



RANDOX
TOXICOLOGY

EVIDENCE MULTISTAT

Rapid Post-Mortem Drug Testing

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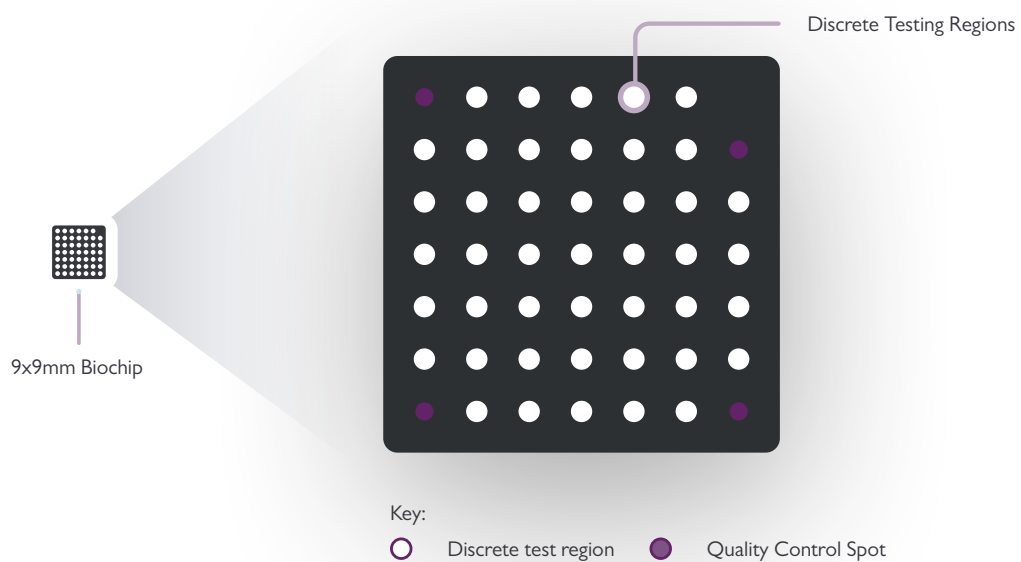
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BIOCHIP ARRAY TECHNOLOGY

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

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



BIOCHIP IN NUMBERS

Up to **48** tests per Biochip

4 spots reserved for quality control

BENEFITS



Results in Under 30 Minutes

Biochip is ideal for Coroner and Medical Examiner Offices to reduce long wait times for toxicology laboratory results.



Semi-Quantitative Results

Semi-quantitative screening with the biochip allows for the identification of substances and metabolites, as well as the quantity that is present in a post-mortem sample.



Multiplexing Technology

From a single sample, biochip can simultaneously detect a range of commonly abused drugs. Designed to achieve a complete profile in the initial screening phase, our test menu can detect over 600 drugs and drug metabolites.



Reduced False Positives

Highly specific antibodies on the biochip enable the separation of drugs with the same parent type. For example:

- Amphetamine, MDMA and methamphetamine
- Benzodiazepines (clonazepam and oxazepam)
- Oxycodone, fentanyl and 6-MAM

POST-MORTEM TOXICOLOGY

Post-mortem toxicology is the legal investigation of specimens for the presence and quantity of drugs to help indicate and determine their contribution to a person's cause of death, specifically if a death is sudden, suspicious, or unexplained.

Drug use may be apparent from evidence found at a crime scene, or from physical indications present on the deceased. When drug use is suspected, a post-mortem toxicology screen can be carried out to assist in further evidence.

There are several different specimen types that can be used in an autopsy examination process, including blood, urine, vitreous humor and tissue.

The wait time for **TOXICOLOGY RESULTS** is reported to be anywhere from **6 WEEKS TO 6 MONTHS** in a number of regions.

Our **BIOCHIP ARRAY TECHNOLOGY** provides **IMMEDIATE** drug testing results and **REAL-TIME DATA** to the pathologist, coroner's office, law enforcement and medical providers.

