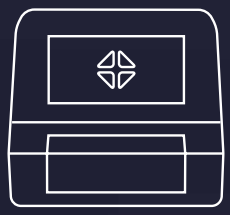
RANDOX



# EVIDENCE MULTISTAT

Revolutionising Patient Management

EVIDENCE
MULTISTAT

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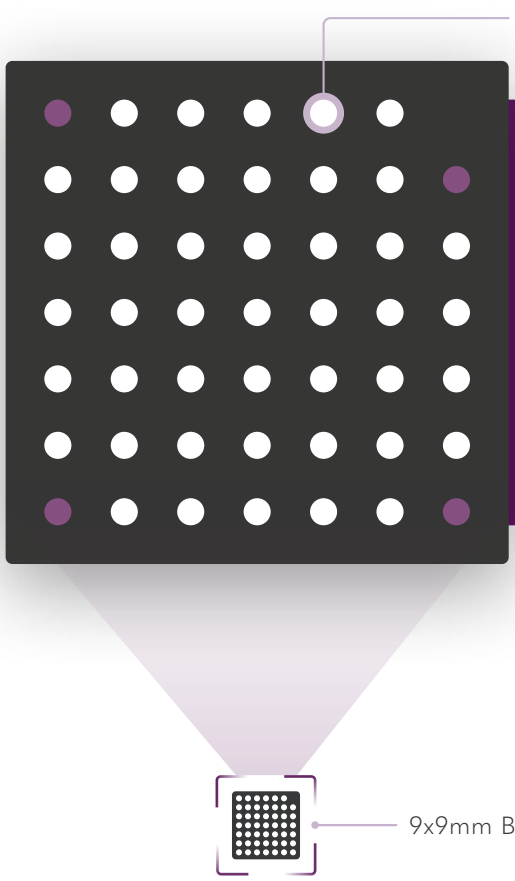
# Biochip Array Technology

Biochip Array Technology boasts cutting-edge multiplex testing capabilities, providing rapid and accurate 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 immobilised and stabilised. Competitive or sandwich chemiluminescent immunoassays are then employed, offering a highly sensitive screen.

Designed to work across a wide variety of matrices, this revolutionary multi-analyte testing platform allows clinicians to achieve a complete immunoassay profile for screening and diagnostic purposes.




Each biochip can have up to 48 Discrete Testing Regions (DTRs), 4 of which are reserved for internal quality control. With the ToxPlex Array, up to 29 DTRs will be utilised to perform tests simultaneously.

Key:

Discrete test region

Quality control spot

48

**Discrete Testing Regions**

**Multi-Marker Technology**

**Save Time & Money**

QC
RANDOX
—evidence—
MULTISTAT

# Evidence MultiSTAT

## Built for Therapeutic Intervention

Using our revolutionary Biochip Array Technology, the Evidence MultiSTAT is a fully automated analyser that enables the detection of up to 44 targets simultaneously from a single sample.

# Analyser Overview

## The Cartridge

Figure 1: MultiSTAT 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.

## The Process

Prepare sample & add to cartridge

Load reagent & tip cartridge to MultiSTAT

Press Play

# Benefits

## Rapid Screening

Minimal sample preparation is required, and results for 2 samples can be provided in under 30 minutes, allowing for quicker clinical decisions and timely patient management.

## Simple Process

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 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** | CE marked (HPRA, Europe), MHRA (UK), Health Canada, TGA (Australia), SFDA MDMA (Saudi Arabia) and ANVISA (Brazil) |
| **Sample Loading** | Single cartridge loading bay |

