

# AS 4308



You too can be a toxicologist in  
two easy lessons

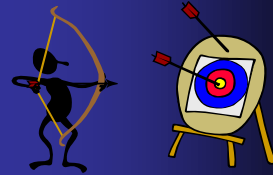
(each of ten years)

John H. Lewis PhD

**Prior to 1995 there were no  
rules in drug testing**



There was an urgent need to identify those laboratories with the necessary expertise and competence to undertake medico-legal drug testing



## Accreditation to 4308

Is merely a *basic* requirement for competence in medico-legal drug testing

**Between 1995 and 2001 (1st Rev), everything went well**



## **Rev. 2 in 2008 saw significant changes**

- ❖ The inclusion of on-site testing
- ❖ *(The requirement to have devices independently verified to ensure they approximate screening cutoffs)*
- ❖ The separation of screening and confirmation

## What's Good and Bad

- ✓ **A number of on-site devices fail and thus those that pass approximate required cutoffs**
- ✗ **Fewer people are doing laboratory screening**
- ✗ **Scientists losing expertise**
- ✗ **You don't confirm your own work**
- ✗ **Scientists are becoming slaves rather than masters of their profession**

## Separating Screening from Confirming

- ♥ **The argument was - "If non-scientists can be accredited for screening, then why can't laboratories?"**
- **However, having on-site testing included was meant to have some form of control over the quality and competency of screening**

**At this stage lab screening  
was mandatory**



**A “convincing” argument  
with the results-----**

No one wants lab-based  
screening with multipoint  
calibrations, independent  
quality controls and a team  
of staff to develop and  
improve methodology

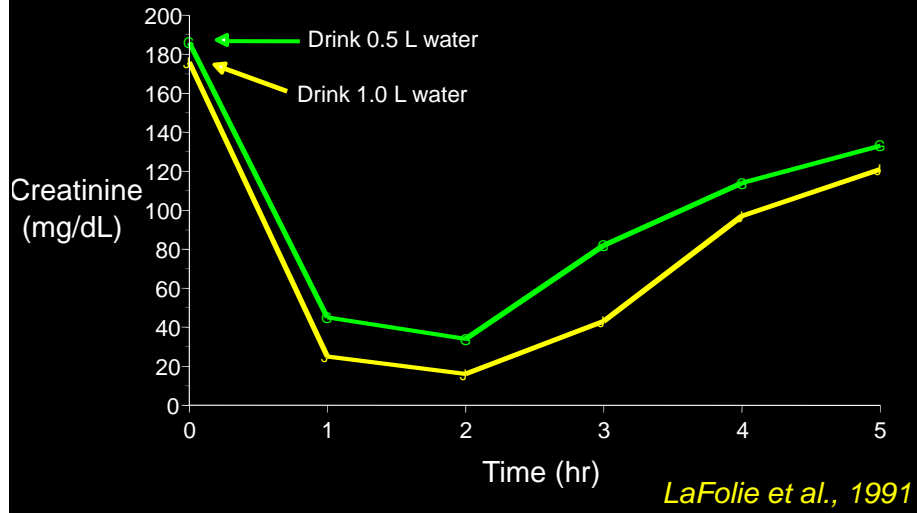


## **Creatinine**

Rev. 2008 made it mandatory  
for collectors to test for  
creatinine

**The Standard says that if the  
urine is “*dilute*” then collect  
another one**

### Effect of Water Consumption on Urinary Creatinine



**When requests get lost in translation**

# Chinese Whispers



Judge  
orders  
test for crack cocaine

Barrister

Solicitor

Doctor  
orders UDS

Pathology Lab  
Report says Immunoassays  
Negative



## So what went wrong?

- \* The issues were:
  - a) Was the laboratory actually told to look for “crack” cocaine?
  - b) The lab report gave no indication
  - c) Did it matter as I.A. was negative?

To demonstrate that crack had been consumed one must identify AEME (Anhydroecgonine methyl ester) in the urine.

