

# Onsite Urine Drug Screening EQA

Grant Moore  
Toxicology Advisory Group  
Canterbury Health Labs

Go the All Blacks!

## EMERGENCY PROCEDURES

\* Sign seen in Christchurch shop:



### EARTHQUAKE HOURS

1.0 – 3.9	OPEN AS USUAL
4.0 – 5.1	OPEN : (But watch your step)
5.2 – 6.0	OPEN : (Hold on)
6.1 – 7.0	LEAVE MONEY ON COUNTER (I'm under it)
7.1 – 8.0	HELP YOURSELF, I'M OUT OF HERE!

## QAP Urine Toxicology Program

- \* Overview
- \* Working Party members
- \* Working Party activities

## Advisory Group members

- \* **Stacey Richards (Chair), NSW Racing, NSW**
- \* **Trisha Andersen, Australian Scientific Enterprise, NSW**
- \* **Grant Moore, Canterbury Health Laboratories, NZ**
- \* **Phillip Paull, Royal Prince Alfred Hospital, NSW**
- \* **David Rutherford, VIC**
- \* **Santiago Vazquez, HAPS, NSW**
- \* **Robert Wardrop, Path West, WA**
- \* **John Zoanetti, SA Pathology, SA**
- \* **Sue Scott, RCPAQAP**

## Toxicology Working Party



## Toxicology Working Party Activities

- \* Advice and interpretation of the Testing Program
- \* Provision of urine samples for the program
- \* Analysis of urine samples by variety of techniques
  - LCMS, IA, GCMS
- \* Advice regarding appropriate drug levels in QA samples
- \* Advice to NATA regarding AS/NZS-4308 issues
- \* Helping implement OUTS program

## Working Party Activities

- \* Annual meeting to discuss program
- \* Responding to queries regarding the Program
- \* Three areas of involvement
  - \* Urine Toxicology Program
  - \* OUTS Program
  - \* AS/NZS-4308:2008 advice

## Urine Toxicology Program

- \* Program for testing competency of Toxicology laboratories
- \* One sample per month
- \* Tested against methodologies used in a laboratory's drug screening process
- \* Appropriate for both immunoassay and chromatographic screening
- \* Sometimes urine is negative
- \* Results are collated and reports generated

## Urine Toxicology Program

- \* Increasingly difficult to get sufficient volume of authentic samples
- \* Pooled samples have added disadvantages
- \* Detection techniques becoming increasingly more sensitive
- \* Report to look at 'drugs of most interest'

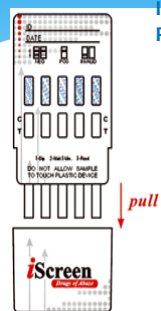
## On-site Urine Toxicology Screening

- \* Setting up the QAP program
- \* Interim Report
- \* Further Improvements

# OUTS Program Set up

- \* Following requests from laboratories a qualitative urine toxicology program was offered in 2010
- \* AS/NZS-4308:2008 allowed for their use in Workplace Drug Testing
- \* There was a need to provide a program for these devices
- \* Levels need to be relevant to the cut-off values being tested against
- \* The AACB Urine Toxicology Working Party instrumental in implementation

# Program Set up



Inverness Medical Sure Step6  
Panel cassette

iScreen One step  
drug card



Thermo Fisher Scientific  
Micro Tox Multi Drug  
Screening Test

Bio-Rad Tox/See



Branan  
QuickTox



## Program Set up

- \* Designed specifically for onsite and laboratories performing qualitative drugs of abuse screening
- \* A qualitative program only
  - \* Report detected or not detected
- \* 6 drugs were offered

