

EVIDENCE MULTISTAT

Fully Automated Drug Testing

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Randox Toxicology are world leaders in drug testing solutions with the capability of detecting over 500 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 21 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.

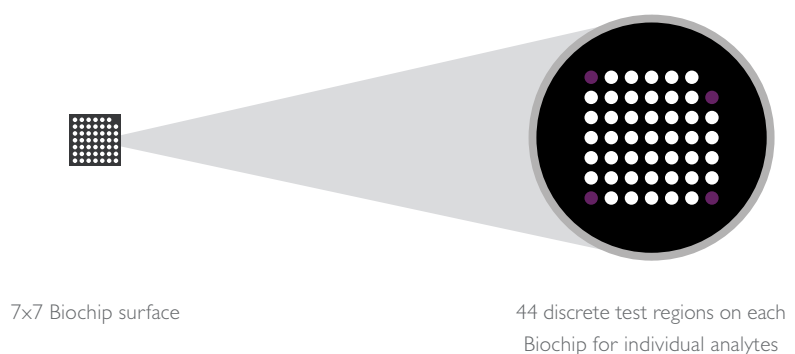
Multiplex Explained

BAT is an immunoassay testing platform for the simultaneous multi-analyte testing 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.

Key

○ Discrete test region

● Quality control spot





RANDOX

evidence
MULTISTAT

Benefits



Rapid Screening

With minimal sample preparation required, qualitative results can be 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

Blood



- 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 ul sample volume required

Urine



- Dedicated kit for urine with the most appropriate cut off
- Detection of parent metabolite
- 200 ul sample volume required
- No Sample Preparation

Oral Fluid



- 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 ul sample volume required
- Sample preparation should be carried out in accordance with the collection device manufacturer's recommendations

Cartridge & Analyser Overview

1

Reference Chamber

Cut off material is added here.

2

Sample Chamber

200µl of sample is added here.

3

Foil Cover & Fluid Reservoirs

All additional fluids required are stored underneath a sealed foil cover and pierced by the analyser during testing.

4

Biochip Wells

Two biochips are placed here, one to test the patient sample and one for the cut off materials, 21 discrete testing regions are placed on each biochip.



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



Emergency/Hospitals

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



Workplace Drug Testing

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

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

The priority for any mine is preventing accidents, reducing costs associated with high false rates from current testing methods and keeping workers who are under the influence of drugs and alcohol off site.



Racing/Anti-Doping

Most commonly performed on racehorses, drug tests are also performed on horses in endurance riding and for competitions such as the Olympics. Many competition horses are regulated by various international and national organisations.



Prisons

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



Doctor's Surgery

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.

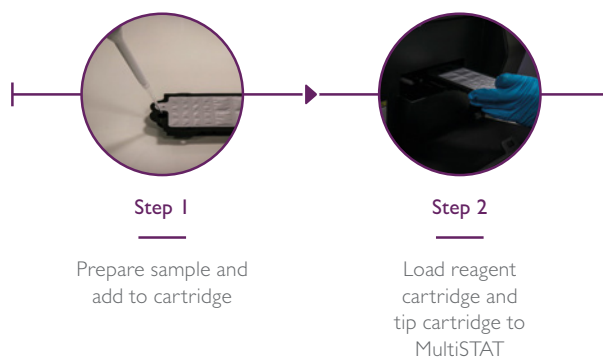


Airports

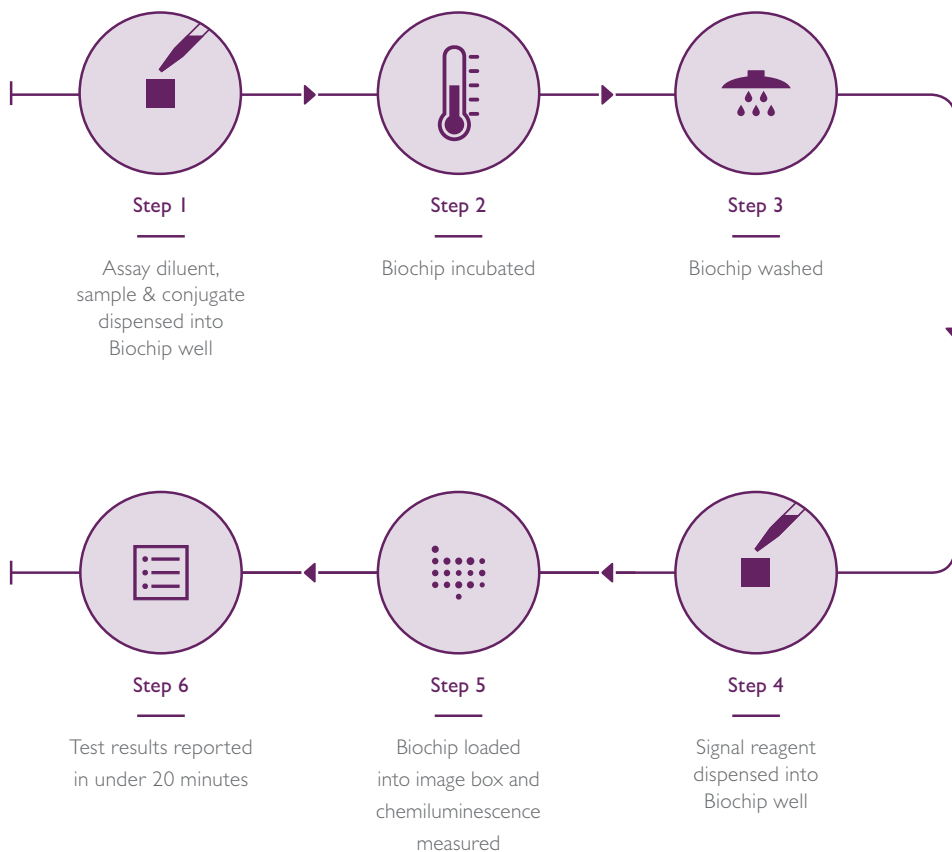
Testing employees for drugs is extremely important. Random tests and tests after an accident or serious incident involving an employee is crucial to passenger safety and airport security.

