Fundamentals of an Effective Drug Testing Program - 101

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The law is not black and white and neither is science.

". . there is a substantial gap between the questions that the legal community would like to have answered by drug testing and the answers that the scientific community is able to provide. The real danger lies in the legal community's failure to "mind the gap" by drawing unwarranted inferences from drug testing results."

Drug Testing Basics

Reasons for Drug Testing - WHY?

- act as a deterrent to future drug use
- identify probationers who are maintaining abstinence
- identify probationers who have relapsed
  - rapid intervention
  - efficient utilization of limited resources
- provides incentive, support and accountability
- adjunct to treatment & frames sanction decisions

Drug Testing Specimens

- urine - current specimen of choice
  - generally readily available - large quantities
  - contains high concentrations of drugs
  - good analytical specimen
  - provides both recent and past usage
- alternative specimens
  - breath
  - hair
  - sweat - patch test
  - saliva - oral fluids

When to Test?

- KEEP 'EM GUESSING !
- effective drug testing must be random
  - unexpected, unannounced, unanticipated
  - limit time between notification & testing
- test as often as possible - twice weekly
- consider use of multiple specimens (hair, saliva, sweat)
- keep frequency constant throughout program

Drug Testing Reality Check

- When developing and administering your drug testing program assume that the probationers you are testing know more about urine drug testing than you do!
- Sources:
  - Internet
  - High Times magazine
  - other probationers

Challenging Urine Collection Strategies

The “witnessed” collection (for urine)

- single most important aspect of effective drug testing program
- urine collections not witnessed are of little or no assessment value
- denial component of substance abuse requires “direct observation” collections of participants

Sample Collection:

- pre-collection preparation
  - site selection
    - minimize access to water sources
    - use an area with a scant floorplan
    - find privacy & security
  - gather supplies beforehand
  - obtain proper collection receptacle
- removal of outer clothing

Sample Collection: (continued)

- wash hands prior to donation
- "witness" collection
  - additional clothing removal
  - body inspection
  - squat and cough
- label sample correctly

Sample Collection: (continued)

- accept sample & inspect
  - temperature (90-100˚ F)
  - color (no color ➔ diluted ?)
  - odor (bleach, sour apples, aromatics, vinegar, etc.)
  - solids or other unusual particulates
- store sample properly
- forensic sample - custody documents

Drug Testing Methods

Two-Step Testing Approach

- screening test – designed to separate negative samples from samples that are "presumptively" positive
- confirmation test – follow-up procedure designed to validate positive test results
  - distinctly different analytical technique
  - more specific and more sensitive

Step One – Screening

- often based on immunoassay technology
- more drug – more binding - more “color” produced – more instrument detector response
- numerous commercial manufacturers
- designed for high throughput instrumentation or on-site devices

On-site DOA screening

- often based on immunoassay technology
- concept of color "switch"
- "dynamic" versus "static" calibration
- hand-held cassettes or test-cup devices
- one test at a time - no batching
- available in DOA panels or single drugs
- numerous commercial manufacturers
  - differential sensitivity & selectivity

Step Two - Confirmation

- gas chromatography-mass spectrometry (GC/MS) or LC/MS
  - drug molecules separated by physical characteristics
  - identified based on chemical “finger-print”
  - considered “gold standard”
- other chromatographic techniques

Why confirm ?

- Is it really necessary to confirm drugs that tested positive by initial screening tests?
- Why can't the court adjudicate cases based on the screening test results?

- FALSE POSITIVES

Drug tests & cross reactivity:

- screening tests can and do react to “non-target” compounds
  - amphetamines
  - benzodiazepines
- obtain list of interfering compounds from lab or on-site test vendor
- initial screening (“instant” tests) may only be 60-70% accurate
- confirm positive results

Interpretation of Drug Test Results

Negative or None Detected Results

- indicates that no drugs or breakdown products (metabolites), tested for, were detected in the sample tested
- no such thing as “zero” tolerance or “drug free”
- negative does not mean NO drugs present

Negative/None Detected Interpretation

- donor is not using a drug that can be detected by the test

<u>Other possible explanations</u>

- donor not using enough drug
- donor's drug use is too infrequent
- collection too long after drug use
- urine is tampered
- test being used not sensitive enough
- donor using drug not on testing list