- ❖ If the laboratory knew, did it have
  - (a) a method
  - (b) reference material

### **Argument #1**

I don't have a method or reference standard, but if the I.A. is negative then I would expect no crack cocaine had been taken

### **Argument #2**

AEME or crack cocaine is not in the Standard, therefore I cannot test for it

## **Hmmmmmm**

How do I know whether BE, EME or AEME disappears last from the urine of a user?

Just because AEME isn't mentioned in AS 4308 doesn't mean I can't look for it

## Adding a new drug to the Standard

### The case for BZP



*The ditch*



- ✓ It's sold OTC in NZ
- ✓ It's a real problem
- ✓ We all want it in the Standard
- ❖ So what?
- ❖ You can still test for it
- ❖ How do you determine a cutoff?
- ❖ It's a small market
- ❖ Unless you have a target population, most screens will be -ve

## Some minor issues

- I. Although BZP acts similarly to an amphetamine, the X-R is poor
- II. Thus, one would have to screen via mass spectrometry and confirm via an alternative technique
- III. The “agreed” cutoff was a figure pulled out of the air

## Currently

BZP is a controlled substance and no one is taking it

People have moved on to other things such as designer amphetamines and the cannabinomimetics

**Should we now add these?**

## **Naughty Labs**

**Labs that do not have 4308 accreditation but  
“comply with 4308 cutoffs”**

*What they mean is they use manufacture's cutoffs just like  
everyone else*



## POCT

### Pretence of Cannabis Testing

- How many smokes can I have so as not to get picked up on Monday?
- Which is why they continue to fight for Saliva testing

