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Technical Specification

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.



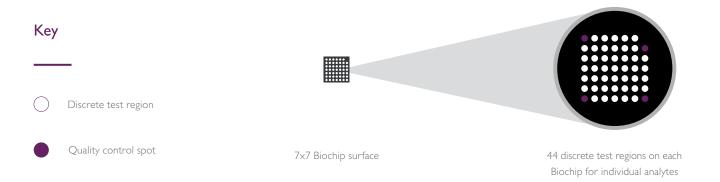
# Evidence+

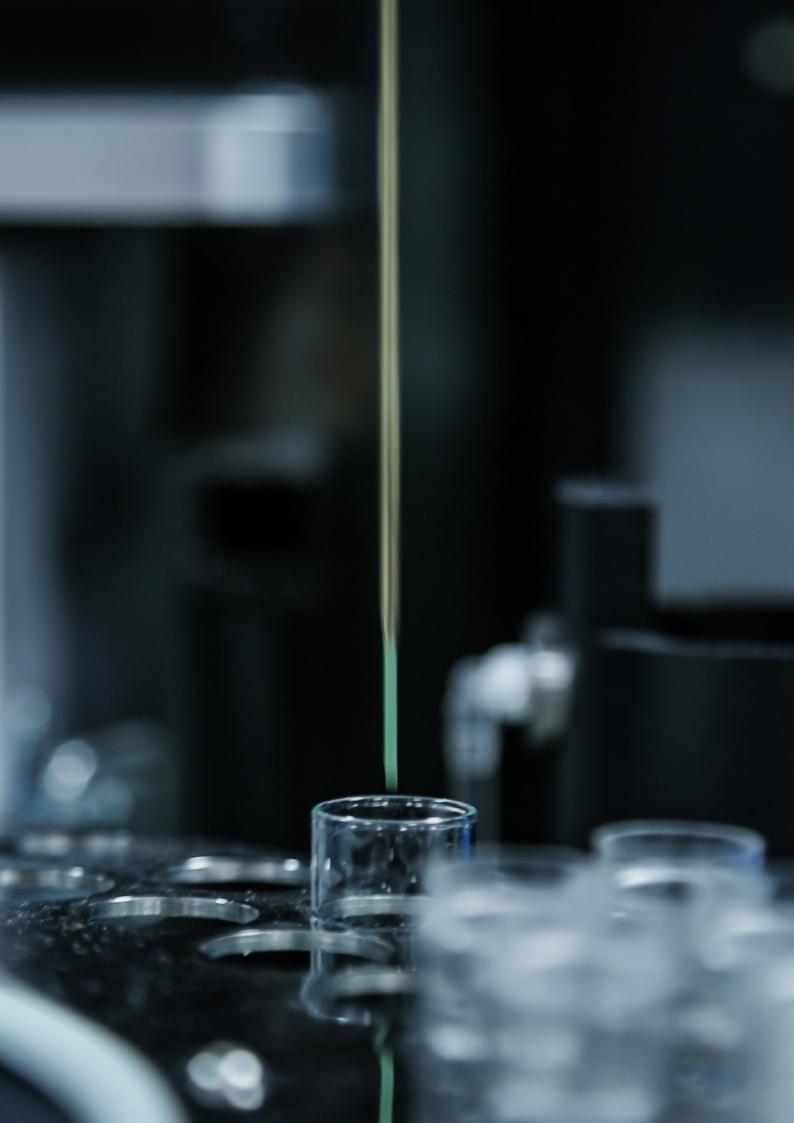
The fully automated Evidence+ analyser is set to truly revolutionise laboratories worldwide. Continuing to provide high standards of quality, efficiency and reliability, the fully automated batch immunoanalyser simultaneously detects multiple drugs and drug metabolites from a single sample.

The Evidence+ analyser enables both efficient and cost-effective testing whilst providing accurate and reliable results to larger high throughput laboratories.