HOW BIOCHIP IS HELPING THE INDUSTRY



Allowing for faster results and providing information to families quickly



Alerting local authorities to prevalence or a rise in dangerous drugs in communities



Decreasing the need for full autopsies, saving huge associated costs



Providing timely data to public health, aiding response and policy



Allowing preliminary death certificates to be issued rapidly*



Assisting in expediting arrest warrants*

*State and country dependent





SEMI-QUANTITATIVE BIOCHIPS

TOXPLEX BIOCHIP

Product Information

Blood or Urine
Samples



Test Two Samples
per Cartridge



Results in Under
30 Minutes



Analytes	Blood Kit (EV4516)		Analytes	Urine Kit (EV4455)	
	Min Cut-off	Max Cut-off		Min Cut-off	Max Cut-off
Acetaminophen	15 µg/mL	50 µg/mL	Acetaminophen	10 µg/mL	100 µg/mL*
Amphetamine	20 ng/mL	130 ng/mL	Amphetamine	200 ng/mL	1000 ng/mL
Barbiturates	50 ng/mL	120 ng/mL	Barbiturates	200 ng/mL	300 ng/mL
Benzodiazepines I (Oxazepam)	6 ng/mL	20 ng/mL	Benzodiazepines I (Oxazepam)	100 ng/mL	300 ng/mL
Benzodiazepines II (Clonazepam)	10 ng/mL	20 ng/mL	Benzodiazepines II (Clonazepam)	100 ng/mL	300 ng/mL*
Buprenorphine	1 ng/mL	4 ng/mL	Buprenorphine	1 ng/mL	10 ng/mL
BZG/Cocaine	40 ng/mL	100 ng/mL	BZG/Cocaine	100 ng/mL	300 ng/mL
Creatinine (Urine only)	-	-	Creatinine (Urine only)	20 mg/dL	100 mg/dL*
Dextromethorphan	5 ng/mL	10 ng/mL	Dextromethorphan	20 ng/mL	37.5 ng/mL*
Ethyl Glucuronide (EtG)	600 ng/mL	2500 ng/mL	Ethyl Glucuronide (EtG)	500 ng/mL	5000 ng/mL*
Fentanyl	0.6 ng/mL	2.5 ng/mL	Fentanyl	1 ng/mL	10 ng/mL
Haloperidol	5 ng/mL	20 ng/mL	Haloperidol	50 ng/mL	187.5 ng/mL*
Ketamine	50 ng/mL	160 ng/mL	Ketamine	100 ng/mL	300 ng/mL
MDMA	40 ng/mL	150 ng/mL	MDMA	100 ng/mL	500 ng/mL
Meprobamate	150 ng/mL	300 ng/mL	Meprobamate	500 ng/mL	1000 ng/mL*
Methadone	5 ng/mL	20 ng/mL	Methadone	200 ng/mL	1000 ng/mL
Methamphetamine	20 ng/mL	100 ng/mL	Methamphetamine	200 ng/mL	1000 ng/mL
Methaqualone	40 ng/mL	150 ng/mL	Methaqualone	200 ng/mL	300 ng/mL
Opiate	10 ng/mL	200 ng/mL	Opiate	200 ng/mL	2000 ng/mL
Oxycodone	8 ng/mL	20 ng/mL	Oxycodone	100 ng/mL	500 ng/mL
Phencyclidine (PCP)	10 ng/mL	25 ng/mL	Phencyclidine (PCP)	10 ng/mL	25 ng/mL*
Pregabalin	1000 ng/mL	2500 ng/mL	Pregabalin	1000 ng/mL	2000 ng/mL
Propoxyphene	30 ng/mL	60 ng/mL	Propoxyphene	100 ng/mL	300 ng/mL
Salicylates	50 µg/mL	200 µg/mL	Salicylates	50 µg/mL	200 µg/mL*
Tricyclic Antidepressants (TCA)	60 ng/mL	350 ng/mL	Tricyclic Antidepressants (TCA)	150 ng/mL	1000 ng/mL
Cannabinoids (THC)	10 ng/mL	40 ng/mL	Cannabinoids (THC)	20 ng/mL	50 ng/mL
Tramadol	50 ng/mL	100 ng/mL	Tramadol	100 ng/mL	300 ng/mL
Zolpidem	5 ng/mL	20 ng/mL	Zolpidem	10 ng/mL	20 ng/mL
6-MAM	2.5 ng/mL	10 ng/mL	6-MAM	10 ng/mL	50 ng/mL*
Xylazine (Blood Only)	8 ng/mL	25 ng/mL	Xylazine (Blood Only)	-	-