Evidence MultiSTAT Process

User Steps



Analyser Steps





Test Menu

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: 17 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: 17 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

Cat. No. EV4117

Time to Result: 17 minutes

3-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	2 ng/ml	LSD	1 ng/ml
Amphetamine	50 ng/ml	Methadone	4 ng/ml
BZG (Cocaine Metabolite)	20 ng/ml	Methamphetamine	50 ng/ml
Barbiturates	50 ng/ml	Opiates	10 ng/ml
Benzodiazepines I	10 ng/ml	Oxycodone	8 ng/ml
Benzodiazepines II	10 ng/ml	PCP (Phencyclidine)	5 ng/ml
Buprenorphine	1 ng/ml	THC (Cannabinoids)	2 ng/ml
Fentanyl	1 ng/ml	Tramadol	4 ng/ml
JWH-018 (Synthetic Cannabinoids)	5 ng/ml	UR-144 (Synthetic Cannabinoids)	10 ng/ml
Ketamine	50 ng/ml	α -PVP	2 ng/ml

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 allows clinicians and investigators to consider the complete picture allowing for well informed decisions and accurate diagnosis.

2 Extensive Test Menu

Our 21 drugs of abuse panels form part of our unrivalled toxicology test menu, capable to detecting over 500 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, it shows test status: Result: Completed, Analytes Detected: 12, Cartridge ID: 85052, Date Run: 12/09/2018 10:39. User information includes User Name, Array Name, Sample ID, and Barcode.

Analyte	Result	Cut-off
FENTANYL	Positive	2ng/ml
ABPINACA	Negative	2.5ng/ml
ETHYLGLUCURONIDE	Positive	750ng/ml
METHAMPHETAMINE	Negative	200ng/ml
BARBITURATE	Positive	200ng/ml
BENZODIAZEPINES1	Negative	150ng/ml
BENZODIAZEPINES2	Positive	150ng/ml

Below the table, there is a search menu with options: Analyte, METHADONE, OPIATE, CREATININE, BENZOYLECGONINE, OXYCODONE, TRAMADOL, and THC. The 'Basic Search' option is highlighted with a purple circle containing the number 3.

At the bottom, there is a navigation bar with icons for Power, Help, Logout, Lock, Home, Basic Search, Advanced Search, and Res. The 'Basic Search' icon is highlighted with a purple circle containing the number 3.

Radox Toxicology Batch QC Date: **4** 12/09/2018 10:33

Drugs of Abuse Urine Batch QC ID: 85051

Sample Tox Run 1

EMU01453858119021234567

Result	Cut-off	Analyte	Result	Cut-off
Positive	300ng/ml	TRICYCLICANTIDEPRESSANTS	Negative	150ng/ml
Negative	200ng/ml	AMPHETAMINE	Positive	200ng/ml
Positive	20mg/dl	BUPRENORPHINE	Negative	1ng/ml
Positive	150ng/ml	6MAM	Negative	10ng/ml
Positive	50ng/ml	JWH-018	Positive	20ng/ml
Negative	5ng/ml	ALPHAPVP	Positive	5ng/ml
Positive	20ng/ml	UR144	Negative	10ng/ml

5

RLU Values Reprocess Results List Export **6**

Results

4 Result Traceability

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

5 Quality Results

Highly reproducible qualitative results. Sample classification displayed in relation to established cut off limits.

6 Connectivity

LIMS integrated for convenient reporting, and fully printable reports.

Evidence MultiSTAT Specifications

Analyser Description	Fully automated Biochip Array analyser
Dimensions	585 (H) x 535 (D) x 570 (W) mm
Weight	48kg (106lbs)
Biochip Format	Cartridge based system – assay reagents sealed in a cartridge
Connectivity	LIMS uni-directional interface
Data Back-up Methods	Data export functionality
Environment	Operating temperature 18°C-32°C, <80% Relative humidity, <2000m Altitude, Pollution: Degree 2 (IEC 664) Stable workbench required
Measurement Principal	Competitive techniques with chemiluminescent reaction
Operator Interface	15.6" touch screen
Peripherals	Barcode scanner Printer can be connected (not included)
Power Requirements	Input Voltage 110-240v
Sample Loading	Single cartridge loading bay
Sample Volume	200µl
Time to Result	17 minutes - 23 minutes



QC

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