Positive Test Result Interpretation

- indicates that drug(s) or breakdown products (metabolites), tested for, were detected in the sample tested
- drug presence is above the “cutoff” level
- greatest confidence achieved with confirmation
- ALWAYS confirm positive results in original sample

Typical Cutoff Levels

screening & confirmation

amphetamines *	500 ng/mL	250 ng/mL
benzodiazepines	300 ng/mL	variable
cannabinoids *	20 & 50 ng/mL	15 ng/mL
cocaine (crack)*	150 ng/mL	100 ng/mL
opiates (heroin) *	300 ng/mL	variable
phencyclidine (PCP) *	25 ng/mL	25 ng/mL
alcohol	20 mg/dL	10 mg/dL

- * SAMHSA (formerly NIDA) drugs

Bad Cop – Good Cop

How should I deal with a client who claims to have used or ingested something that caused a “false” positive?

Client Accountability:

- the court should not assume the role of client "excuse evaluator"
- clients need to be held responsible for their own behavior and maintaining a drug-free physiology
- if testing performed appropriately (with confirmation) –
- HOW the drug got into their sample is mostly irrelevant
- a positive drug test results put the client in violation
- as a practical and resource matter – the court cannot afford to argue over or dispute with every client who has a positive test result or comes up with a new excuse

Therapeutic Use of Test Results

- Isn't any amount of drug in a client's sample a violation worthy of sanction?
  - punishment model vs. therapeutic model
- therapeutic – enhance behaviors that lead to recovery
- learning to live with addiction is a gradual process
- elimination of client resistance to change is critical
- drug testing is a large component of the drug court experience
- its perceived fairness is critical to outcomes
- It's NOT "Gotcha" - - - It's "help ya"

Therapeutic Use of Test Results

- drug testing has the potential to build resistance
- particularly if a client is falsely accused
- it may be better to let a client "get away with one"
- risk a false accusation & re-establishment of resistance
- resistance leads to learned helplessness & loss of engagement
- clients should be held responsible
- consequences are critical to outcomes But . . .
- the prudent use of drug testing results can certainly enhance the path to recovery

The Issue of Urine Drug Concentrations

Drug Tests are Qualitative

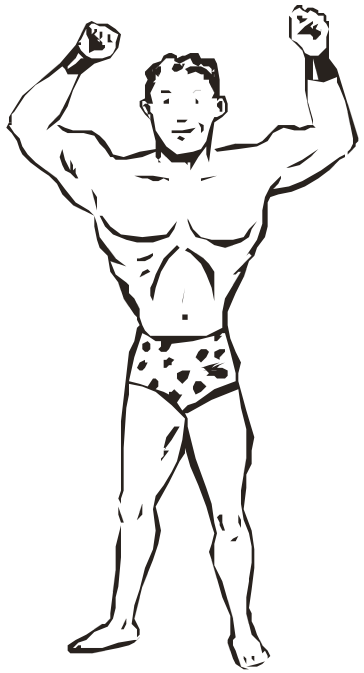
- screening/monitoring drug tests are designed to determine the presence or absence of drugs - NOT their concentration
- drug tests are NOT quantitative

Drug concentrations or levels associated with urine testing are, for the most part, USELESS !

- cannabinoids — 517 ng/mL
- opiates — negative
- cocaine metabolite — negative
- amphetamines — negative