# Software Overview

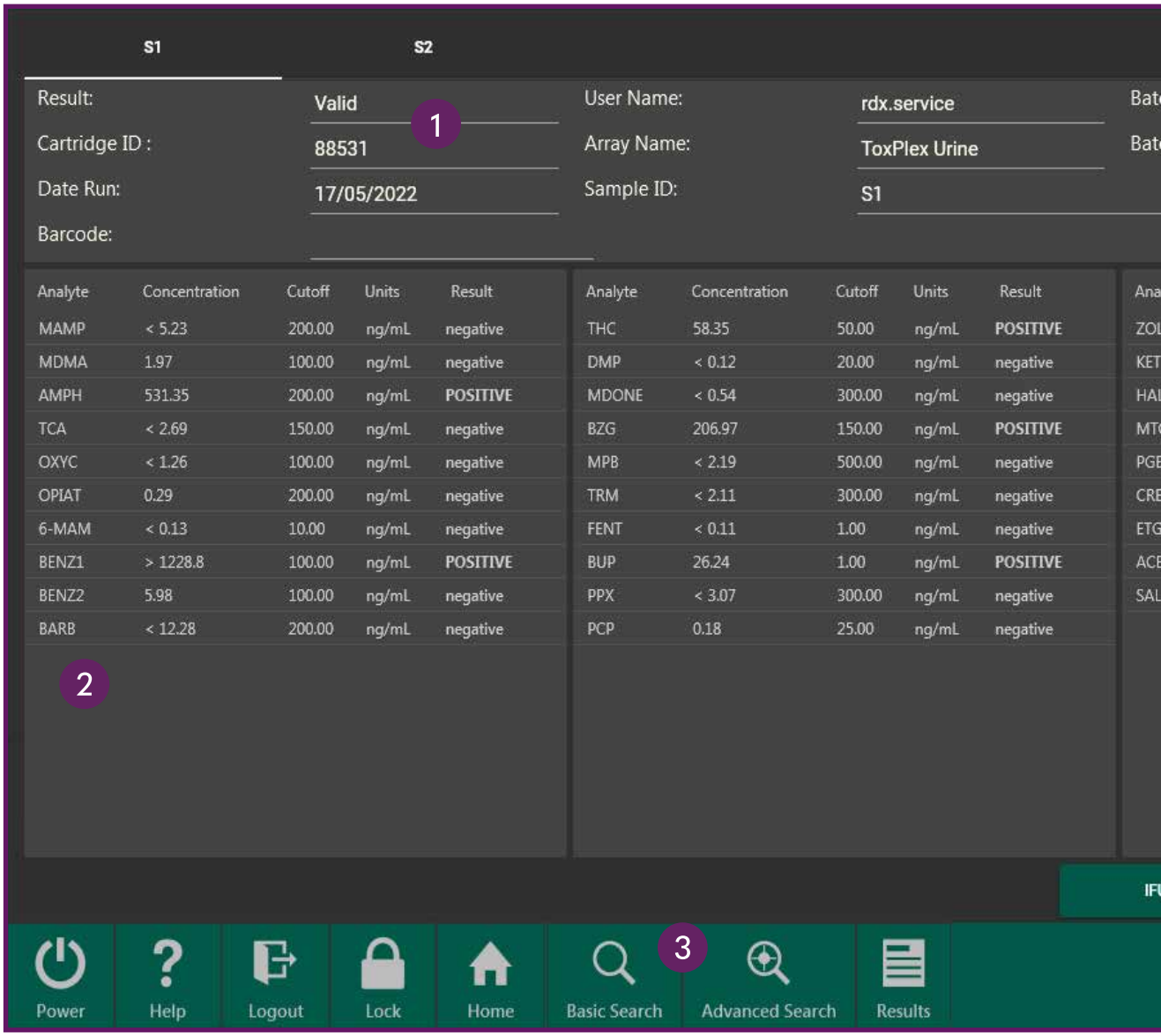
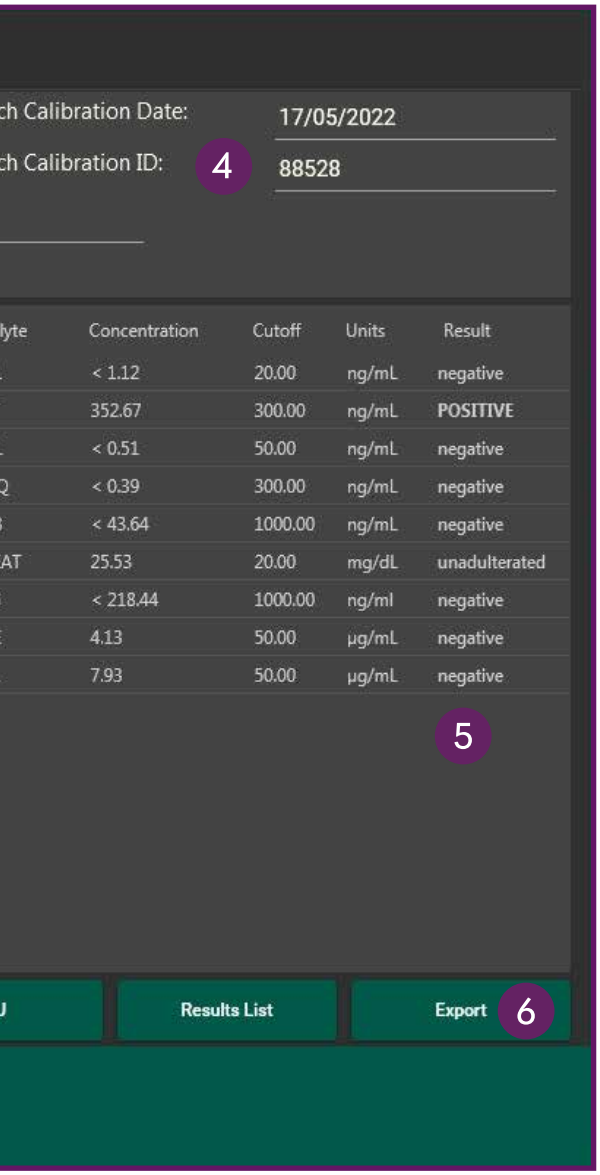