### Amphetamine Type Substances

- Amphetamine
- Methamphetamine

Cocaine metabolites

- Benzoylecgonine

Opiates

- morphine

Cannabis metabolites

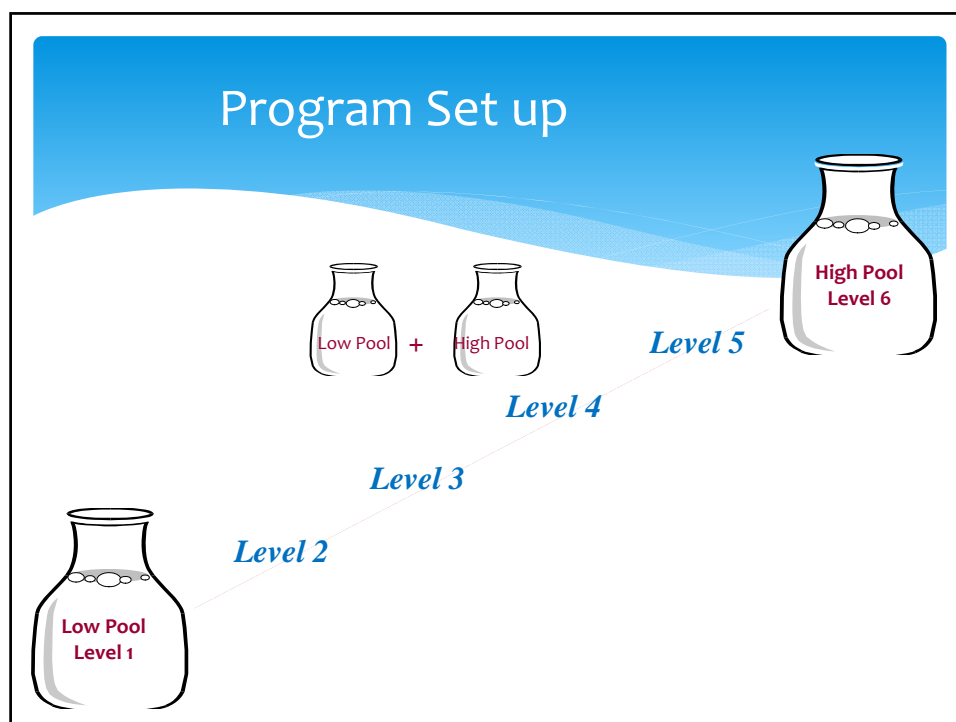
- carboxy-THC

Benzodiazepines

- oxazepam

## OUTS Program Set up

- \* Material was manufactured by Australian Scientific Enterprise (ASE)
  - \* Human urine specimens
  - \* 6 linear concentration levels
    - \* A low and high pool (L1 and L6) & 4 intermediate levels



- ## OUTS Program Set up
- \* Material was manufactured by Australian Scientific Enterprise (ASE)
    - \* Human urine specimens
    - \* 6 linear concentration levels
      - \* A low and high pool (L1 and L6) & 4 intermediate levels
      - \* Used the AS/NZS:4308 Standard cut off limits to offer a range of concentrations from 0 ug/L through to significantly above the cut-off value for each drug
    - \* Participants could purchase either 1ml or 10ml vials
    - \* One 12 month cycle January to December 2010 & 2011
      - \* 1 sample per month

## Interim Report

- \* Specifically designed report for each participant can evaluate their results according to the cut-offs for their device
- \* Drug concentrations given for all drugs in all samples
  - \* GCMS and LCMSMS methods set targets in 2010.
  - \* In 2011 we have again used GCMS and LCMSMS methods to set target values.
- \* The AACB Urine Toxicology Working Party reviewed all data and set target values for the 6 drugs being offered this year.

## Interim Report

- \* In 2010 - 26 participants enrolled & 2011 – 32 participants enrolled

Device / Instrument	2010	2011
Abbott AxSYM	2	2
ACON Laboratories Multi-Drug 1 step	2	1
AirMed DT4308		1
Ameditech Pro Screen Drugs of Abuse		2
Biosite Triage Meter	1	1
BIO-RAD Tox/See	2	2
Branan Medical corporation QuickTox	1	
Instant Technologies iCup		1
Inverness Medical Innovacon	2	1
Inverness Medical Sure Step 6 Panel	6	7
iScreen One Step Drug Card	1	1
Roche Diagnostics Hitachi cobas c501/c502		1
Thermo Fisher Scientific MicroScreen	3	5
Thermo Fisher Scientific MicroCup	1	1
Thermo Fisher Scientific MicroCheck	2	2
Varian Inc OnTrak	1	1

