Why Roadside Oral Fluid Testing?

A Forensics View

(Or, how the law informs the science, and the science (hopefully) informs the law)

David Astles PhD
Criminalist
Washoe County Sheriff's Office – Forensic Science Division

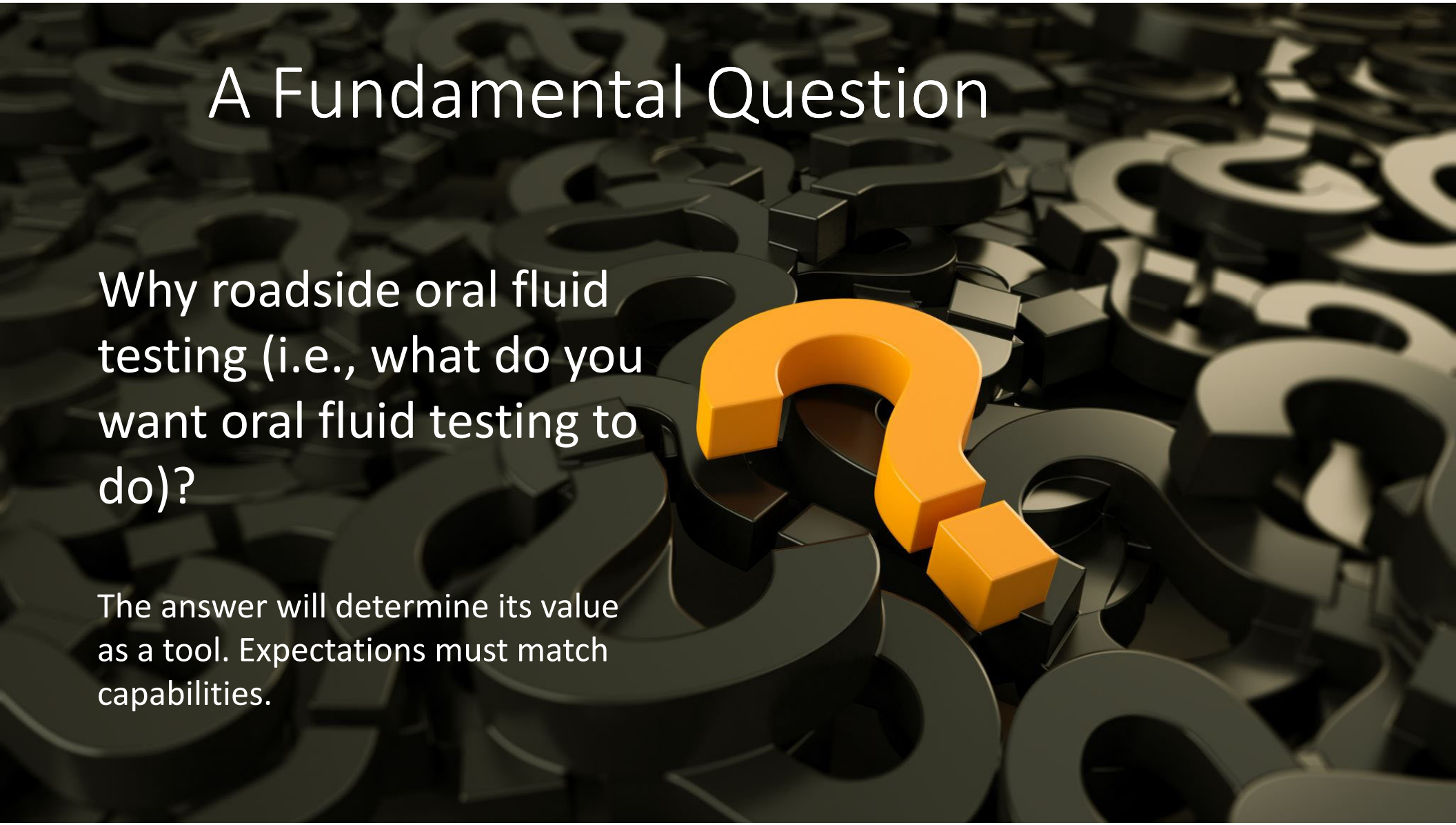
Disclaimer

Any opinions expressed in this presentation are solely those of the presenter and do not necessarily represent the positions of the Washoe County Sheriff's Office nor of anyone else, anywhere, ever.

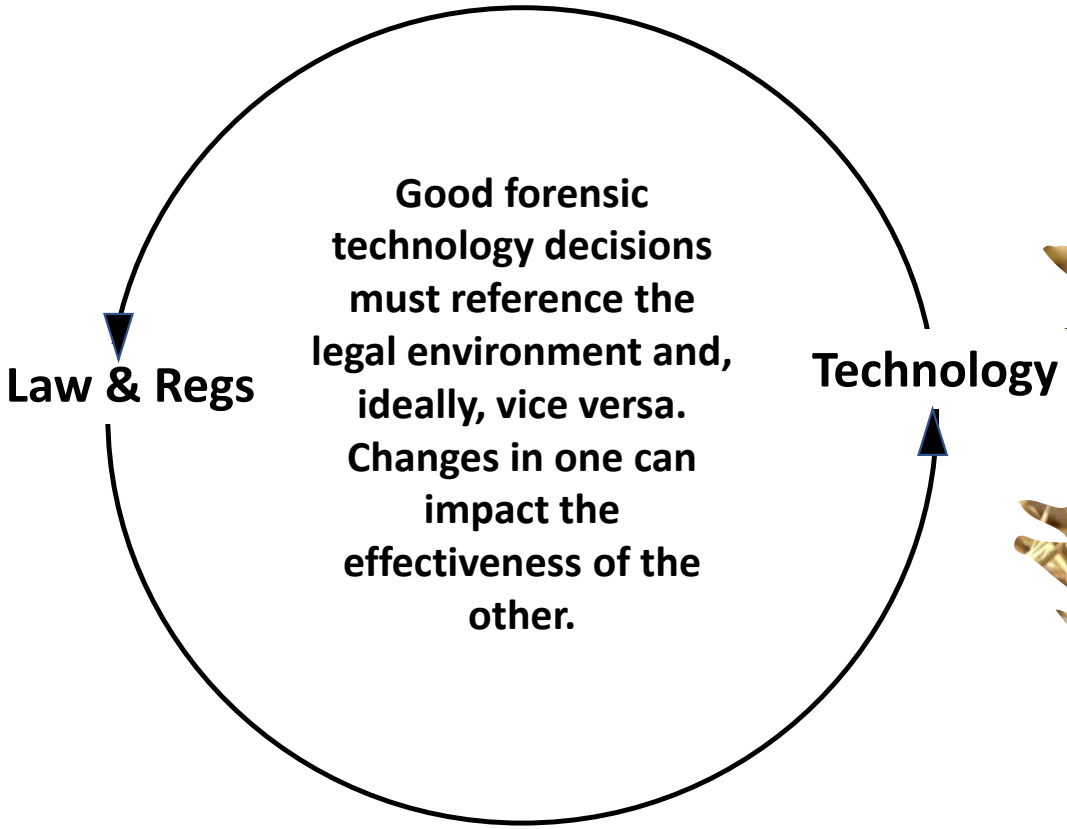
A Fundamental Question

Why roadside oral fluid testing (i.e., what do you want oral fluid testing to do)?