The Twins

A



B

200 mg Wonderbarb
@ 8:00 AM

Collect urine 8:00 PM
12 hours later

The Twins - urine drug test results

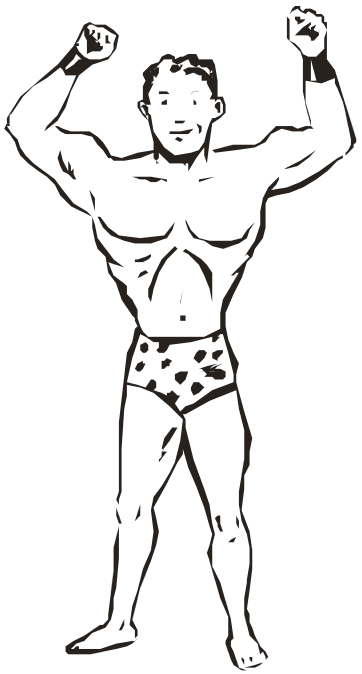
A

Wonderbarb = 638 ng/mL

B

Wonderbarb = 3172 ng/mL

The Twins - urine drug test results



A

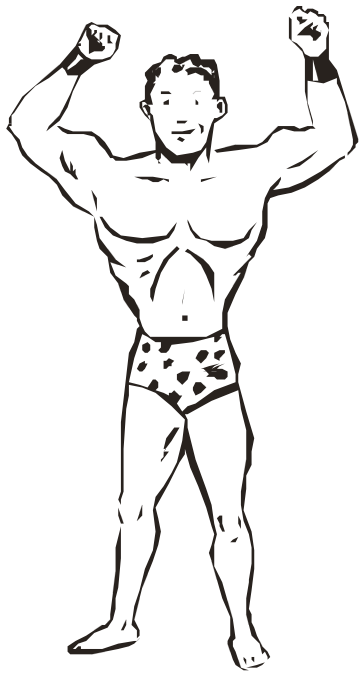
physiological make up

exact amount drug consumed

exact time of ingestion

exact time between drug exposure and urine collection

AND YET . . . . .



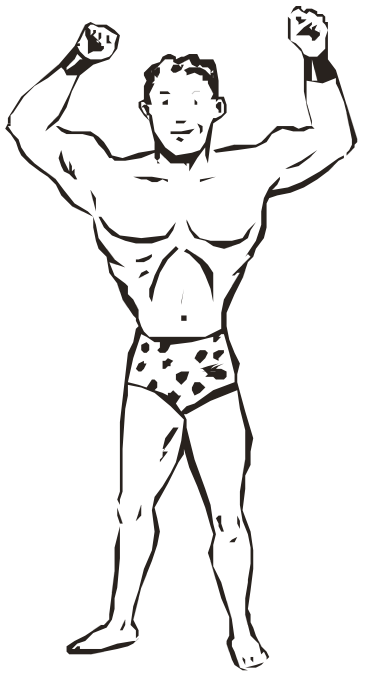
B

The Twins - urine drug test results

A

Wonderbarb = 638 ng/mL

Twin B's urine drug level is 5 times higher than Twin A



B

Wonderbarb = 3172 ng/mL

Are any of the following questions being asked in your court?

- How positive is he/she?
- Are his/her levels increasing or decreasing?
- Is that a high level?
- Is he/she almost negative?
- Is this level from new drug use or continued elimination from prior usage?
- What is his/her baseline THC level?
- Does that level indicate relapse?
- Why is his/her level not going down? (or up?)

THE ISSUE

Urine drug concentrations are of little or no interpretative value. The utilization of urine drug test levels by court programs generally produces interpretations that are inappropriate, factually unsupportable and without a scientific foundation. Worst of all for the court system, these urine drug level interpretations have no forensic merit.

National Drug Court Institute
Karen Freeman-Wilson, Executive Director
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Drug Court Practitioner

Fact Sheet

Urine Drug Concentrations: The Scientific Rationale for Eliminating the Use of Drug Test Levels in Drug Court Proceedings

By Paul L. Cary, M.S.

Preface

As the title implies, the objective of this fact sheet is to provide drug court professionals with a scientifically based justification for discontinuing the interpretation of urine drug levels in an effort to define client drug use behavior. As the premise of this document is not without some controversy, clarification of its intent seems warranted.

This fact sheet is intended for drug court practitioners who are routinely engaged in the interpretation and evaluation of urine drug testing results for the purpose of participant case adjudication, particularly client sanctioning. Given that most drug courts do not have routine access to biomedical or pharmacological expertise, this fact sheet recommends that the use of urine drug concentrations be eliminated from the court's decision-making process in order to protect client rights and ensure that evidentiary standards are maintained.

It is not the intention of this document to prohibit the interpretation of laboratory data by qualified scientists. Nor is it the objective of this fact sheet to assert that urine drug levels have no interpretative value. However, drug court practitioners are cautioned that the interpretation of urine drug levels is highly complex and even under the best of circumstances provides only limited information regarding a participant's drug use patterns. Further, such interpretations can be a matter of disagreement even between experts with the requisite knowledge and training to render such opinions.