**Due Date : 30/11/2010** **Specimen Number I-11** **Laboratory Number**

Your Results		Sample I-11 Concentrations	
Amphetamine:	ND Your Method: 73B 276 A. Inverness Medical Sure Step 6 Panel	Amphetamine	0 ug/L
Methamphetamine:	ND Your Method: 73B 276 A. Inverness Medical Sure Step 6 Panel	Methamphetamine	0 ug/L
Benzodiazepines:	ND Your Method: 73B 276 A. Inverness Medical Sure Step 6 Panel	Benzodiazepines	406 ug/L
Cannabis:	D Your Method: 73B 276 A. Inverness Medical Sure Step 6 Panel	Cannabis	109 ug/L
Cocaine:	ND Your Method: 73B 276 A. Inverness Medical Sure Step 6 Panel	Cocaine	0 ug/L
Opiates:	ND Your Method: 73B 276 A. Inverness Medical Sure Step 6 Panel	Opiates	0 ug/L

**All Results**

**Review**

Evaluate your result according to the drug cut-offs for your device.

Amphetamine \_\_\_\_\_

Methamphetamine \_\_\_\_\_

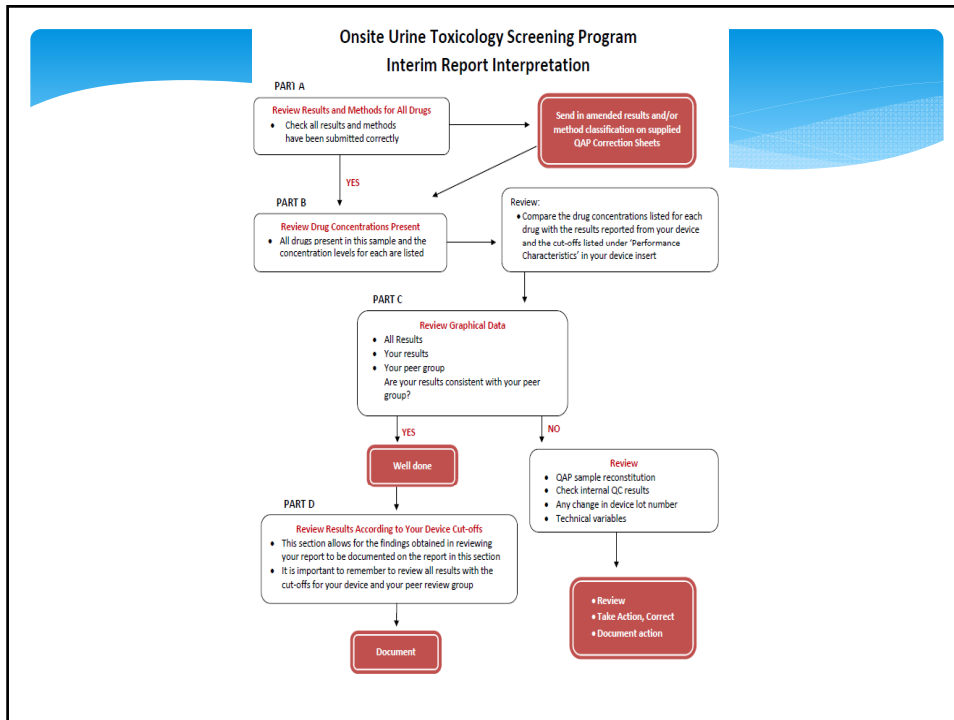
Benzodiazepines \_\_\_\_\_

Cannabis \_\_\_\_\_

Cocaine \_\_\_\_\_

Opiates \_\_\_\_\_

**On-Site Urine Toxicology Screening**



## Further Improvements

- \* End-of-Cycle Report development completed and distributed to participants
  - \* This will include interpretation notes
- \* Survey distributed to all participants in 2011
  - \* Feedback and suggestions for improvements
- \* Investigating distributing reconstitution water with the samples
  - \* 10ml distilled water
- \* Reconstitution sheets to all participants to assist with the reconstituting the samples