The answer will determine its value as a tool. Expectations must match capabilities.

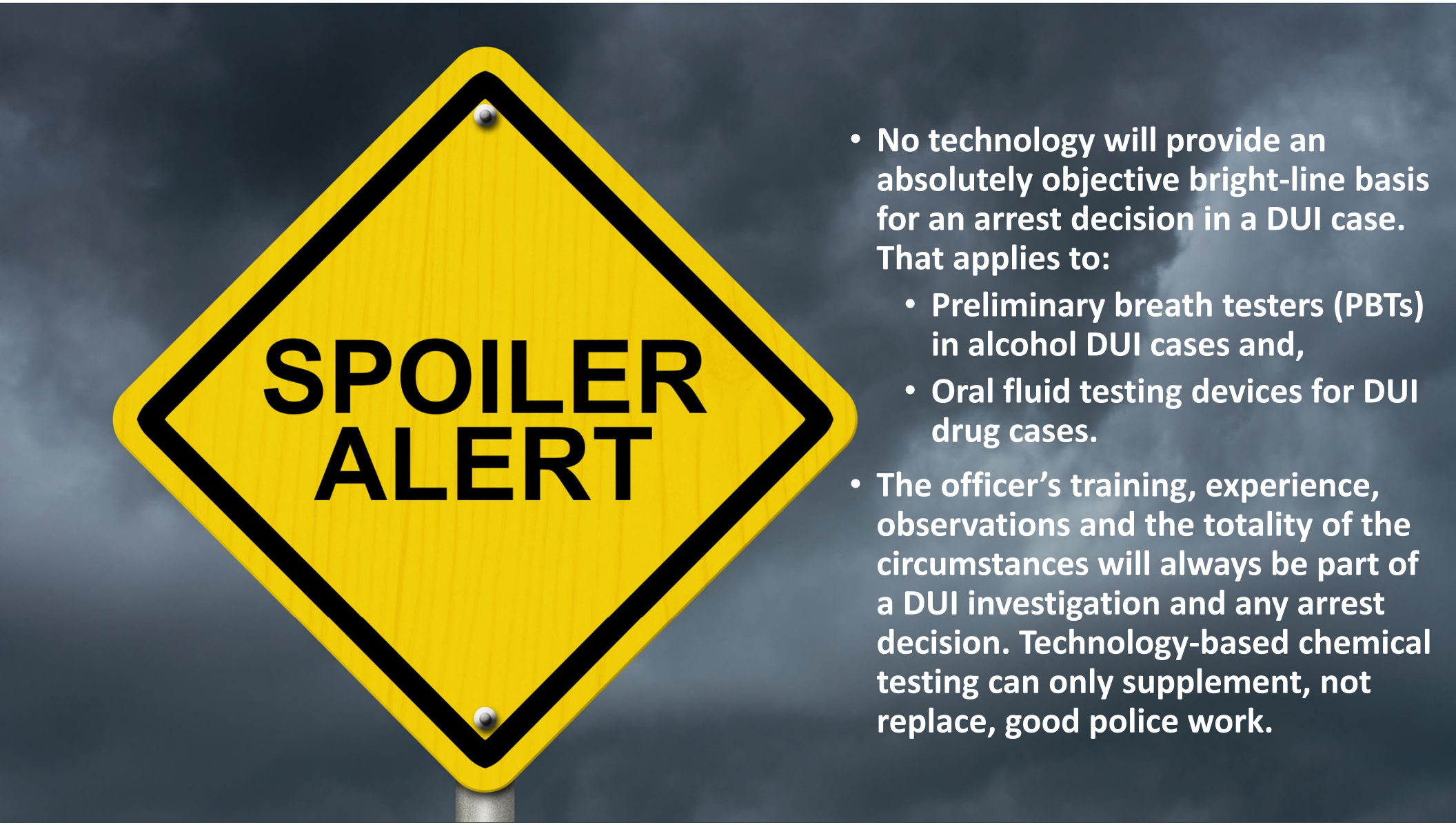


The chicken or the egg?



A Major Challenge

- Drug-impaired driving is a growing problem. Nevada is no exception.
- Legalization of cannabis has created challenges.
  - No good correlation between blood THC levels and impairment. Legislature eliminated THC per se levels for most DUI THC cases, this makes prosecuting more difficult
  - Detecting drug impairment is not as easy or established as it is for alcohol. ARIDE training is common, full DRE training less so.
  - No “easy” technology like PBT/PAS for drugs.



- No technology will provide an absolutely objective bright-line basis for an arrest decision in a DUI case. That applies to:
  - Preliminary breath testers (PBTs) in alcohol DUI cases and,
  - Oral fluid testing devices for DUI drug cases.
- The officer's training, experience, observations and the totality of the circumstances will always be part of a DUI investigation and any arrest decision. Technology-based chemical testing can only supplement, not replace, good police work.

Presentation Outline

1. Some facts about oral fluid testing
    1. What is oral fluid
    2. Drugs in oral fluid
    3. How do the tests work?
2. Understanding roadside OF testing
    1. Real world applications
    2. Some important caveats
3. DUI Drugs in Nevada
    1. Legal Framework
    2. AB 239 and future directions
4. Discussion and/or Questions

What is oral fluid?

- **Oral Fluid (O.F., a.k.a. saliva) is about 99% water plus electrolytes (salts), mucus, white blood cells, epithelial cells, and enzymes.**

Drugs in OF

- **Oral fluid can contain residual materials from the mouth (food, smoking residue, etc.)**
- **Oral fluid can contain water-soluble substances via diffusion from blood (i.e., substances that have been inside the body, including alcohol and some drugs.)**
- **Thus, drugs of interest can be found in oral fluid from either residue from oral consumption or diffusion from inside the body.**

Evidentiary Drug Testing of Oral Fluid

- **Oral fluid can be collected and tested in the laboratory using analytical techniques like those used for blood toxicology. Testing can provide substance confirmation and quantitation, but…**
  - **Stability of samples is an issue due to presence of enzymes in the oral fluid.**
  - **Results are not “immediate.”**
  - **There are questionable or unknown relationships between OF drug levels and impairment.**
  - **There are currently no “illegal per se” levels for drugs in oral fluid in Nevada.**

Roadside Testing of Oral Fluid for Drugs

- **Roadside testing can be done using commercial test systems. This can provide presumptive results quickly but…**
  - **Generally, results are not quantitative (test just indicates presence or absence).**
  - **Tests can have issues of sensitivity and specificity (false positives and negatives).**
  - **Testing can be very dependent on ambient conditions and procedure.**