Figure 2: MultiSTAT results screen based on ToxPlex Urine Array




## 1 Complete Patient Profiling

Multiplex testing enables clinicians to consider the complete picture, allowing for better informed decisions and accurate diagnosis.

## 2 Extensive Test Menu

Screen for up to 29 targets with the ToxPlex Array.

## 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.

## 4 Result Traceability

Chain of custody features enable better management and accountability.

## 5 Quality Results

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

## 6 Connectivity

LIMS integrated for convenient reporting, and printable reports.

# Cytokine Storm Array

Cytokine storm or cytokine-associated toxicity is an acute hyperinflammatory response, where the body releases too many cytokines into the blood too quickly. This exaggerated immune response can cause collateral damage, which is greater than the immediate benefit of the immune response[1].

Whilst cytokine storm has been known in the clinical setting for around 30 years, COVID-19 has raised awareness of the condition. Severity of acute respiratory distress syndrome (ARDS)[2] has been linked to cytokine storm. Further, specialised treatments, such as chimeric antigen receptor (CAR) T-cell therapy[3] and allogeneic hematopoietic stem-cell transplantation[4], where the human immune system is compromised, have resulted in cytokine storm.

It is important that clinicians can recognise and monitor cytokine storm because it has prognostic and therapeutic implications[5]. The Evidence MultiSTAT Cytokine Storm Array detects 9 key plasma-based biomarkers shown to be important in the development and severity of cytokine storm[6].

## Assay Performance

| Marker | Sensitivity | Range |
|---|---|---|
| Interleukin-1 beta (IL-1β) | 1.71 pg/mL | 0 - 250 pg/mL |
| Interleukin-2 (IL-2) | 9.83 pg/mL | 0 - 1000 pg/mL |
| Interleukin-6 (IL-6) | 2.87 pg/mL | 0 - 500 pg/mL |
| Interferon gamma (IFN-γ) | 10.40 pg/mL | 0 - 500 pg/mL |
| Tumour Necrosis Factor alpha (TNF-α) | 20.11 pg/mL | 0 - 1000 pg/mL |
| Monocyte Chemoattractant Protein-1 (MCP-1) | 11.03 pg/mL | 0 - 500 pg/mL |
| Interleukin-15 (IL-15) | 9.46 pg/mL | 0 - 1000 pg/mL |
| Ferritin | 7.42 ng/mL | 0 - 1000 ng/mL |
| D-Dimer | 35.34 ng/mL | 0 - 4500 ng/mL |

# ACCURATE MONITORING OF HOST IMMUNE RESPONSE

## Benefits

### Detects Key Markers Implicated in Cytokine Storm

Includes biomarkers of interest most frequently reported within peer reviewed journal articles.