## Results of Survey

- \* Respondents approx 20
- \* Detected test reported 0-135 per month
- \* Accredited to AS/NZS-4308 65% yes
- \* Who carries out drug screen?
  - \* AS/NZS4308 collector 60%
  - \* Lab Staff 25%
  - \* Nurse 15%

## Results of Survey



- Who trains your staff
  - In-house trainers
  - Independent accredited trainers
  - HOD
  - National Risk, Compliance and Training Manager
  - Accredited Training Facilities

## Results of Survey

- |   |         |
|---|---------|
| * Training records kept   | 100%!!! |
| * Testing context   |         |
| * Pre-employment  | 65%     |
| * Continuing employment   | 70%     |
| * Legal requirement i.e. court, parole  | 25%     |
| * Drug clinics  | 25%     |
| * Others (ED screening, Random, Random onsite, Product performance monitoring, Technical Support) | 35%     |

## Results of Survey

- \* Send samples on for confirmation
  - \* Yes 60%
  - \* No 40%
- \* Non-collections from patients
  - \* Yes 50%
  - \* No 50%
- \* -variety of reasons, some due to nature of work normally performed, some due to behaviour of donor

## Results of Survey

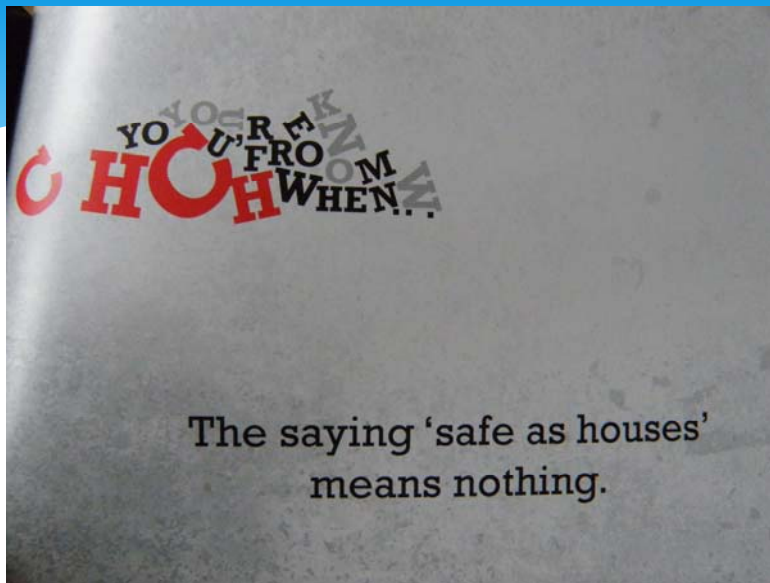
- \* Device cut-off values
  - \* Amphetamine 3/18 use 1000 ng/mL
  - \* Methamphetamine 2/17 use 1000 ng/mL
  - \* Cannabis 1/18 use 200 ng/mL !?
  - \* Benzodiazepines 3/18 use 300 ng/ml, 1/18 use 50
  - \* Cocaine 18/18 use 300 ng/mL
  - \* Opiates 1/18 use 2000 ng/mL
- \* Other compounds requested:
  - \* Methadone (3), MDMA(2), , Phencyclidine(3), Barbiturates(2), Ketamine
- \* Other EQA schemes 84% - no, possibly higher

## End-of-Cycle(EOC) Report

- \* Summary produced of results for full cycle
- \* Bar graphs summarising overall responses plus device specific detail
- \* Breakdown of each individual specimen results as well as a combined result for the repeats
- \* 6 samples produced and randomly run as duplicates during cycle

YOU  
KNOW  
YOU'RE  
FROM  
**CHCH** WHEN...