Roadside Oral Fluid Testing Technology

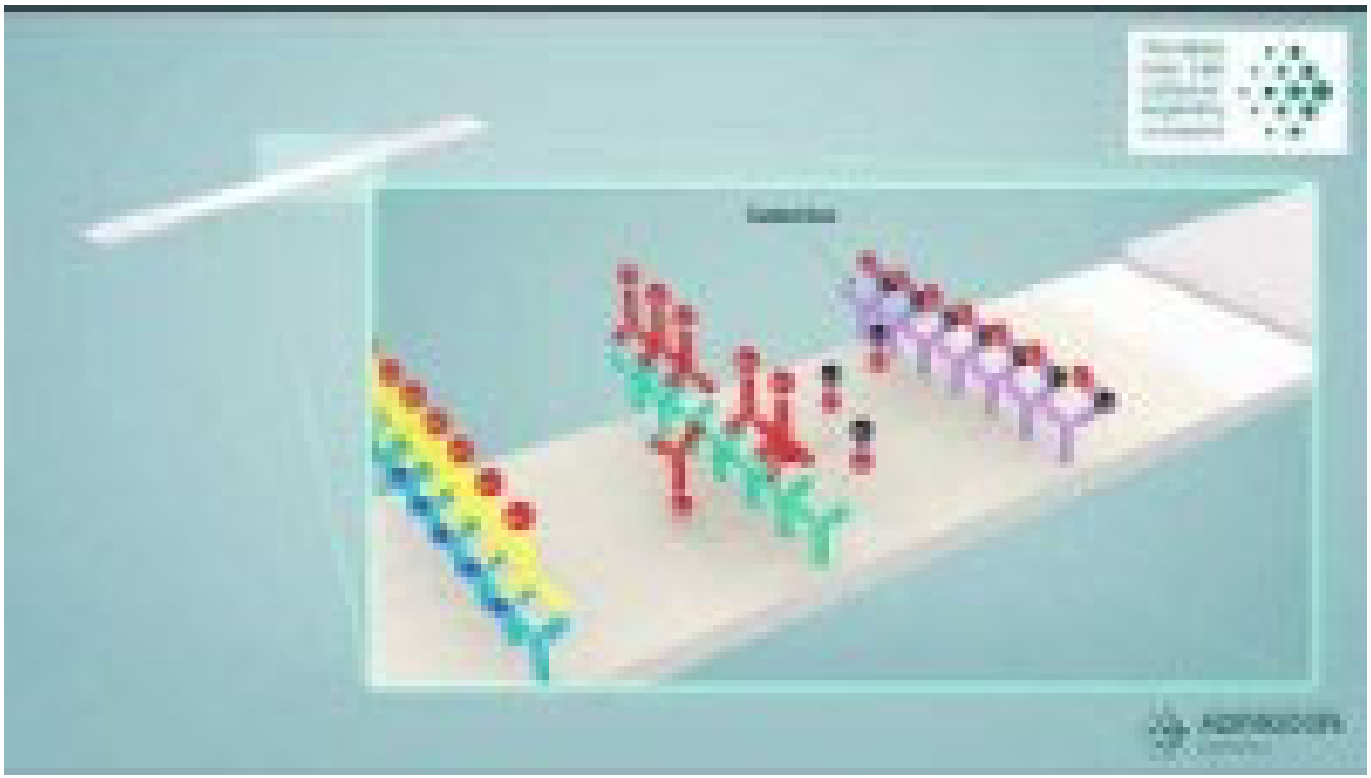
Commercial Point-of-Collection (POC) systems generally use lateral flow immunoassay technology

- Widely used, proven technology (think home pregnancy or COVID-19 test kits).
- May use “sandwich assay” (presence of line = positive) or “competitive assay” (presence of line = negative)

Many systems use an electronic device to read the test strips

- Eliminates subjectivity of determining presence/absence of an indicator line.
- Can document test results electronically and/or with printout.

How Lateral Flow Immunoassay Tests Work



Immunoassay Test Considerations

Potential considerations include:

- Unit cost and limited life of single-use components (kits/cartridges)
- Significant temperature and procedural sensitivity
  - Testing temperature and storage temperature of test kits
  - Kit orientation or other procedural factors can impact the test
- Reading kits is time-sensitive (limited window before lines may change)
- All these suggest formal usage policy and training
  - Test can be very sensitive to procedure and conditions, must be conducted properly

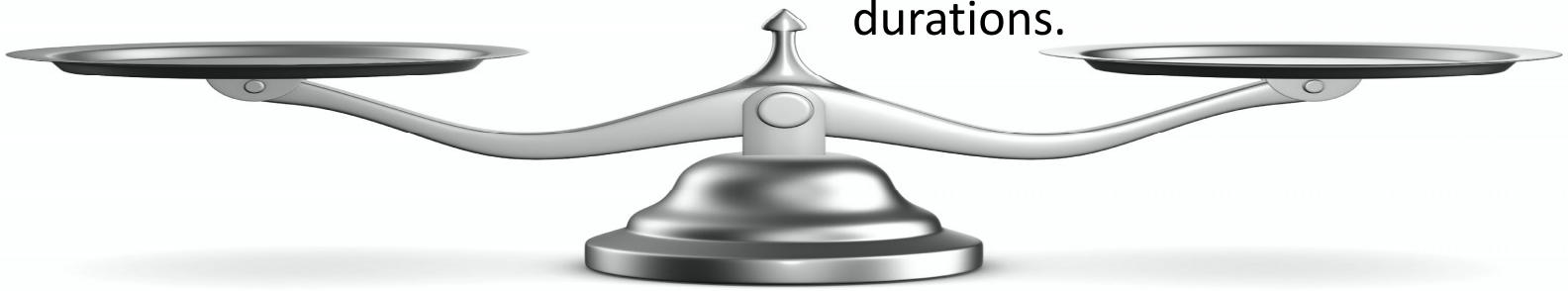
Is Roadside Oral fluid like a PBT?

PBT

- PBT can provide reasonably accurate **quantitative** indication of subject's BAC at that moment.
- Because of known correlation between BAC and types/levels of impairment expected, PBT can corroborate suspicion of alcohol impairment or suggest other causes of impairment (through inconsistent BAC).

Roadside O.F.

- Can provide reasonably reliable **qualitative** indication of recent use of certain drugs.
- Can corroborate suspicions of drug presence if properly trained (ARIDE or DRE) investigator but correlation between drug presence in OF and impairment is poorly known or questionable. Evidence exists that detection windows in OF can significantly exceed impairment durations.