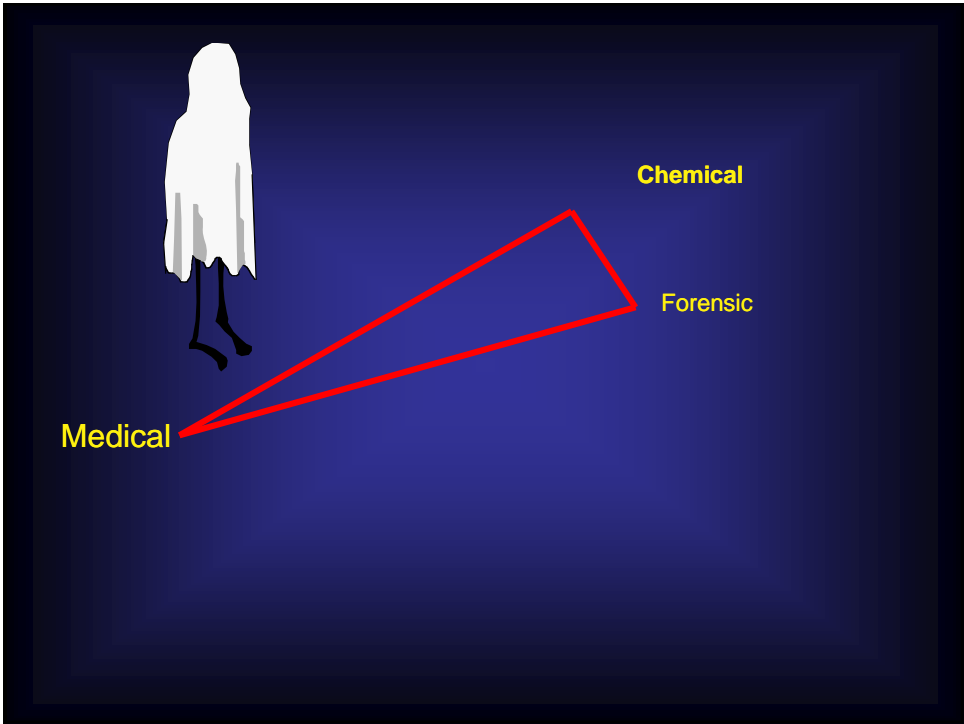
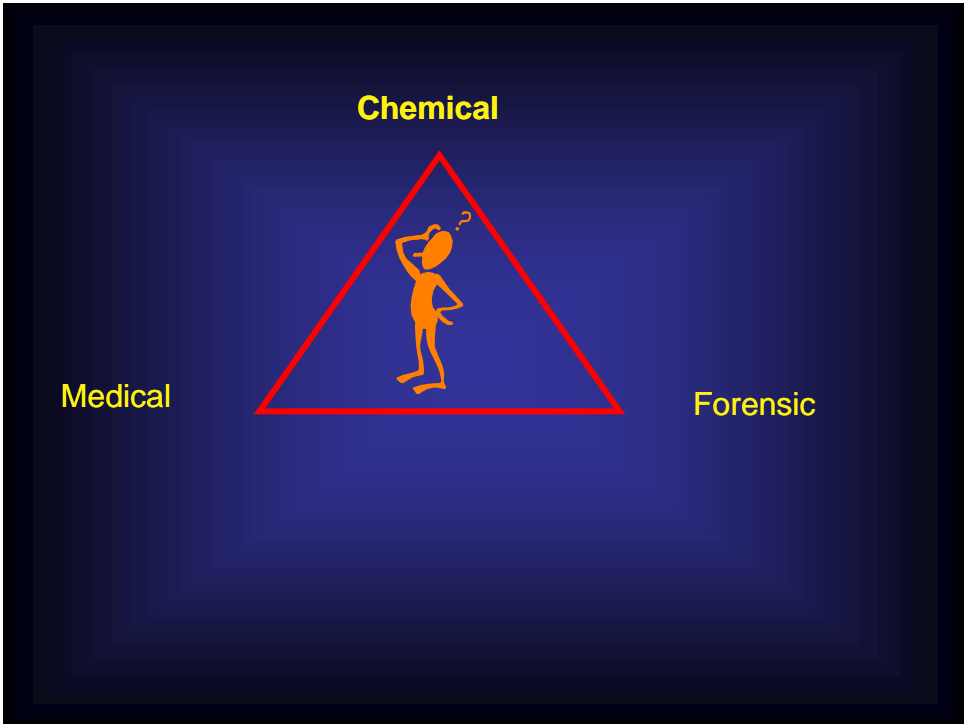
## POCT

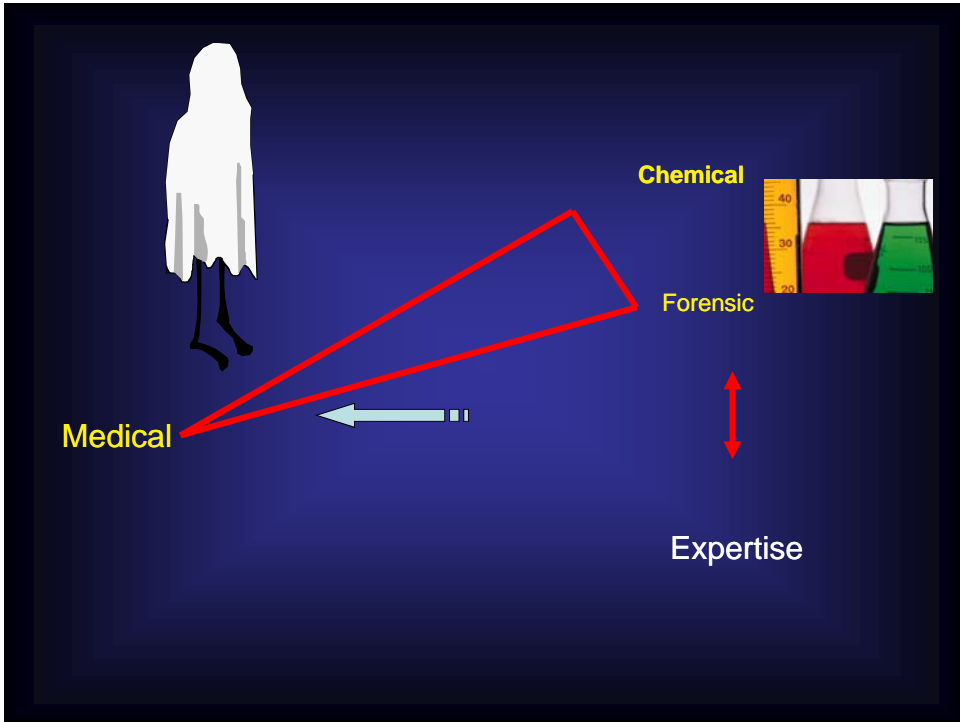
### {What's the} Point of Cannabis Testing