### Fully Quantitative Results

Excellent assay performance facilitates monitoring of biomarker levels throughout the patient treatment process.

### Results in 60 Minutes

Avoid delays associated with other lab-based testing approaches.

### Validated for Plasma

Requires significantly less sample volume compared to conventional testing techniques.

### 9-Plex Biochip Array

Simultaneous detection of all markers from a single sample.

## Product Information

**Sample Type:**
Plasma

**Time to Result:**
60 minutes

# Stroke Array

Stroke is the second leading cause of death globally[7], with 1 in 4 people over the age 25 experiencing a stroke in their lifetime[8]. Stroke occurs when blood supply to the brain is interrupted suddenly. The two main types of stroke are:

**Haemorrhagic Stroke;** occurs when a blood vessel bursts and bleeds into the brain. Treatment involves reducing pressure on the brain. Haemorrhagic Stroke, including intracerebral haemorrhage and aneurysmal subarachnoid haemorrhage, represents 13% of all strokes[9].

**Ischemic Stroke;** occurs when blood supply to the brain's tissue is restricted, resulting in less oxygen. Treatment involves restoring the blood flow. Ischemic stroke is considered a time-dependent disease due to the availability of acute treatments and represents 87% of all strokes. Thrombolytic therapy is still the only proven treatment for these patients within 4.5 hours of symptom onset[10,11].Overall, the general prognosis of ischemic stroke is considered better than that of haemorrhagic stroke, in which death occurs especially in the acute and subacute phases[12, 13].

In addition to haemorrhagic and ischemic stroke, there are a variety of conditions which result in patients presenting with similar symptoms to stroke, for example, seizures, migraines, syncope, sepsis, brain tumor and metabolic derangement (low sodium or low blood sugar). These 'mimics' account for 19 - 30% of suspected stroke presentations[14]. To facilitate efficient classification thereby expediting patient treatment, Randox has developed a multiplex biochip array to positively identify acute stroke and classify stroke subtype.

## Assay Performance

| Marker | Range |
|---|---|
| Glutathione S-transferase Pi (GSTPi) | 0 - 200 ng/mL |
| Parkinson Disease Protein 7 (PARK7) | 0 - 100 ng/mL |
| Nucleoside Diphosphate Kinase A (NDKA) | 0 - 250 ng/mL |
| Glial Fibrillary Acidic Protein (GFAP) | 0 - 100 ng/mL |
| Fatty Acid Binding Protein 3 (FABP3) | 0 - 150 ng/mL |
| Interleukin-6 (IL-6) | 0 - 500 pg/mL |
| Soluble Tumour Necrosis Factor Receptor 1 (sTNFR1) | 0 - 25 ng/mL |
| D-Dimer | 0 - 5000 ng/mL |

# RAPID IDENTIFICATION AND STRATIFICATION OF ACUTE STROKE SUBTYPES

## Benefits

### Unique Solution for Stroke Classification

Unique solution for simultaneous detection of multiple stroke-associated biomarkers from a single sample, facilitating rapid and accurate stroke subtype classification.

### Enhances Existing Scanning Technologies

Complements and enhances existing CT scanning approaches which enables a more comprehensive evaluation of a suspected stroke patient upon admission.

### Improves Patient Care

Ensuring appropriate timely therapeutic intervention. Rapid thrombolytic therapy ensures a better outcome.

### Results in 39 Minutes

Fully automated analyser that is easy to use and provides a fast turnaround time.

### Accessible Stroke Management

Unlike larger CT/MRI scanning technologies, the MultiSTAT is a benchtop analyser with a small footprint.

## Product Information

**Sample Type:**
Plasma

**Time to Result:**
39 minutes

# ARDS Array

Acute respiratory distress syndrome (ARDS) is a heterogeneous syndrome. It is a life threatening condition characterised by insufficient oxygen (hypoxia), and requires invasive mechanical ventilation in patients[15].

Considerable evidence exists for the presence of patient subgroups in ARDS with exaggerated inflammation. Two phenotypes, termed hyperinflammatory and hypoinflammatory, have been consistently identified[16-19].