PBT vs Roadside O.F. (continued)

PBT

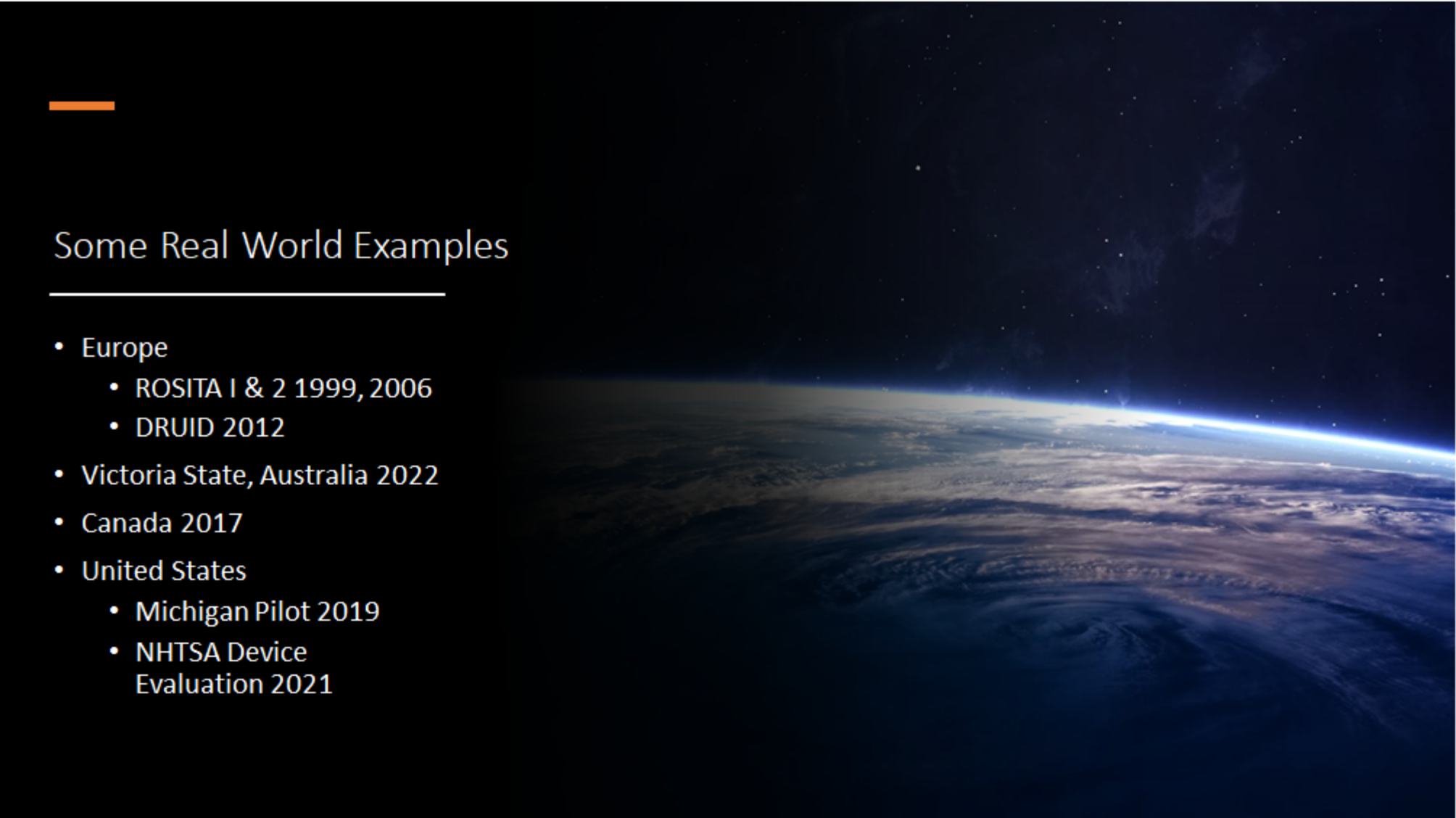
- Devices are generally very easy to use and are relatively inexpensive.
- Per test cost is very low (price of disposable mouthpiece).
- PBT supplies (mouthpieces) are stable and don't expire.

Roadside O.F.

- Reader devices are somewhat more complex and expensive than PBTs.
- Per test cost is substantially higher than PBT due to unit cost of test cartridges.
- Test cartridges expire and require proper storage.

Some Real World Examples

- Europe
  - ROSITA I & 2 1999, 2006
  - DRUID 2012
- Victoria State, Australia 2022
- Canada 2017
- United States
  - Michigan Pilot 2019
  - NHTSA Device Evaluation 2021



European Studies

- ROSITA (Roadside Testing Assessment) I and II 1999 to 2006 – OF promising but not ready
- DRUID (Driving Under the Influence of Drugs) 2012 – broader study of the problem and solutions. None of the devices tested met sensitivity, specificity and accuracy targets.

Victoria State, Australia

- Widespread (supposedly 100,000 /year) random roadside stops and testing introduced in 2004.
- Zero-tolerance regime for drugs.
- Found reduction in DUID fatalities – attributed to deterrence effect of frequent random checkpoints (perceived high probability of being caught).

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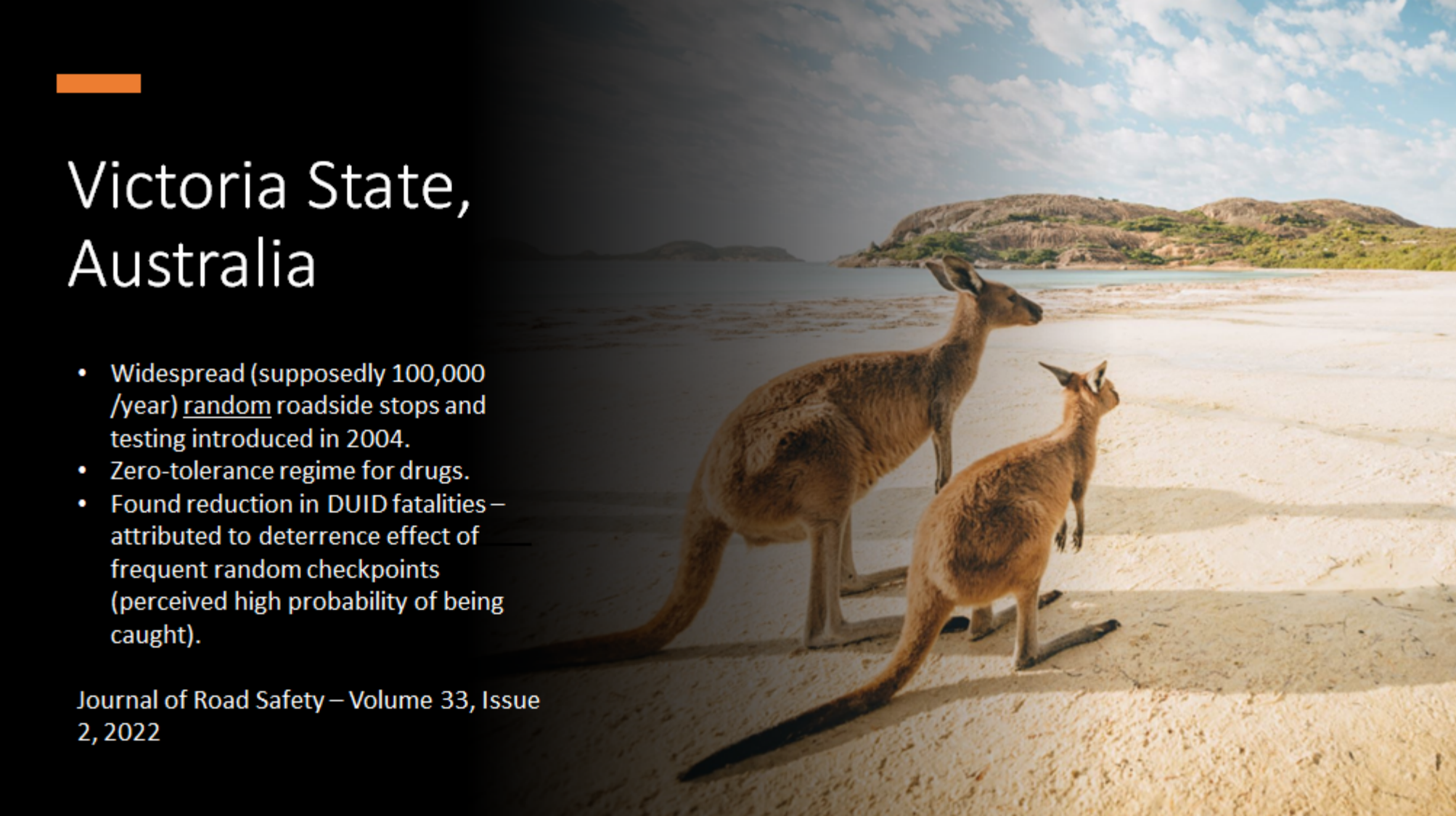