It is for these stated reasons that the NDCI strongly encourages drug court programs to utilize the information contained herein to evaluate their drug testing result interpretation practices. This organization recognizes that the use of urine drug levels to assess client behavior may be widespread and longstanding. However, because courts rarely have the necessary toxicology expertise, the routine use of urine drug levels by court personnel in formulating drug court decisions is a practice that in most cases would not withstand scientific or judicial scrutiny. It is hoped that this fact sheet will serve as the foundation for those drug court programs routinely interpreting urine drug levels to transition to a strictly qualitative (positive or negative only) result format. Drug courts are also encouraged to seek expert toxicology advice when necessary and appropriate to assist in the interpretation of testing data associated with challenging cases.

Scientific Rationale

- Technical Issues
  - testing not linear
  - tests measure total drug concentrations
- Physiological
  - variability of urine output
  - differential elimination of drug components

THIS ?

432 indicates he going up, right?

is 22 above the cutoff?

does 219 mean new use?

307 – well she's almost negative, correct?

639 is really high for THC, isn't it?

115 is down from yesterday, probably continued elimination?

I think 1200 is a new record, isn't it?

515 is much higher than last week, right?

don't we need to consider relapse at 57?

OR THIS ?

Negative or Positive

The Drug Detection Window

Drug Detection Times - by Drug
(this is general guidance!)

- amphetamines: up to 4 days
- cocaine: up to 72 hours
- opiates: up to 5 days
- PCP: up to 6 days
- barbiturates: up to a week
- benzodiazepines: up to a week
- . . then there's alcohol & cannabinoids

Amphetamines - Results Interpretation

- screening tests - drug class assays
- interpret positive results with caution
- some screening assays often have cross-reactivity with structurally similar compounds:
  - phenylpropanolamine - PPA
  - ephedrine
- confirm results whenever possible
- detection time: up to 4 days

Amphetamines - Ecstasy

- methylene-dioxymethamphetamine (MDMA)
- will cross-react with many immunoassay initial screening tests for amphetmaines/methamphetamines
- confirm procedures for AMP and METHAMP will not identify MDMA and/or metabolites
- may have to specify MDMA confirmation

Cocaine - Results Interpretation

- drug specific assays
- positive results indicate presence of cocaine metabolites
- virtually no interferences
- positive results almost always associated with illicit drug use
- detection time: up to 3 days maximum
- negative result may not be clear indication of non-use

Opiates - Results Interpretation

- screening tests - drug class assays
- positive results indicate presence of opiates
- most assays not reactive toward synthetic narcotic analgesics; meperidine (Demerol), propoxyphene (Darvon), methadone, pentazocine (Talwin), fentanyl (Sublimaze)
- difficult to separate legitimate use from abuse
- detection time: up to 4 days following therapeutic use of codeine or morphine

Cannabinoid Detection in Urine

- Conventional wisdom has led to the common assumption that cannabinoids will remain detectable in urine for 30 days or longer following the use of marijuana.
- RESULT:
  - delay of therapeutic intervention
  - hindered timely use of judicial sanctioning
  - fostered denial of marijuana usage by clients

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Karen Freeman-Wilson, Executive Director
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Drug Court Practitioner

Fact Sheet

The Marijuana Detection Window: Determining The Length of Time Cannabinoids Will Remain Detectable in Urine Following Smoking

A Critical Review of Relevant Research and Cannabinoid Detection Guidance for Drug Courts

By Paul L. Cary, M.S.

Preface

The duration of the urinary cannabinoid detection window is not settled science. The number of days, following the cessation of marijuana smoking, necessary for cannabinoids to become non-detectable using traditional drug testing methods is the subject of debate among forensic toxicologists and a matter of on-going scientific research. This article makes no pretense to limit this important discussion, but rather, seeks to enhance it. It is hoped that drug court practitioners will find that this information clarifies some of the complex issues associated with the elimination of marijuana from the human body.