*Not validated

QUALITATIVE BIOCHIPS

BLOOD BIOCHIP

Product Information

Blood Samples



Test One Sample
per Cartridge



Results in 23
Minutes



DOA MultiSTAT Whole Blood (EV4195)			
Analytes	Cut-Off	Analytes	Cut-Off
α-PVP (Flakka)	5 ng/mL	Methamphetamine	50 ng/mL
Amphetamine	50 ng/mL	Opiate	80 ng/mL
Barbiturates	50 ng/mL	Oxycodone	10 ng/mL
Benzodiazepines	20 ng/mL	Phencyclidine (PCP)	5 ng/mL
Benzoylgonine (Cocaine Metabolite)	25 ng/mL	Pregabalin	1000 ng/mL
Buprenorphine	2 ng/mL	AB-CHMINACA (Synthetic Cannabinoids)	5 ng/mL
Cannabinoids (THC)	10 ng/mL	AB-PINACA (Synthetic Cannabinoids)	2 ng/mL
Ethyl Glucuronide (EtG)	500 ng/mL	Tramadol	5 ng/mL
Fentanyl	1 ng/mL	Tricyclic Antidepressants (TCA)	60 ng/mL
Methadone	10 ng/mL	6-MAM	10 ng/mL

URINE BIOCHIP

Product Information

Urine Samples



Test One Sample
per Cartridge



Results in 19
Minutes



DOA MultiSTAT Urine (EV4193)			
Analytes	Cut-Off	Analytes	Cut-Off
α-PVP (Flakka)	5 ng/mL	Methadone	300 ng/mL
Amphetamine	200 ng/mL	Methamphetamine	200 ng/mL
Barbiturates	200 ng/mL	Opiate	200 ng/mL
Benzodiazepines I (Oxazepam)	150 ng/mL	Oxycodone	50 ng/mL
Benzodiazepines II (Lorazepam)	150 ng/mL	JWH-018 (Synthetic Cannabinoids)	20 ng/mL
Benzoylgonine (Cocaine Metabolite)	150 ng/mL	UR-144 (Synthetic Cannabinoids)	10 ng/mL
Buprenorphine	1 ng/mL	AB-PINACA (Synthetic Cannabinoids)	2.5 ng/mL
Cannabinoids (THC)	20 ng/mL	Tramadol	5 ng/mL
Creatinine	20 mg/dL	Tricyclic Antidepressants (TCA)	150 ng/mL
Ethyl Glucuronide (EtG)	750 ng/mL	6-MAM	10 ng/mL
Fentanyl	2 ng/mL	-	-



RANOX

-evidence-
MULTISTAT



EVIDENCE MULTISTAT

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

TECHNICAL SNAPSHOT

Catalogue Number	EV4115
Dimensions	585 (H) x 535 (D) x 570 (W) mm
Weight	48 kg, 106 lbs
Analyzer Description	Fully automated touchscreen biochip array analyzer
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
Device Registration	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

ANALYZER OVERVIEW

The Cartridge



1

Well One

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

The 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 reporting.

The Analyzer



1

Touch Screen

A large touchscreen interface allows the user to easily navigate through the analyzer 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

4 x USB Ports

USB Ports allow the user to add accessories, such as a barcode scanner, printer, or USB to export test results.