Canada 2017

- Focused on operability and training issues.
- Recommends standardized testing protocols and training.
- Training to include “…the science related to per se limits, oral fluid and the functionality of the device” and “drugs that impair.”

Michigan

- Zero-tolerance jurisdiction for DUI Schedule I drugs (including non-medical marijuana) and/or cocaine.
- Small scale but formal pilot study enabled by statute: oral fluid tests only administered by certified Drug Recognition Experts (DREs).
- Study recognized its small scale, recommended continued study.
- Report includes detailed statistical analysis by a professional statistician. Concluded results were generally good but with “lower than expected” positive predictive value.

NHTSA Device Evaluation

- **Detailed laboratory study of different models (using spiked saliva). Included cross-reactivity, interferents and environmental impacts.**
- **Significant difference in performance between different makes of device.**

What Does This All Mean?

1. Europe: The technology is improving, but is it ready?
2. Australia: Widespread testing can have a deterrent effect (but in a jurisdiction with random stops).
3. Canada: Officer training & protocols important.
4. Michigan: Can be effective in zero-tolerance jurisdiction.
5. NHTSA: Device make matters.

What About Nevada?

- Nevada has both impairment and “illegal per se” statutes.
- Impairment must be proven by the facts and circumstances of the case. State must demonstrate that the subject was “incapable of safely driving or exercising physical control of a vehicle.”
- Illegal per se is a violation to have a blood level (for named drugs) exceeding the stated limit, regardless of impairment.

Marijuana

- **DUI Marijuana can generally only be prosecuted on impairment (exception for 3rd offense DUI).**

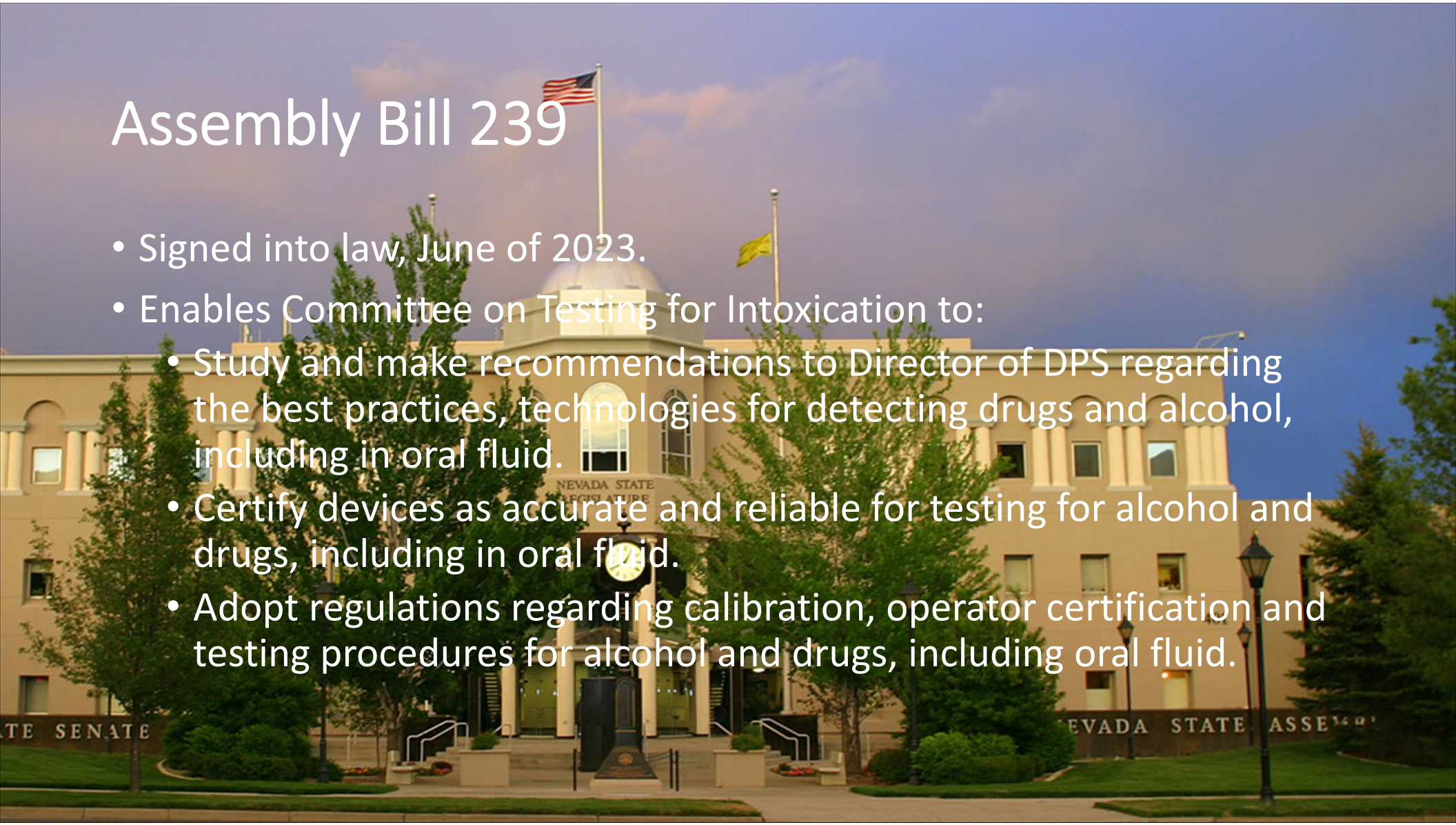
The Impairment Definition is a High Bar

Compare Nevada's "incapable of safely driving or exercising physical control of a vehicle" with California's "no longer able to drive a vehicle with the caution of a sober person."

Nevada "Prohibited Substances"

- The following are designated "prohibited substances" in Nevada if used without a prescription:
  1. Amphetamine, methamphetamine
  2. Cocaine or cocaine metabolite
  3. Heroin or heroin metabolite (morphine or 6-monoacetyl morphine)
  4. Lysergic acid diethylamide
  5. Phencyclidine

- Ironically, this means it is not illegal to drive with "prohibited substances" in one's system provided one is not legally impaired and has levels below the illegal per se levels.