Faster identification of the hyperinflammatory phenotype allows the clinician to make informed decisions with regards the patient management options essential to improve survival. The Evidence MultiSTAT ARDS Array allows fast and accurate detection of Interleukin-6 (IL-6) and Soluble Tumour Necrosis Factor Receptor 1 (sTNFR1) to enable differentiation of the ARDS phenotypes.

## Assay Performance

| Marker | Range |
|---|---|
| Soluble Tumour Necrosis Factor Receptor 1 (sTNFR1) | 0 - 25 ng/mL |
| Interleukin-6 (IL-6) | 0 - 1600 pg/mL |

# RAPID STRATIFICATION OF ARDS PATIENT PHENOTYPES

## Benefits

### Fast & Accurate Detection

Fast and accurate detection of biomarkers to enable differentiation of the ARDS hypo and hyper-inflammatory phenotypes.

### Improves Patient Management

This array facilitates a precision medicine approach in ARDS patients. Informed decision making with regards to patient management options is essential for patient care.

### Simple Process

Simple 3 step analyser process with fully quantitative results available within 36 minutes from a single plasma sample.

### High Quality

Highest quality immunoassay testing with internal control material available.

### Rapid Stratification

Rapid stratification compared to other lab-based biomarker testing.

## Product Information

**Sample Type:**
Plasma

**Time to Result:**
36 minutes

# ToxPlex Array

The misuse of drugs can lead to a range of health detriments including mental health conditions, hepatitis-related liver cirrhosis and cancer, overdose and even death[20]. On a global scale, illicit drug use is attributable to more than half a million deaths per year[21].

The Randox Toxicology ToxPlex Array is a 29-analyte panel that offers flexibility, customisation and is ideal for the semi-quantitative determination of the parent molecule and metabolites of drugs in human urine or blood.

With the multiplex ToxPlex Array, clinicians can conduct an initial screen for drugs of abuse in a patient presenting acute overdose symptoms. This will determine recent illicit drug use, facilitating clinical management and critical care prior to confirmatory testing.

## Drug of Abuse Array

| Analytes | | |
|---|---|---|
| Acetaminophen | Fentanyl | PCP (Phencyclidine) |
| Amphetamine | Haloperidol | Pregabalin |
| Barbiturates | Ketamine | Propoxyphene |
| Benzodiazepines 1 (Oxazepam) | MDMA | Salicylates |
| Benzodiazepines 2 (Clonazepam) | Meprobamate | TCA (Tricyclic Antidepressants) |
| Buprenorphine | Methadone | THC (Cannabinoids) |
| BZG/Cocaine | Methamphetamine | Tramadol |
| Creatinine | Methaqualone | Zolpidem |
| Dextromethorphan | Opiate | 6-MAM |
| EtG (Ethyl Glucuronide) | Oxycodone | - |

## Benefits

### User-Defined Cut-Offs

Select the cut-off that conforms with the legal requirements in your country within a minimum and maximum range.

### Fast Analysis

Generates up to 58 results from 2 samples in under 30 minutes.

### Semi-Quantitative

A concentration is given with our new Evidence MultiSTAT update.

### Simultaneous Multiplex Testing

Detect up to 29 drugs of abuse from a single sample.

### Highly Accurate Drug Screening

Reach lower limits of detection with the ToxPlex Array.

## Product Information

**Sample Type:**
Urine & Blood

**Time to Result:**
Under 30 minutes

# Additional Arrays

## Blood

Time to Result:
23 minutes

Sample Type:
Blood

| 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 | Opiate | 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

Time to Result:
19 minutes

Sample Type:
Urine

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

## Oral Fluid

Time to Result:
17 minutes

Sample Type:
Oral Fluid

| 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 | Opiate | 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 |

# Why MultiSTAT?

Since **2000,**
**cytokine storms**
have been frequently
reported across a variety
of serious infectious diseases[22]

Around the world, there are
**12.2 MILLION**
new strokes per year
**ONE EVERY 3 SECONDS**[8]

Among ICUs in 50 countries
**the prevalence of ARDS**
was **10.4%** of all
**ICU admissions**[23]

Drug related problems contribute to
**MORE THAN 15%**
**of hospital admissions**[24]

Evidence MultiSTAT
**provides results from**
**30 MINUTES**

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