Compiled by Bruce Raines

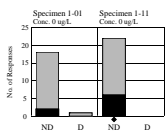


# Amphetamine EOC

## DATA RECEIVED FOR CYCLE 1

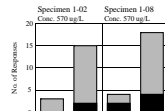
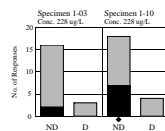
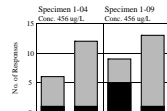
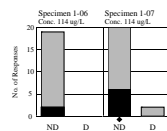
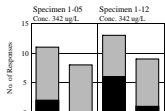
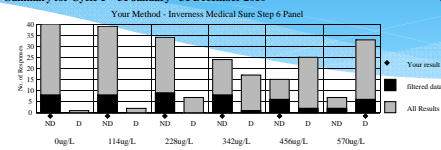
Spec	Method	Conc. (ug/L)	Result
1-01	F73B 276 A	0	
1-02	F73B 276 A	570	
1-03	F73B 276 A	238	
1-04	F73B 276 A	456	
1-05	F73B 276 A	342	
1-06	F73B 276 A	114	
1-07	F73B 276 A	114	ND Late
1-08	F73B 276 A	570	D Late
1-09	F73B 276 A	456	ND
1-10	F73B 276 A	238	ND
1-11	F73B 276 A	0	ND
1-12	F73B 276 A	342	ND

ND - Not Detected D - Detected



## Amphetamine Summary for Cycle 1 - 31 January - 31 December 2010

Laboratory Number



# Amphetamine EOC

- \* 0 ng/mL - 1/19 detected
- \* 340 ng/mL - 11 /19 and 13/22 not detected
- \* 456 ng/mL - 6/19 and 9/22 not detected
- \* 570 ng/mL - 3/18 and 4/22 not detected
  
- \* Is it the screener or the screening device?

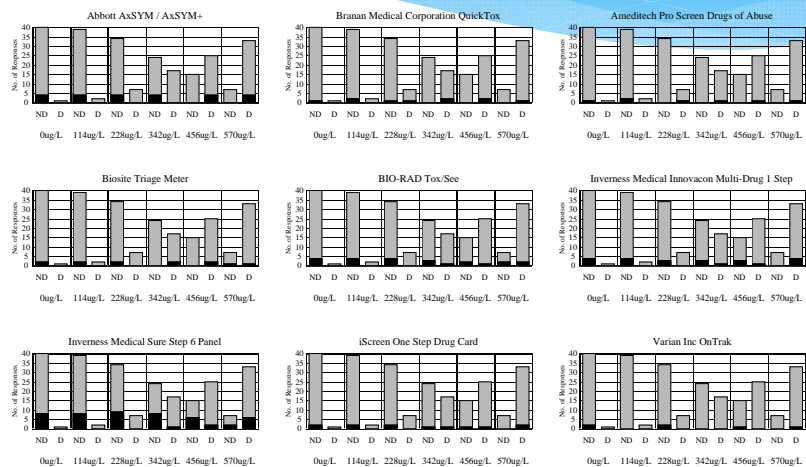
# Amphetamine by device

Printed  
Jun 30 13:46:30 2011

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ABN 32 003 520 072

Prepared by:  
RCPA Chemical Pathology QAP Group

## Amphetamine Device Summary of All Instruments for Cycle 1 - 31 January - 31 December 2010



# Amphetamine EOC

- \* Some suppliers over represented in outliers
- \* 456 ng/mL is >50% above cut-off
- \* AS/NZS-4308:2008 criteria for testing devices say should be able to detect at 30% above cut-off value.
- \* Using same cut-off value or something higher?
- \* 570 ng/mL is 2x cut-off! - 16-18% of devices didn't detect at this concentration!