Assembly Bill 239

- Signed into law, June of 2023.
- Enables Committee on Testing for Intoxication to:
  - Study and make recommendations to Director of DPS regarding the best practices, technologies for detecting drugs and alcohol, including in oral fluid.
  - Certify devices as accurate and reliable for testing for alcohol and drugs, including in oral fluid.
  - Adopt regulations regarding calibration, operator certification and testing procedures for alcohol and drugs, including oral fluid.

A Balancing Act

Deterring illegal unsafe driving versus right to engage in legal activities.

- Alcohol has over 100 years of study. For other drugs of abuse, the science is more limited.
- There are no definitive, universal, objective measures of impairment.
- “Gold standard” blood testing is invasive and expensive and unclear links between blood levels and impairment for most drugs.
- What are appropriate uses of presumptive “present/absent” tests in a non-zero tolerance environment?

What is lying in wait?

- Desire to have “bright-line” grounds for DUI enforcement – often unease with “subjective” impairment determinations.
- (Mis)perception that alcohol DUI arrests based on PBT results instead of “subjective” assessments (driving pattern, driver behavior, SFSTs).
- Are there unrealistic expectations for POC-OFT as “PBT for drugs?”

Adoption Issues to Consider

- **Under what circumstances would Point-of-Collection (POC) oral fluid testing (OFT) be permitted? What does a positive result mean? When is POC-OFT used relative to SFSTs or other assessments?**
- **OFT can be very procedurally and environmentally sensitive, oral interferents can impact tests. Would formal procedural protocols (like deprivation periods) and device storage and handling regulations be required? Training/certification requirements?**
- **POC-OFT uses lateral flow immunoassay technology (like COVID-19 or pregnancy test kits). Would electronic readers be required or is visual reading acceptable? What is the "device"? What is regulated?**

Technical/Practical Issues to Consider

- Minimum detection thresholds?
- Minimum sensitivity/specificity values?
- Test kit stability or longevity?
- Ease of use and reliability?
- Availability of different drug panels?
- Cost – for both readers and test kits?


Questions?

Studies Cited

- Rosita-2 Project:
  - https://citeseerx.ist.psu.edu/document?repid=rep1&type=pdf&doi=d02488911b2edeac75ff313e4d460cca5abd7f90
- DRUID Final Report:
  - https://www.bast.de/Druid/EN/Dissemination/downloads_and_links/Final_Report.pdf?__blob=publicationFile&v=1
- Evaluation of Victoria Australia:
  - https://journalofroadsafety.org/article/35235-evaluation-of-an-increase-in-roadside-drug-testing-in-victoria-based-on-models-of-the-crash-effects-of-random-and-targeted-roadside-tests
- Canada Pilot Study:
  - https://www.publicsafety.gc.ca/cnt/rsrcs/pblctns/rl-fld-drg-scrnng-dvc-plt/index-en.aspx
- Michigan Pilot Study:
  - https://www.michigan.gov/-/media/Project/Websites/msp/reports/phase_ii_oral_fluid_report.pdf?rev=911dc2c7042d444eb8918395a2211915
- NHTSA Evaluation of Devices:
  - https://rosap.ntl.bts.gov/view/dot/54911