Benefits



No-Fuss Procedure

Pre-filled reagent cartridges and a simple interface mean that minimal training is required. This versatile benchtop analyser achieves accurate semi-quantitative and qualitative results in minutes.



Multi-Panel

The Evidence MultiSTAT can run a variety of panels and test for multiple drugs across different sample types.

WHY MULTISTAT?

THE ISSUE



In the 12-month period ending May 2023,
108,435 PEOPLE DIED of a
DRUG OVERDOSE
in the USA*



In the same period, **82,339** of those
DEATHS were **OPIOID** involved
OVERDOSES, almost double
compared to five years prior*

THE PROBLEM



In 2022 approximately **23%** of fentanyl
powder and **7%** of fentanyl pills seized by the
DEA contained **XYLAZINE**
(DEA 2023)



Wait times for toxicology laboratory
results vary from **6 WEEKS** to
6 MONTHS

THE SOLUTION



Our newly established test for
XYLAZINE is the **FIRST**
immunoassay test in the world
for this drug of abuse



Evidence MultiSTAT
provides results in under
30 MINUTES

PROPERTY OF
RANDOLPH LABORATORIES LTD
019554



RAND

evidence
MULTISTAT

WHAT OUR CUSTOMERS SAY ABOUT US

CHARLESTON COUNTY CORONER'S OFFICE

SOUTH CAROLINA, USA

"If we are conducting an autopsy, we'll take a blood sample and we send it off to a forensic lab, and it will take us six to eight weeks to get those results back. In less than half an hour, using less than a milliliter of blood, the MultiSTAT can scan for traces of 29 drugs." Charleston Coroner Bobbi Jo O'Neal explains.



LEHIGH COUNTY CORONER'S OFFICE

PENNSYLVANIA, USA

"We're saving quite a bit of time with this analyzer, not only do we identify the drug, but it'll also give us the amount that's in the body so we can get a good analysis in a very short period of time, a half hour instead of several weeks." said Deputy Coroner Rick Pender.



KING COUNTY MEDICAL EXAMINER'S OFFICE

WASHINGTON, USA

"Blood samples are tested using an Evidence MultiSTAT (Randox®) automated immunoanalyzer[,] King County's process for identifying possible drug overdoses and streamlining death certification has proved to add value."



Shute R, Bollinger K, Tucker M, and Ropero-Miller JD. (2021). Use of Rapid Toxicology Screening Tools in Medical Examiner/Coroner Offices. U.S. Department of Justice, National Institute of Justice, Office of Investigative and Forensic Sciences.

NORTH AMERICA DRUG OVERDOSE CRISIS GRANTS



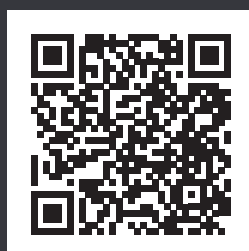
OVER \$1.5 BILLION IN FUNDING AVAILABLE

Grants can be used to aid in the purchase of the Evidence MultiSTAT.
Drug overdose deaths are continually rising in North America. To combat
substance abuse, various bodies are offering grants to a wide variety of groups.

GRANTS AVAILABLE FROM:



Scan Me to Find Out if You're Eligible for a Grant



POST-MORTEM BIOCHIP CASE STUDY

An independent study was carried out by the OCME, North Carolina, in order to evaluate the applicability of Biochip arrays for screening post-mortem blood specimens.

Results found excellent agreement with confirmatory methods.