Conventional wisdom has led to the common assumption that cannabinoids will remain detectable in urine for 30 days or longer following the use of marijuana. These prolonged cannabinoid elimination projections have likely resulted in the delay of therapeutic intervention, thwarted the timely use of judicial sanctioning, and fostered the denial of marijuana usage by drug court participants.

This review challenges some of the research upon which the 30-plus day elimination assumption is based. Careful scrutiny of these studies should not be interpreted as an effort to discredit the findings or the authors of this research. However, as our knowledge evolves, the relevancy of previously published scientific data should be evaluated anew. One fact is clear—more research is needed in the area cannabinoid elimination.

Cannabinoids - Recent/Relevant Research

- 30+ day detection window often exaggerates duration of detection window
- reasonable & pragmatic court guidance
- detection time: at 50 ng/mL cutoff
  - up to 3 days for single event/occasional use
  - up to 10 days for heavy chronic use
- detection time: at 20 ng/mL cutoff
  - up to 7 days for single event/occasional use
  - up to 21 days for heavy chronic use

Recent Cannabinoid Use versus Non-recent use (double sanction issue):

- How do drug courts discriminate between new drug exposure and continued elimination from previous (chronic) use ?
  - an issue only in first phase of program
  - only drug that poses concern is cannabinoids
  - “two negative test” rule – two back-to-back negative drug tests post clean out

Alcohol - Results Interpretation

- screening tests specific for ethanol, ethyl alcohol
- positive results indicate presence alcohol
- alcohol is rapidly cleared from the body
- negative results don't necessarily document abstinence
- detection time = hours
- example - person intoxicated at 11:00 PM, collect second urine sample of next day (11:00 AM), most likely test negative for alcohol

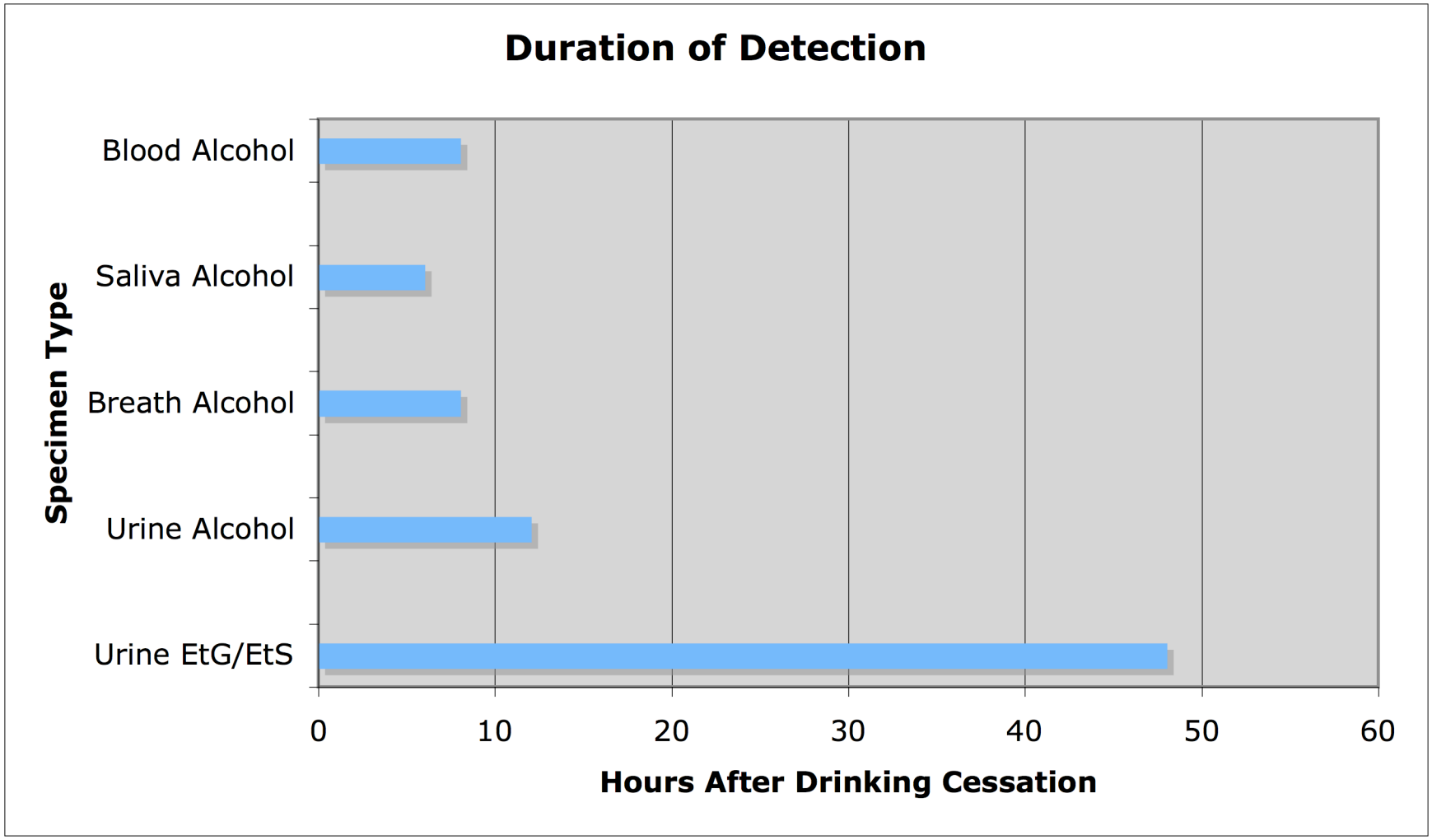
EtG & EtS – Strategy for Monitoring Alcohol Abstinence