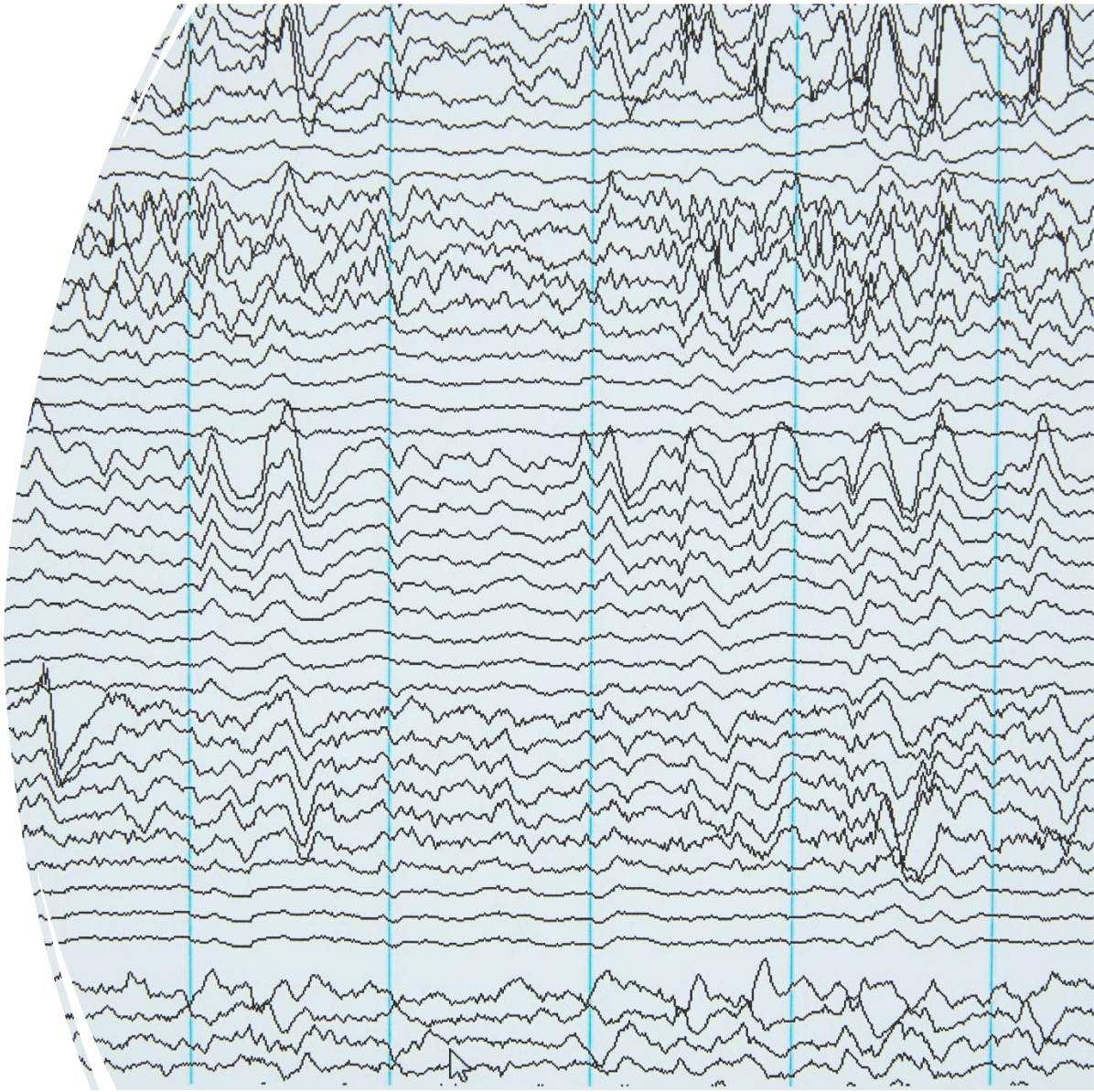
Getting in the Weeds

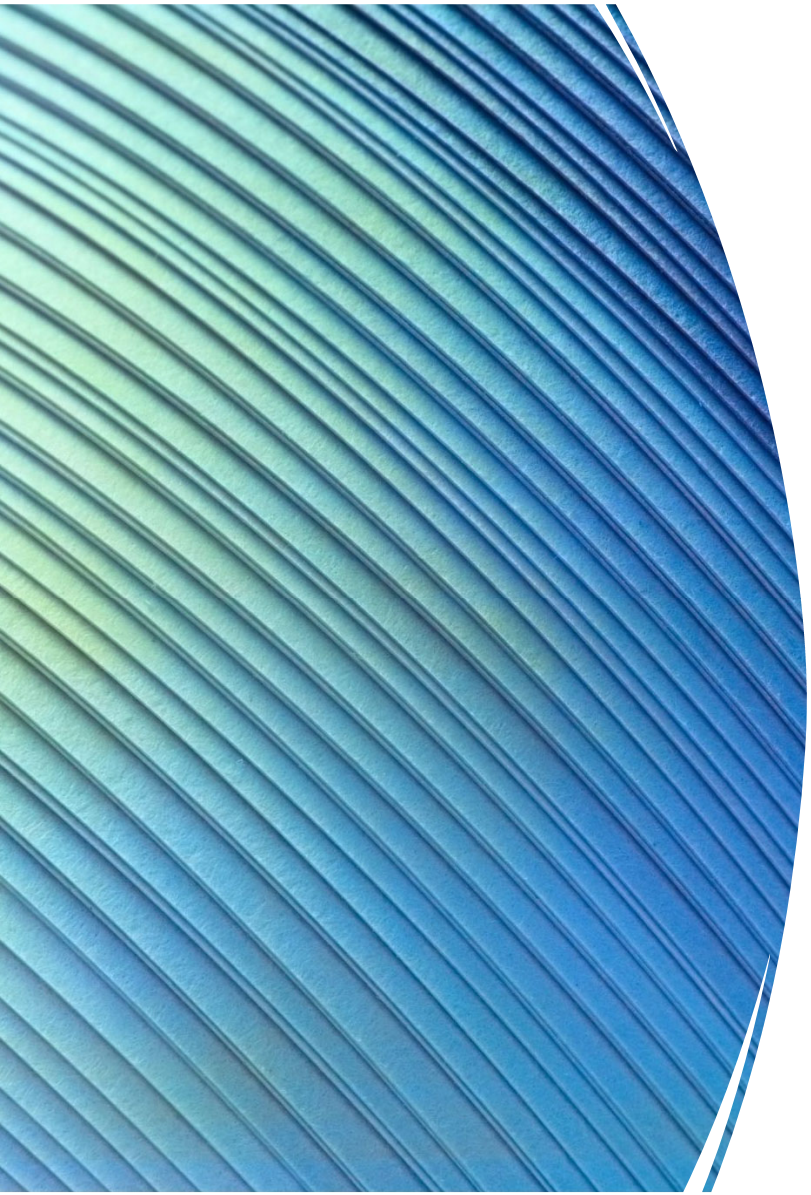
Lies, Damn Lies, and Statistics

Or, Understanding the statistics of screening tests – More than a few grains of salt needed!

Some Testing Terminology

- P = Positive Condition. I.e., the actual positive cases in a population
- N = Negative Condition. I.e., the actual negative cases in a population
- TP = True Positive (test results that correctly indicate the positive condition)
- TN = True Negative (test results that correctly indicate the negative condition)
- FP = False Positive (test results that incorrectly indicate the positive condition)
- FN = False Negative (test result that incorrectly indicate the negative condition)



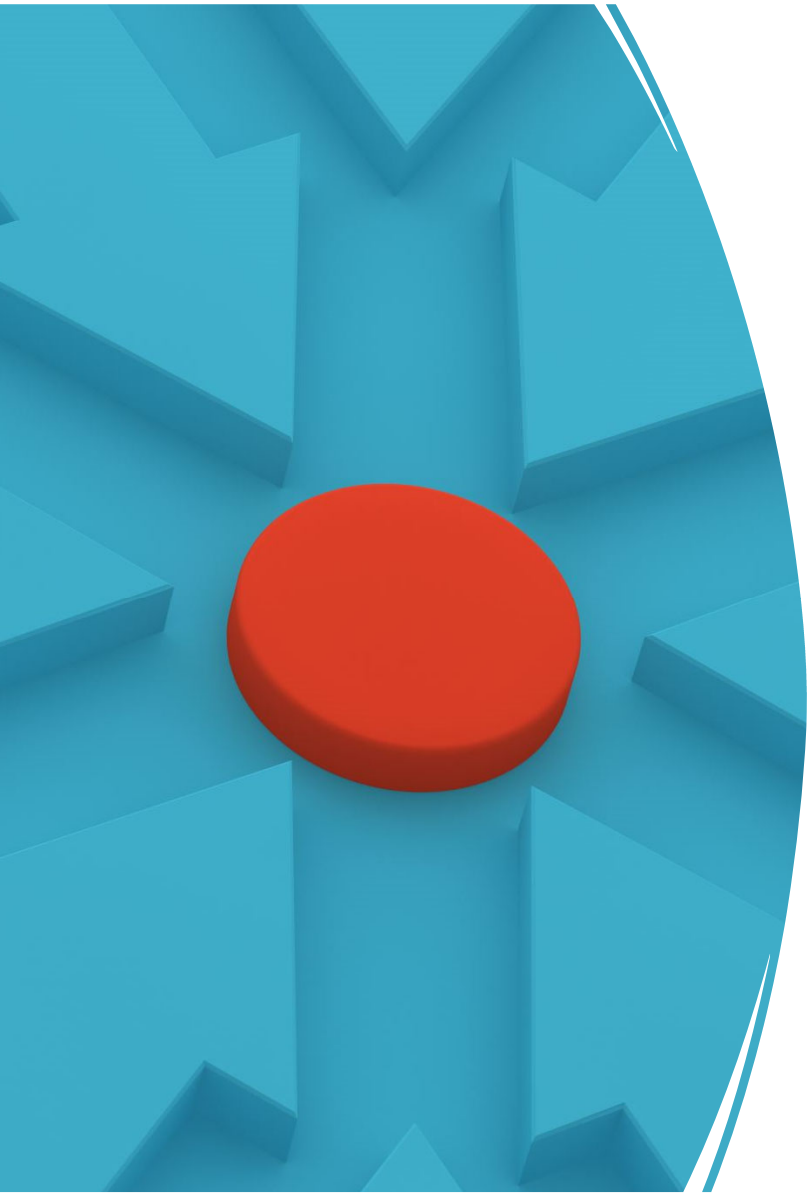


Sensitivity

Aka True Positive Rate (TPR)

$$\text{TPR} = \frac{TP}{P} = \frac{TP}{TP+FN}$$

Sensitivity is a statement of what percentage of truly positive samples will be detected as positive. High sensitivity means that there are few false negatives (aka low “miss rate”).



