 ng/ml	JWH-018 (Synthetic Cannabinoids)	20 ng/ml
AB-PINACA	2.5ng/ml	Methadone	300 ng/ml
Amphetamine	200 ng/ml	Methamphetamine	200 ng/ml
BZG (Cocaine Metabolite)	150 ng/ml	Opiates	200 ng/ml
Barbiturates	200 ng/ml	Oxycodone	50 ng/ml
Benzodiazepines I	150ng/ml	TCA (Tricyclic Anti-depressants)	150ng/ml
Benzodiazepines II	150ng/ml	THC (Cannabinoids)	20 ng/ml
Buprenorphine	1 ng/ml	Tramadol	5 ng/ml
Creatinine	20mg/dl	UR-144 (Synthetic Cannabinoids)	10 ng/ml
EtG (Ethyl Glucuronide)	750 ng/ml	α-PVP	5 ng/ml
Fentanyl	2 ng/ml	-	

## Urine II

Cat. No. EV4292

Time to Result: 19 minutes

Assay	Cut-Off	Assay	Cut-Off
6-MAM	10ng/ml	Methadone	300ng/ml
AB-CHMINACA	10ng/ml	Methamphetamine	500ng/ml
AB-PINACA	3ng/ml	Opiates	300ng/ml
Amphetamine	500ng/ml	PCP (Phencyclidine)	25ng/ml
BZG (Cocaine Metabolite)	300ng/ml	Pregabalin	300ng/ml
Barbiturates	200ng/ml	TCA (Tricyclic Anti-depressants)	150ng/ml
Benzodiazepine	200ng/ml	THC (Cannabinoids)	50ng/ml
Creatinine	20mg/dl	Tramadol	20ng/ml
EtG (Ethyl Glucuronide)	750ng/ml	UR-144 (Synthetic Cannabinoids)	10ng/ml
Fentanyl	2ng/ml	α-PVP	5ng/ml

## Oral Fluid II

Cat. No. EV4279

Time to Result: 17 minutes

4-fold dilution applied by the collection device has been accounted for in the cut-off material provided

Assay	Cut-Off	Assay	Cut-Off
6-MAM	3 ng/ml	LSD	1.5 ng/ml
Amphetamine	60 ng/ml	Methadone	5 ng/ml
BZG (Cocaine Metabolite)	30 ng/ml	Methamphetamine	70 ng/ml
Barbiturates	60 ng/ml	Opiates	15 ng/ml
Benzodiazepines I	15 ng/ml	Oxycodone	10 ng/ml
Benzodiazepines II	15 ng/ml	PCP (Phencyclidine)	7 ng/ml
Buprenorphine	1.5 ng/ml	THC (Cannabinoids)	5 ng/ml
Fentanyl	1.5 ng/ml	Tramadol	5 ng/ml
JWH-018 (Synthetic Cannabinoids)	20 ng/ml	UR-144 (Synthetic Cannabinoids)	25 ng/ml
Ketamine	65 ng/ml	α-PVP	2.5 ng/ml

## Easy to Use Software

### 1 Complete Patient Profiling

Multiplex testing with Biochip Array Technology enables clinicians and investigators to consider the complete picture allowing for well informed decisions and accurate diagnosis.

### 2 Extensive Test Menu

Screen for up to 29 drugs of abuse as part of our unrivalled toxicology test menu, capable of detecting over 600 drugs and drug metabolites.

### 3 Data Integrity

Users are able to log in to access data and lock the MultiSTAT to ensure data integrity. Search options are available to retrieve previous results.