# Methamphetamine EOC

**Methamphetamine**  
**Summary for Cycle 1 - 31 January - 31 December 2010**

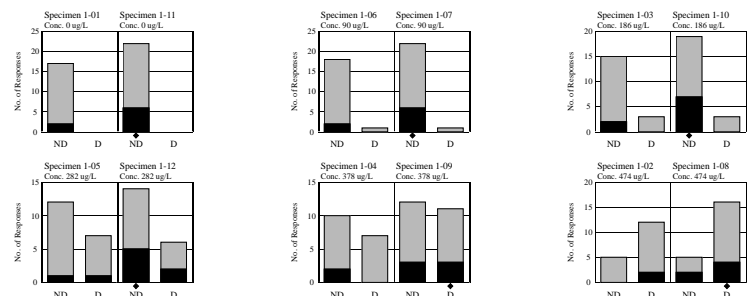
DATA RECEIVED FOR CYCLE 1

Spec	Method	Conc. (ug/L)	Result
1-01	J73B 276 A 0		
1-02	J73B 276 A 474		
1-03	J73B 276 A 186		
1-04	J73B 276 A 378		
1-05	J73B 276 A 282		
1-06	J73B 276 A 90		
1-07	J73B 276 A 90	ND	Late
1-08	J73B 276 A 474	D	Late
1-09	J73B 276 A 378	D	
1-10	J73B 276 A 186	ND	
1-11	J73B 276 A 0	ND	
1-12	J73B 276 A 282	ND	

Your Method - Inverness Medical Sure Step 6 Panel

Laboratory Number

ND - Not Detected D - Detected



## Methamphetamine EOC

- \* 0 ng/mL - 100% not detected
- \* 378 ng/mL - 10/17 and 12/23 not detected - >50%
- \* 474 ng/mL - 5/17 and 5/21 not detected
- \* Top OUTS sample is >50% above cut-off.
- \* 25-30% of testing devices didn't detect Methamphetamine at this concentration
- \* AS/NZS-4308:2008 Appendix A – 'Testing device should be able to detect positive at 30% above cut-off'

4WD owners finally get to use their  
vehicles for the purpose for which  
they were designed ...

YOYOGR  
FROM  
CHCHWHEN...

...and not just because of earthquakes!



# Benzodiazepines EOC

Printed  
Jun 20 11:46:52 2011

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ABN 32 003 520 072

Prepared by:  
RCQA Chemical Pathology QAP Group

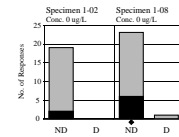
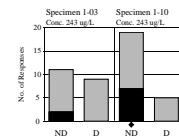
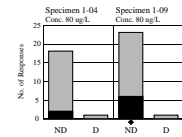
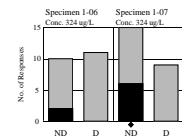
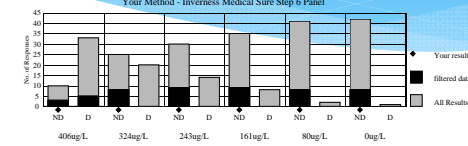
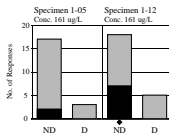
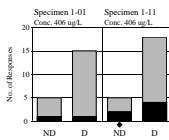
## Benzodiazepines Summary for Cycle 1 - 31 January - 31 December 2010

Laboratory Number

### DATA RECEIVED FOR CYCLE 1

Spec	Method	Conc (ug/L)	Result
1-01	J 73B 276 A	406	
1-02	J 73B 276 A	0	
1-03	J 73B 276 A	243	
1-04	J 73B 276 A	80	
1-05	J 73B 276 A	161	
1-06	J 73B 276 A	324	
1-07	J 73B 276 A	324	ND Late
1-08	J 73B 276 A	0	ND Late
1-09	J 73B 276 A	80	ND
1-10	J 73B 276 A	243	ND
1-11	J 73B 276 A	406	ND
1-12	J 73B 276 A	161	ND