Specificity

Aka selectivity, aka True Negative Rate (TNR)

$$\text{TNR} = \frac{TN}{N} = \frac{TN}{TN+FP}$$

Specificity is a statement of what percentage of truly negative samples will be detected as negative. High specificity means that there are few false positives (aka low “false discovery rate”).

Caveat Emptor (Buyer Beware)

- Calculating sensitivity & specificity requires knowing the number of actual positives and actual negatives. This requires controlled experimental tests. Sensitivity & specificity calculated “in the wild” (e.g., from field tests followed by lab confirmations) may yield different numbers. Beware data “errors” in studies. Pay attention to how “confirmation”” is defined.

Accuracy

Aka Accuracy (ACC)

$$\text{ACC} = \frac{TP+TN}{P+N}$$

Accuracy is a statement of what proportion of all results correctly indicate the correct condition.

Precision

Aka Positive Predictive Value (PPV)

$$\text{PPV} = \frac{TP}{TP+FP}$$

Precision is a statement of how likely a positive result means that the sample is truly positive.

Precision (PPV) and Prevalence

Consider a test with 90% sensitivity and 90% specificity:

- First, imagine the positive condition exists in 25% of the population of 1000 people.
  - True Positive Results = 90% of 250 actual positives = 225 TP results
  - True Negative Results = 90% of 750 actual negatives = 675 TN results
  - False Negative Results = 10% of 250 actual positives = 25 FN results
  - False Positive Results = 10% of 750 actual negatives = 75 FP results

$$\text{PPV} = \frac{TP}{TP+FP} = \frac{225}{225+75} = \frac{225}{300} = 75\%$$

This means 75% of positive results should be truly positive but 25% are truly negative.

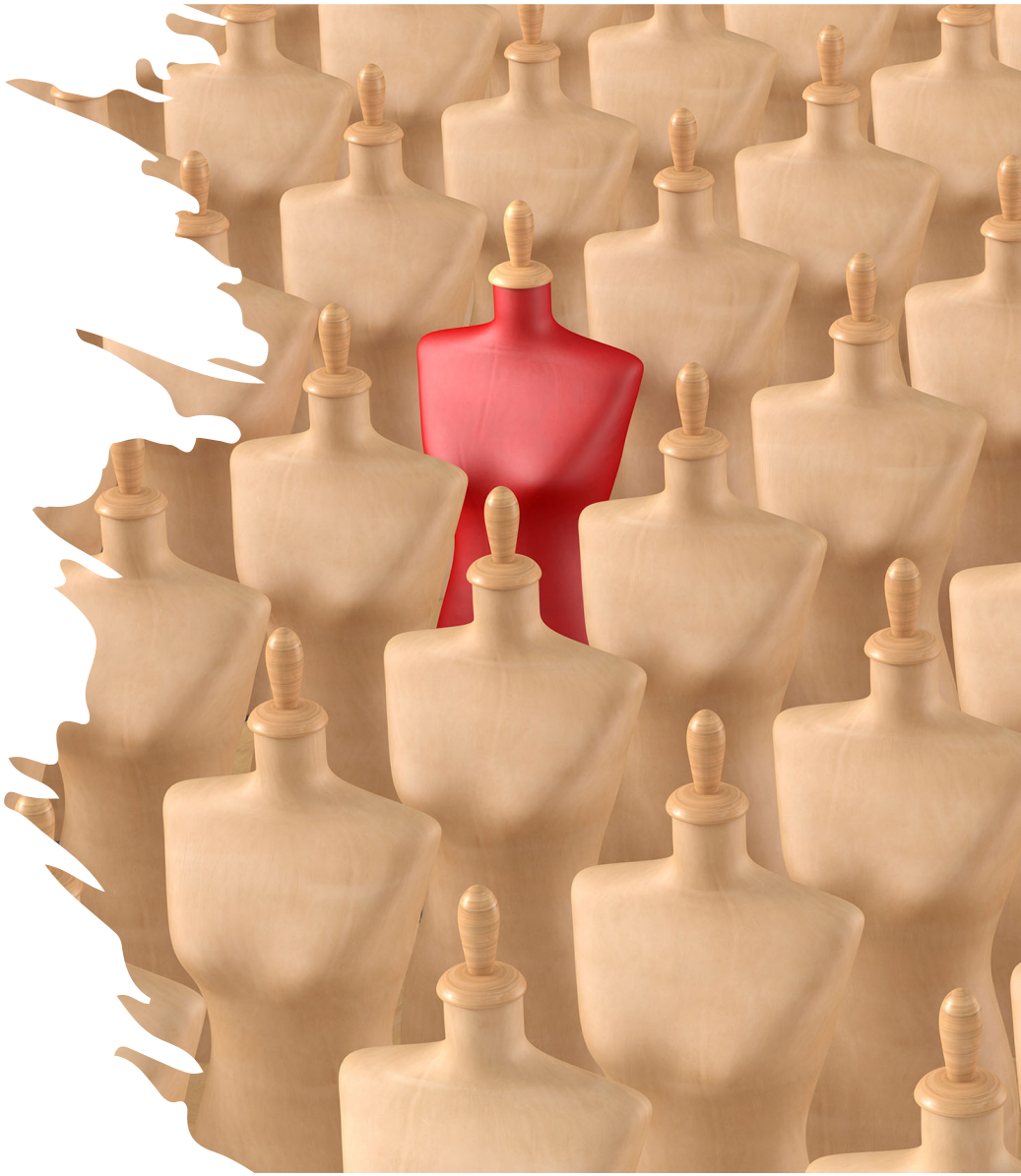
Precision (PPV) and Prevalence

Consider same test with same 90% sensitivity and 90% specificity:

- Now, imagine the positive condition exists in only 5% of the population of 1000 people.
  - True Positive Results = 90% of 50 actual positives = 45 TP results
  - True Negative Results = 90% of 950 actual negatives = 855 TN results
  - False Negative Results = 10% of 50 actual positives = 5 FN results
  - False Positive Results = 10% of 950 actual negatives = 95 FP results

$$\text{PPV} = \frac{TP}{TP+FP} = \frac{45}{45+95} = \frac{45}{140} \approx 32\%$$

Now, only 32% of positive results are likely truly positive.



What Does This Mean?

- Even with good sensitivity and specificity, low prevalence of positives in the population can yield unacceptably low positive predictive value (low precision). There is a concept called prevalence threshold – the prevalence point below which PPV drops precipitously. For 90% sensitivity and specificity, that point is about 25% prevalence. Where are drugs of interest?
- Implications:
  - POC oral fluid not well suited for random screens of drivers, especially for low prevalence drugs.
  - Increasing prevalence by focusing on drivers displaying signs of impairment will increase PPV.
  - Basing an arrest only on a positive OF result is, at best, a risky proposition – especially for low prevalence substances.
  - Combining POC oral fluid testing with solid DUID impairment training makes it a better tool.