- JWH-018
- JWH-015
- JWH-016
- JWH-073
- JWH-122
- JWH-200
- JWH-203
- JWH-210
- JWH-250
- RCS-4
- RCS-4 C-4
- RCS-8
- HU-308
- HU-331
- CB-25
- CB-52

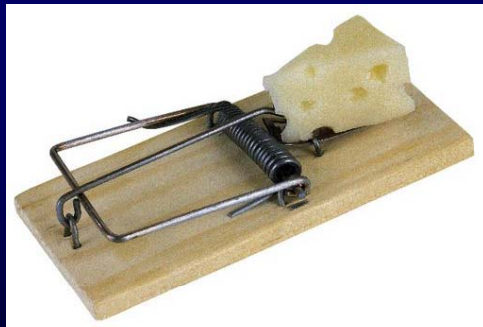
**Staffing and Interpersonal  
issues in 4308**

**Medico-legal drug testing sits  
uncomfortably between  
Chemical, Forensic and  
Medical testing**





## Traps for the toxicologist



The client only wants a screening  
test and it's a presumptive  
positive

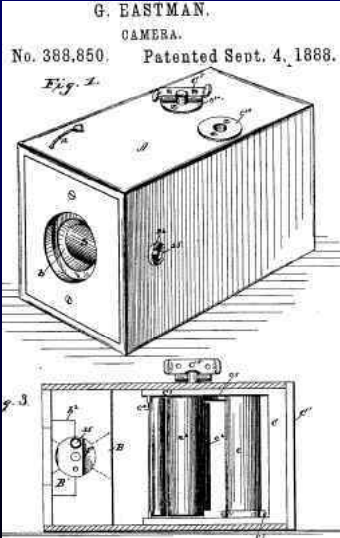
The client demands to know if  
there was any drug at all i.e. below  
the cutoff

**Neither of these requests  
comply with AS 4308**

**Employees have been  
dismissed due to a  
screening test alone, a  
below cutoff result or a high  
creatinine**

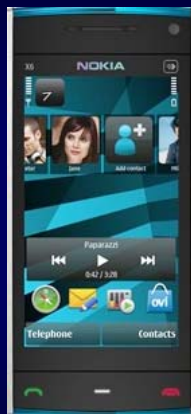


# George Eastman



## His most famous line

*You push the button and we'll do the rest*



## **So what's the analogy?**

1888-2011 v 1968-2011

**NATA and assessing to  
AS 4308**

## **A NATA assessor's job is tricky**

Everyone can run the basics - immunoassays and GC/MS, but understanding X-R, why you use certain reagents, applying the most appropriate tests and changing thinking from clinical to medico-legal, often remains a challenge

## So, where are we?

We have a much higher probability of laboratories fully compliant with AS 4308 generating accurate and reproducible results

There is a much better approach to QC, QAP, use of instrumentation and an understanding of acceptance criteria

## However

- ★ We need more and better trained scientists
- ★ Less reliance on George Eastman's business model
- ★ Less reinterpretation of the Standard to save on \$\$

**Like other disciplines -  
medicine, law, engineering,  
accreditation to a Standard  
is not for everyone**