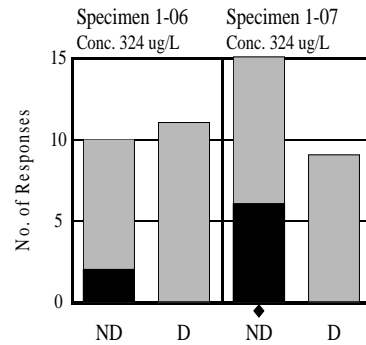
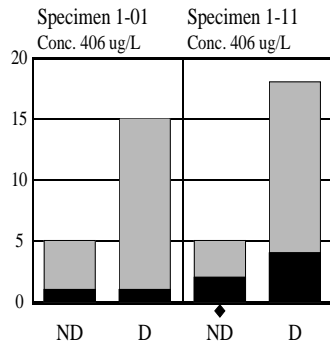
ND - Not Detected D - Detected



On-Site Urine Toxicology Screening

## Benzodiazepines EOC

ND - Not Detected D - Detected



## Benzodiazepines EOC

- \* At 406 ng/mL 11/45 not detected
  - \* So at 2 x cut-off (+ 100%), 25% of devices unable to detect oxazepam!
- \* At 324 ng/mL 25/46 not detected
  - \* At cut-off +60%, more than half of the devices didn't detect oxazepam
- \* Oxazepam is a pretty common benzodiazepine
- \* Standardisation issue?
- \* Cross-reactivity issue?
- \* **Is anybody worried?**

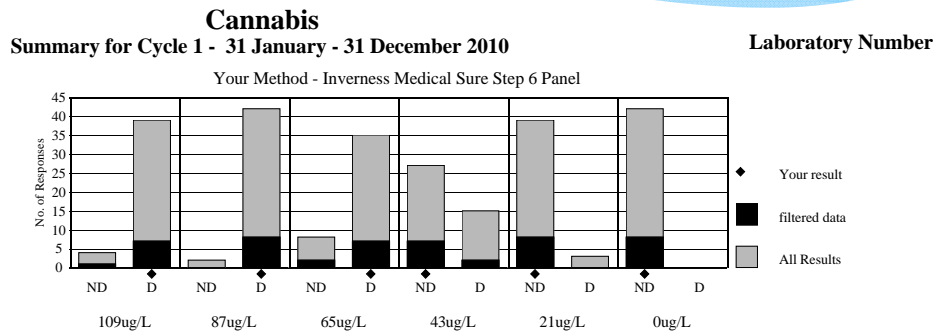
# An old Irish blessing!



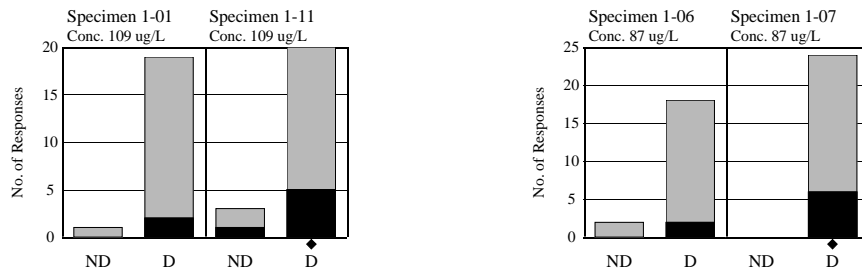
... that starts with  
 “May the road rise to  
 meet you...”

It’s not often used back  
 home now!

# Cannabis EOC



## Cannabis EOC



## Cannabis EOC

- \* At 109 ng/mL 4/43 not detected
- \* At 87 ng/mL 2/43 not detected
- \* At face value OK, i.e. 10% not detected at 2 x cut-off!
- \* Only 5% not detected at cutoff +70%
- \* Shouldn't be a cross-reactivity issue
- \* Perhaps a training issue
- \* More than one manufacturer's device
- \* Standard allows up to 10% of devices inaccurate at +30%.