Objectives

- Evaluate the use of Randox Biochip arrays for the detection of drugs in post-mortem blood
- To determine the agreement of Randox screening assay to the gold standard confirmatory method in post-mortem blood

Methodology

- 225 post-mortem blood specimens were obtained
- Specimens were diluted 4 fold - 50 µl sample + 150 µl sample diluent prior to application on the DoA I biochip

Results

- Biochip arrays achieved 100% agreement with the gold standard confirmatory method for Methamphetamine, Benzodiazepines, Methadone, Opiates and Benzoyllecgonine
- Overall Biochip arrays offered 99.6% agreement with the gold standard confirmatory method in post-mortem blood specimens

Evidence	Methamphetamine		Amphetamine		Benzodiazepines		Methadone		Opiates		Benzoyllecgonine	
	GC-MS											
		+	-	+	-	+	-	+	-	+	-	+
+	1	0	0	1	7	0	4	0	3	0	10	0
-	0	32	0	30	0	23	0	29	0	29	0	20
% Agreement	100.0		96.8		100.0		100.0		100.0		100.0	

Overall		
Evidence	GC-MS	
	+	26
-	0	198
% Agreement	99.6	

Conclusions

The post-mortem blood study found that Biochip Array Technology had 100% agreement with the gold standard confirmatory method for Methamphetamine, Benzodiazepines, Methadone, Opiates and Benzoyllecgonine. The laboratory was satisfied with the specificity and accuracy of Biochip arrays for post-mortem screening.

MULTI MATRIX FORENSIC SCREENING

Randox Toxicology whole blood biochip arrays provide a comprehensive drug screen in Blood, Liver, Urine, Muscle and Vitreous Humour Samples in post-mortem specimens.

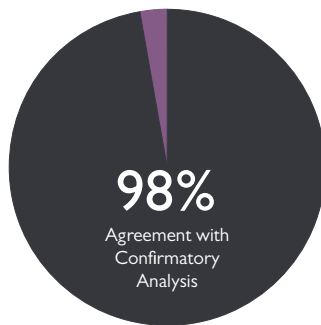
An independent study carried out at a UK Institute of Forensic Science, highlighted the applicability of Biochip Arrays for drug screening in postmortem specimens. Two simplistic sample preparation methods were used to significantly reduce the turnaround time for toxicology results.

Methodology

Biological fluid was prepared through a simple sample dilution.

Tissue specimens 1g were homogenized, centrifuged and the resultant supernatant collected.

261 post-mortem specimens were screened using one or a combination of the commercially available DoA I, DoA I+ and DoA II kits as well as a custom made panel consisting of Acetaminophen, Zaleplon, Zolpidem, Zopiclone, Salicylate and Salicylic Acid assays. The specimens were then confirmed using liquid chromatography with mass spectrometer.



Pie chart showing the percentage of cases in agreement with confirmatory analysis

Results

Liver and muscle specimens were obtained from each of the 261 post-mortem cases; femoral blood, vitreous humor and urine were available in 98%, 92% and 72% of the cases, respectively.

As such, the equivalent of 12,978 individual drug-specific, or drug-group, immunoassay tests were undertaken. Overall >98% of the 12,978 screening tests undertaken agreed with laboratory confirmatory tests performed on femoral blood.

Conclusions

The Randox DOA I, I+, II and Custom array drug screening panels offer pathologists and toxicologists the opportunity to screen a range of tissue specimens for the presence of common therapeutic and abused drugs in the absence of conventional matrices.

The screening procedure is simple, sufficiently sensitive to make it appropriate for use in forensic toxicology, and the speed with which the assay can be completed enables a drug screen to be undertaken whilst an autopsy is in progress.

Reference

Poppy McLaughlin, Peter D Maskell, Derrick Pounder, David Osselton, Use of the Randox Evidence Investigator immunoassay system for near-body drug screening during post-mortem examination in 261 forensic cases., *Forensic Science International* <https://doi.org/10.1016/j.forsciint.2018.11.018>



EVIDENCE SERIES

Randox Toxicology, 515 Industrial Boulevard, Bardane Industrial Park, Kearneysville West Virginia, 25430

Tel: +1 304 728 2890 **Toll Free:** 866 4 RANDOX **E** info@randoxtoxicology.com **I** randoxtoxicology.com

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