# Multiplex Explained

Biochip Array Technology 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 discrete test regions on the Biochip is simultaneously detected using digital imaging technology and compared to that from a calibration curve.





# **Benefits**



# Large Sample Throughput

With the potential of up to 5,280 test results\*, and up to 44 tests per sample, the Evidence+ analyser is uniquely designed for fast and accurate batch analysis.



## **Precise Testing**

Biochip Array Technology has a proven high standard of precise testing with CV's typically <10% and multiplex capabilities minimising analytic variation between tests, representing greater value for money as fewer samples and consumables deliver a more in-depth analysis.



## Worklist Loading

Allows the operator to save frequently used worklists, reload them onto the system and apply them to different arrays with a few simple clicks, ensuring time to first result is firmly fixed at <45 minutes.



# **Quality Control Extension**

Extended quality control viewing allows results to be displayed on the system for up to 180 days, facilitating the operator with trend analysis for recalibration and control performance.



### **Email Alerts**

Configuration of the system enables message notifications and alerts to be emailed to the user, speeding up the day-to-day running of the laboratory whilst increasing walk away time and productivity.



# **Barcoded Reagents**

Reagent barcodes and signal usage calculation reduces human error and the possibility of using the incorrect reagents allowing a truly effective end-to-end solution.

# **Matrices**



### Blood

- Simple sample preparation
- Matrix dedicated kit for whole blood ensures optimum performance
- Adjustable cut-offs can be selected avoiding re-calibration/use of different calibrators



### Post-Mortem Blood

- Small sample volume requirements
- No SPE columns or solvents needed
- Simple sample preparation



# Urine

- No sample preparation
- Proven reduction in false results



# Oral Fluid

- Compatible for use with multiple oral fluid collection devices
- Matrix dedicated kit for oral fluid ensures optimal assay performance

### Tissue\*



- Invaluable for drug screening programs
- Separation of drugs with same parent type ensures fewer false results
- Biochips offer accuracy and precision in a wide range of tissue homogenates

# Meconium\*



- Considered the best method for detecting drug exposure in pregnancy
- Separation of drugs with same parent type ensures fewer false results
- Multiplex testing facilitates simultaneous screening of various drugs and drug metabolites from a single meconium sample

### Hair\*



- Sample collection is relatively easy and non-invasive
- Monitoring abstinence is possible over an extended length of time
- Can be used to determine drug abuse history over a period of months

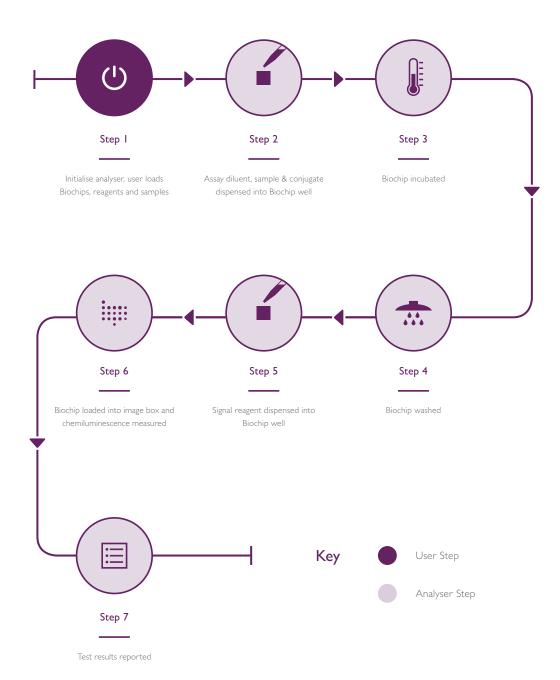
### Vitreous Humor\*



- Increased stability of certain drugs with this matrix
- Facilitates testing when other matrices are unavailable
- Multiplex is advantageous due to limited sample volume

<sup>\*</sup>Test menu validated for blood, urine and oral fluid but all other matrices are applicable.