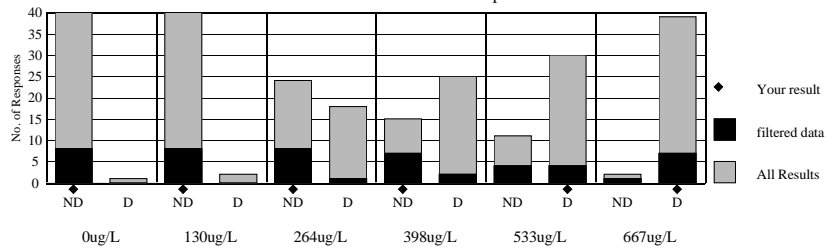
## Cocaine EOC

### Cocaine

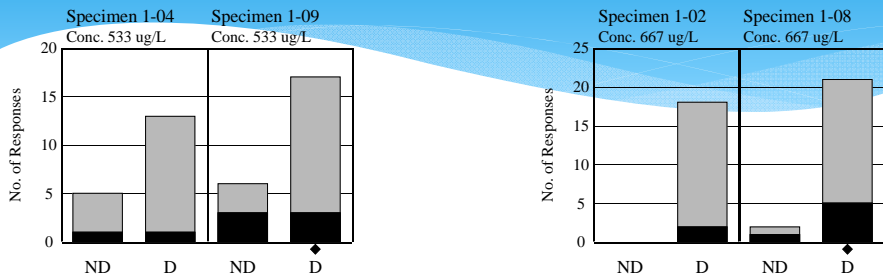
Summary for Cycle 1 - 31 January - 31 December 2010

Laboratory Number

Your Method - Inverness Medical Sure Step 6 Panel



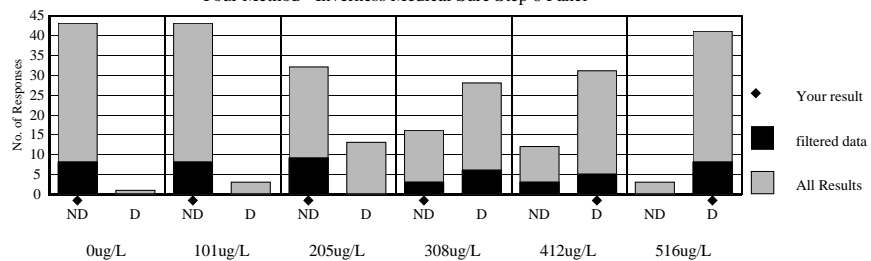
# Cocaine EOC



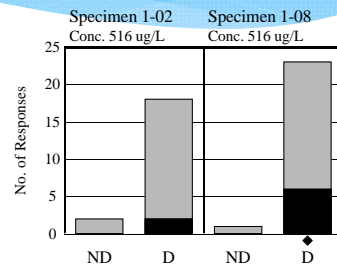
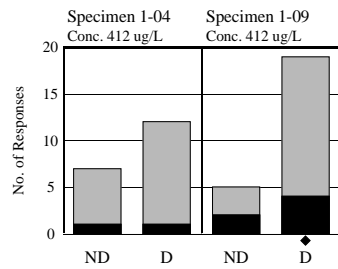
- ◇ At 533 ng/mL      12/43 not detected      -cutoff + 70%
- ◇ At 667 ng/mL      2/41 not detected      -5%
  
- ◇ Cross-reactivity?      Shouldn't be!
- ◇ Training or device?

# Opiates EOC

**Opiates**  
**Summary for Cycle 1 - 31 January - 31 December 2010**      **Laboratory**  
 Your Method - Inverness Medical Sure Step 6 Panel



## Opiates EOC



- ✧ At 412 ng/mL (cut-off +30%) 12/43 not detected  
- 25% not able to detect opiates(morphine)
- ✧ At 516 ng/mL (cut-off +60%) 3/45 not detected

## Is an EQA program needed

- \* Absolutely!
- \* Identifies problem analytes
- \* Assists in identifying screeners requiring up skilling
- \* Identifies screening devices that may be problematic
- \* Assists in decision making about screening device
  - \* Is the device 'fit for purpose'?
- \* Continues to push improvement of service
- \* Provides clarity for clients around expertise.

Thank you!

\* Any questions?

Who will win Sunday?

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