Alcohol is the most commonly abused substance by probationers and the most difficult substance to detect in abstinence monitoring.

Advantages of Ethyl Glucuronide & Ethyl Sulfate

- unique biological marker of alcohol use (no false positives)
- direct marker indicating recent use
- longer detection window than alcohol
- stable in stored specimens (non-volatile)
- is not formed by fermentation
- is not detected in the urine of abstinent subjects

Extending the detection window



Disadvantages of EtG/EtS

- testing available at relatively few laboratories
- EtG testing more costly than abused drugs
  - expensive LC/MS/MS technology
- introduction of new testing approaches

- most significant concern – casual, inadvertent, environmental alcohol exposure causing positive results

Sources of "Incidental" Alcohol Exposure

- OTC medications (Nyquil, Vicks Formula 44)
- mouthwashes (Listermint & Cepacol)
- herbal/homeopathic medications (i.e., tincture of gingko biloba - memory)
- foods containing alcohol (such as vanilla extract, baked Alaska, cherries jubilee, etc.)
- "non-alcoholic" beers (O'Doul's, Sharps)
- colognes & body sprays
- insecticides (DEET)
- alcohol-based hand sanitizers (Purell, GermX)

Consensus Cutoffs:

- EtG minimum of 500 ng/mL
- EtS minimum of 100 ng/mL

Positive EtG Result (500 ng/mL):

- a result reported as EtG positive in excess of the 500 ng/mL cutoff is consistent with the recent ingestion of alcohol-containing products (1-2 days prior to specimen collection) by a monitored client
- studies examining "incidental" exposure widely conclude that results in excess of the 500 ng/mL cutoff are <u>not</u> associated with inadvertent or environment ethanol sources

Negative EtG Result (500 ng/mL):

- a result reported as EtG negative is indicative of a client who has not ingested beverage alcohol within 1-2 days prior to specimen collection
- a negative result is not proof of abstinence
- advertised “80-hour” window of detection not “real-world” applicable

The Effective Use of Urine Creatinine Measurements in Abstinence Monitoring

The most common form of specimen tampering is sample dilution.

Creatinine testing is a specimen validity issue!

EVERY urine sample collected for drug detection should be tested for creatinine!

What Is Creatinine & Why Measure It?

What is creatinine ?