# **Evidence+ Process**





# Evidence+ System Overview



Sample Carousel



2 Bulk Reagent Unit



3 Cassette Collection







4 Cassette Loading Tower



Refrigerated Reagent
Carousel



Biohazard Waste Collection Unit





# Test Menu

# Drugs of Abuse Array Ultra/DUID

	Assays
Amphetamine	Meprobamate
Barbiturates	Methadone
Benzodiazepines I (Oxazepam)	Methamphetamine
Benzodiazepines II (Lorazepam)	Opiate
Benzodiazepines III (Clonazepam)	Oxycodone I
Benzoylecgonine (Cocaine Metabolite)	Oxycodone II
Buprenorphine	Phencyclidine (PCP)
Cannabinoids (THC)	Tramadol
Dextromethorphan	Tricyclic Antidepressants (TCA)
Fentanyl	Zolpidem
Generic Opioids	-

# New Psychoactive Substances I

Assays	
AB-CHMINACA (Synthetic Cannabinoids)	Mescaline
AB-PINACA (Synthetic Cannabinoids)	Phenylpiperazines I
Bath Salts I (Mephedrone / Methcathinone)	Phenylpiperazines II
Bath Salts II (α-PVP / MDPV)	Salvinorin
Benzylpiperazines	UR-144/XLR-11 (Synthetic Cannabinoids)
JWH-018 (Synthetic Cannabinoids)	-

# New Psychoactive Substances II

Assays	
Acetylfentanyl	Mitragynine
AH-7921	MT-45
Buprenorphine	Naloxone
Carfentanil/Remifentanil	Ocfentanyl
Clonazepam	Sufentanil
Etizolam	U-47700
Furanylfentanyl	W-19

# Customisable Test Menu

# Analgesics

Assays	
6-MAM	O-desmethyltramadol
Acetaminophen	Opiate
Buprenorphine / Norbuprenorphine	Oxycodone I
EDDP	Oxycodone II
Fentanyl	Phencyclidine (PCP)
Generic Opioids	Propoxyphene
Hydrocodone	Salicylate
Hydromorphone	Tapentadol
lbuprofen	Tilidine / Nortilidine
Meperidine	Topiramate
Methadone	Tramadol
Naloxone	-

# Prescription Drugs

As	says
Baclofen	Olanzapine
Bumetanide	Oxcarbazepine
Carbamazepine	Paroxetine
Clonidine	Phenytoin
Clozapine	Pipradrol
Diphenhydramine	Quetiapine
Escitalopram	Rimonabant (STR141716A)
Fluoxetine	Ritalinic Acid
Fluvoxamine	Scopolamine
Haloperidol	Sertraline
Lamotrigine	Tadalafil
Levetiracetam	Theophylline
Loperamide	Trazodone
Methocarbamol	Tricyclic Antidepressants (TCA)
Methylphenidate	Tripelennamine
Mirtazapine	Valproic Acid
Modafinil	Venlafaxine / O-desmethylvenlafaxine
Naltrexone	-

# New Psychoactive Substances

	Assays
α-PVP / MDPV (Bath Salts)	MDMD-CHMZCA (Synthetic Cannabinoids)
Acetylfentanyl	Mescaline
AB-CHMINACA (Synthetic Cannabinoids)	Methoxydiphenidine (2-MeO-Diphenidine, MXP)
AB-FUBINACA (Synthetic Cannabinoids)	Mephedrone / Methcathinone (Bath Salts)
AB-PINACA (Synthetic Cannabinoids)	Mitragynine
ADBICA (Synthetic Cannabinoids)	MN-18 / 5F-MN-24 (Synthetic Cannabinoids)
AH-7921	MT-45
APP-CHMINACA (Synthetic Cannabinoids)	NBOMe
APP-FUBINACA (Synthetic Cannabinoids)	Ocfentanyl
BB-22 (Synthetic Cannabinoids)	PB-22 (Synthetic Cannabinoids)
Benzylpiperazines	Phenylpiperazines I
Carfentanil/Remifentanil	Phenylpiperazines II
Cumyl-PINACA (Synthetic Cannabinoids)	Salvinorin
FUB-AMB (Synthetic Cannabinoids)	Sufentanil
Furanylfentanyl	UR-144/XLR-11 (Synthetic Cannabinoids)
JWH-018 (Synthetic Cannabinoids)	U-50488
JWH-250 / RCS-8 (Synthetic Cannabinoids)	U-47700
MAB-CHMINACA (Synthetic Cannabinoids)	URB's
MDMB-CHMICA (Synthetic Cannabinoids)	W-19