The screenshot displays the MultiSTAT software interface. At the top, there are two columns labeled 'S1' and 'S2'. Below these, there are fields for 'Result: Valid', 'Cartridge ID: 88531', 'Date Run: 17/05/2022', 'Barcode:', 'User Name:', 'Array Name:', and 'Sample ID:'. A large number '1' is overlaid on the 'Valid' result. Below this is a table with columns for 'Analyte', 'Concentration', 'Cutoff', 'Units', and 'Result'. The table lists various analytes such as MAMP, MDMA, AMPH, TCA, OXYC, OPIAT, 6-MAM, BENZ1, BENZ2, BARB, THC, DMP, MDONE, BZG, MPB, TRM, FENT, BUP, PPX, and PCP. A large number '2' is overlaid on the table. At the bottom, there is a navigation bar with icons for Power, Help, Logout, Lock, Home, Basic Search, and Advanced Search. A large number '3' is overlaid on the 'Advanced Search' icon.

Analyte	Concentration	Cutoff	Units	Result
MAMP	< 5.23	200.00	ng/mL	negative
MDMA	1.97	100.00	ng/mL	negative
AMPH	531.35	200.00	ng/mL	POSITIVE
TCA	< 2.69	150.00	ng/mL	negative
OXYC	< 1.26	100.00	ng/mL	negative
OPIAT	0.29	200.00	ng/mL	negative
6-MAM	< 0.13	10.00	ng/mL	negative
BENZ1	> 1228.8	100.00	ng/mL	POSITIVE
BENZ2	5.98	100.00	ng/mL	negative
BARB	< 12.28	200.00	ng/mL	negative



rdx.service	Batch Calibration Date:	17/05/2022
ToxPlex Urine	Batch Calibration ID:	4 88528
S1		

Cutoff	Units	Result	Analyte	Concentration	Cutoff	Units	Result
0.00	ng/mL	POSITIVE	ZOL	< 1.12	20.00	ng/mL	negative
0.00	ng/mL	negative	KET	352.67	300.00	ng/mL	POSITIVE
0.00	ng/mL	negative	HAL	< 0.51	50.00	ng/mL	negative
50.00	ng/mL	POSITIVE	MTQ	< 0.39	300.00	ng/mL	negative
0.00	ng/mL	negative	PGB	< 43.64	1000.00	ng/mL	negative
0.00	ng/mL	negative	CREAT	25.53	20.00	mg/dL	unadulterated
0.00	ng/mL	negative	ETG	< 218.44	1000.00	ng/ml	negative
0.00	ng/mL	POSITIVE	ACE	4.13	50.00	µg/mL	negative
0.00	ng/mL	negative	SAL	7.93	50.00	µg/mL	negative
5.00	ng/mL	negative					

IFU	Results List	Export 6
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Results
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#### 4 Result Traceability

Chain of custody features enable better management, accountability and responsibility of those using sample/data.

#### 5 Quality Results

Highly reproducible qualitative and semi-quantitative results. Sample classification displayed in relation to established cut off limits (ToxPlex only). Creatinine levels indicate whether or not a sample has been adulterated (ToxPlex Urine only).

#### 6 Connectivity

LIMS integrated for convenient reporting, and fully printable reports.

# Evidence MultiSTAT Specifications

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<b>Analyser Description</b>	Fully automated Biochip Array analyser
<b>Dimensions</b>	585 (H) x 535 (D) x 570 (W) mm
<b>Weight</b>	48kg (106lbs)
<b>Biochip Format</b>	Cartridge based system – assay reagents sealed in a cartridge
<b>Connectivity</b>	LIMS uni-directional interface
<b>Data Back-up Methods</b>	Data export functionality
<b>Environment</b>	Operating temperature 18°C-32°C, <80% Relative humidity, <2000m Altitude, Pollution: Degree 2 (IEC 664) Stable workbench required
<b>Measurement Principal</b>	Competitive techniques with chemiluminescent reaction
<b>Operator Interface</b>	15.6" touch screen
<b>Peripherals</b>	Barcode scanner Printer can be connected (not included)
<b>Power Requirements</b>	Input Voltage 110-240v
<b>Sample Loading</b>	Single cartridge loading bay
<b>Sample Volume</b>	170-200µl (kit dependent)
<b>Time to Result</b>	17 minutes - 30 minutes (kit dependent)





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