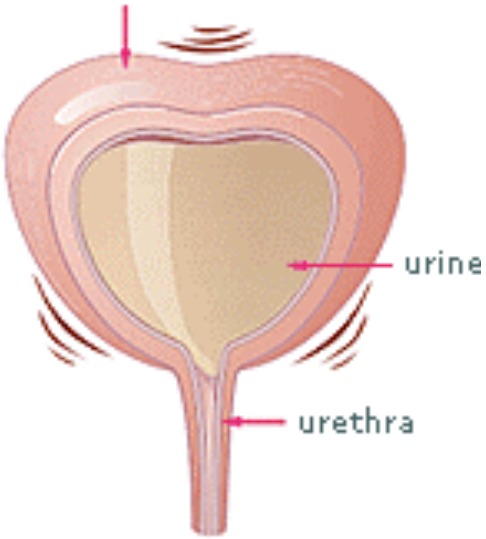
- creatinine is produced as a result of muscle metabolism
- creatinine is produced by the body at a relatively constant rate throughout the day
- creatinine is a compound that is unique to biological material (i.e. urine, other body fluids)
- creatinine measurements can:
  - determine the "strength" or concentration of a urine sample
  - ensure the sample being tested *IS* urine

Two Types of Urine Specimen Dilution

- pre collection dilution
  - consumption of large quantities of fluids *prior* to collection
- post collection dilution
  - adding fluid to specimen *post* collection

Pre-Collection Dilution

- high-volume ingestion of fluids (water loading, flushing, hydrating, etc.)
- may be in conjunction with products designed to "enhance" drug elimination or removal of drugs (Gold Seal, Clean 'n Clear, Test-Free, Naturally Klean, etc.)
- no evidence these products have any additional effect on drug elimination



DILUTION GOAL

Client has a bladder full of urine with a drug concentration of greater than the cutoff level of the test - thus producing a positive result.

Urine in the bladder is diluted by the consumption of large amounts of non-drug containing fluid; which results in a drug concentration that is less than the cutoff level of the test - thus producing a negative result.

Water contains no drugs!

- easiest, cheapest, simplest
- urines with a creatinines of less than 20 mg/dL are considered “dilute” and rarely reflect an accurate picture of recent drug use
- dilute samples are more like water than like urine
- incidence of low creatinines in a population undergoing random drug testing is significantly (up to 10 times) greater than a non-drug tested population

How are creatinine measurements used ?

- urine samples with a creatinine of less than 20 mg/dL should be considered “dilute”
- a dilute sample does not accurately reflect the recent drug use history of the person being tested
- normal human creatinine levels will vary during the day based upon fluid intake - healthy individuals will rarely produce urine samples with creatinines of less than 20 mg/dL
- meets a “preponderance” standard

More Creatinine Issues

- rapid ingestion (90 minutes) of 2-4 quarts of fluid will almost always produce low creatinines & negative urine drug tests within one hour
- recovery time of urine creatinine and drug concentrations can take up to 10 hours

“Dilute” Result Interpretation:

- negative or none detected results should never be interpreted as indicating no drug use (abstinence), because if, in fact, drugs were present, they probably could not be detected by the test

- positive drug test results from a dilute sample however, are considered valid (donor was not able to dilute the sample sufficiently to deceive the test)

Final thought about dilute urine samples . . . . .

- a creatinine of less than 20 mg/dL (associated with a drug test) is nearly always an attempt by the donor to avoid drug use detection - REGARDLESS of how much liquid was consumed in order to achieve this result

Specimen Tampering

Basics of Specimen Tampering - The Three Approaches

- dilution
- adulteration
- substitution

Urine Specimen Adulteration

- addition of foreign substances designed to “mask” drug presence
- post-collection tampering
- low-tech adulterants that cause “pH shift” (lime, vinegar, bleach, ammonia, lemon, drano)
- low-tech adulterants that disrupt testing chemistry (salt, methanol, detergent)
- “high-tech” adulterants

Urine Specimen Substitution

- replacing donor urine sample with another drug-free specimen
- biological substitution - someone else's "clean" urine
- non-biological substitution - replacing urine with urine "look-a-like" sample (diet Mountain Dew, water with food coloring)
- non-biologicals can be detected with creatinine testing

Controlling Specimen Tampering

- develop challenging collection strategy - ie. make the testing unannounced and RANDOM!
- directly observed collections is the most effective approach to preventing adulteration and substitution
- inspect sample - train collection staff
- keep abreast of tampering techniques
- take temperature measurements (90˚ - 100˚ F)
- use laboratory employs specimen validity tests & use with on-site devices

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