# Sedative Hypnotics

Assays	
Barbiturates	Methaqualone
Benzodiazepines I (Oxazepam)	Methoxetamine
Benzodiazepines II (Lorazepam)	Norketamine
Benzodiazepines III (Clonazepam)	Phenobarbital
Chloral Hydrate Metabolite	Primidone
Etizolam	Propofol
Flunitrazepam	Zaleplon
Ketamine/Norketamine	Zolpidem
Meprobamate	Zopiclone

### Stimulants

Assays	
Amphetamine	Mazindol
Benzoylecgonine (Cocaine Metabolite)	MDMA
Diethylpropion	Methamphetamine
DMAA	Phenmetrazine / Fluorophenmetrazine
DOx Series	Tetrahydracannabinol (THC)
LSD	-

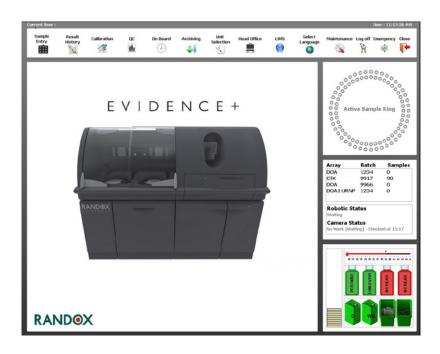
# Other

Assays	
Atropine	Ethyl Glucuronide (EtG)
Benzhexol	Gabapentin
Bupropion	Methotrexate
Creatinine	Pregabalin
Doxylamine	Sildenafil (Viagra)
Dextromethorphan	-

# Intuitive Software

### Home Screen

The Evidence+ software provides the operator with easy navigation tabs for frequently used system features.



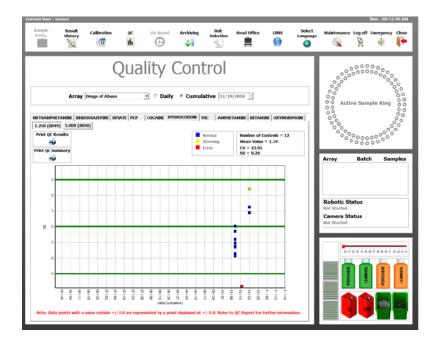
### Dashboard

The dashboard screen allows the operator to easily and quickly view the status of on board modules and consumables via colour coded displays.



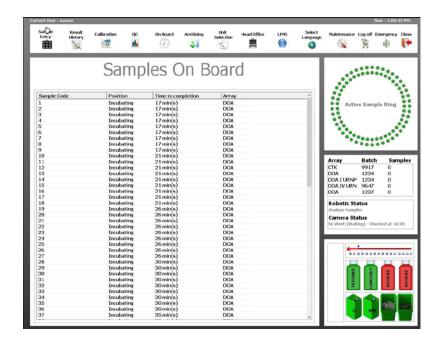
# **Quality Control**

The Evidence+ QC software provides automated statistical analysis including Mean, Standard Deviation (SD), Coefficient of Variation (CV) and Levey-Jennings Charts for all analytes. Controls are graphically displayed for up to 180 days and can be viewed on a daily or cumulative basis.



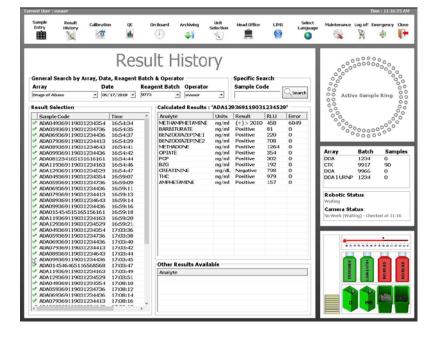
# Samples on Board

The system software allows the operator to view the operational status and time to completion (to nearest minute) of each sample as it is processed through the analyser.



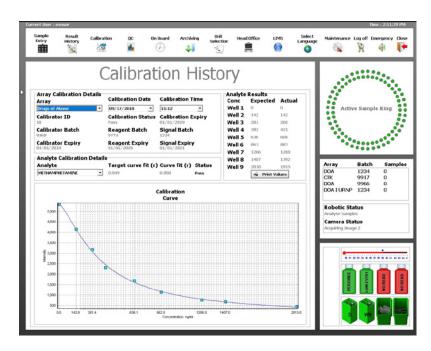
# Result History

Results for specific samples can be viewed, printed or exported by selecting the sample(s) of interest. Results will be presented as qualitative or quantitative values dependent on the test array.



# Calibration History

The Calibration History screen allows for the operator to review analyte by analyte calibration curve performance on the analyser based on the test array and reagents used.



# Reporting



# Results Reporting

Colour coded reporting allows for the operator to easily identify positive, negative and borderline results. Customisable report headings allow for the laboratory to personalise the reports with their own company branding. Summary reports incorporate essential information pertaining to the calibration, control and sample results on the one colour formatted report.

# Local Engineers. Global Coverage

Randox Toxicology provides customers with an unrivalled support service. A team of highly trained specialists are on-hand to deal with any technical and service issues you may have.



Global Offices

We have 25 international offices acting as direct points of contact for customers

100+ Specialists

Randox has over 100 engineers and tech support specialists placed around the world to ensure an efficient response to customer requests

# 350 Scientists

Randox has 350 scientists placed around the world, dedicated to providing a quality product offering



# Global Distributors

We have official Randox Toxicology technical distributors in over 100 countries



We offer the ultimate after-care support with tailored service packages to suit your available budget

# **Evidence+ Specifications**

Analyser Description Fully automated Biochip Array analyser

 $170 (H) \times 100 (D) \times 200 (W) cm$ Dimensions

Weight 620kg (approx)

**Biochip Capacity** 4 x Biochip cassettes (40 Biochip Carriers, 360 Biochips)

**Biochip Format** I × Biochip carrier (holds 9 individual Biochips)

Calibration Principal 9 point calibration

LIS / LIMS compatiable Connectivity

Ambient environment 16°C - 30°C, <80% relative humidity Environment

Incubation Time 30 minutes (Array specific)

Installation Requirements Evidence+ must be connected to a three-wire power supply with a safety ground

Liquid Waste Removed to an external drain or tank

LIS Connectivity Bi-Directional: ASTM standard (RS232 Connection)

Maximum Throughput Up to 5,280 tests per hour (Array specific)

Measurement Principal Chemiluminescence Windows® based

Operational Modes

Quality Control Extensive QC package including full QC reports, Levey-Jennings charts and multi-rule QC options

Reagent Capacity 16 reagent wedges

Sample Barcode Code 39, Codabar, Code 128, I 2 of 5, Code 93, UPC/EAN, Pharmacode

Sample Capacity

Sample Tube Compatibility 12mm or 16mm diameter by 100mm, 16mm diameter by 75mm length tubes with minimum volume 500µl.

Sample cups of 15mm diameter by 23-38mm length and minimum volume  $350\mu l$  can be placed into 16mm

diameter tubes on the carousel

2 sample rings capable of holding 90 sample test tubes or cups per ring Sample Rings

Sample Volume 6 - I50µl per Biochip (Array specific)

System Fluids Refrigerated reagent storage, bulk storage for wash and displacement

Start Up / Shut Down Time 8-10 minutes start up/shut down

Time to First Result < 45 minutes (Array specific)



