The Use of Urine Creatinine Concentrations for Abstinence Monitoring in Treatment Courts

By Paul L. Cary, M.S.
Forensic Toxicologist

Paul L. Cary, M.S., retired as director of the Toxicology and Drug Monitoring Laboratory at the University of Missouri in Columbia, Missouri, in 2015. For forty years, Mr. Cary was actively involved in the management of a nationally recognized toxicology laboratory. He has authored numerous scientific publications, has served on a variety of clinical and technical advisory committees, has taught at the university, is involved in drug testing research, and serves as a consultant in toxicology-related matters. He has been certified as an expert and provided expert testimony in court (local, state, and federal) and in labor arbitration and is a member of the Society of Forensic Toxicology. Mr. Cary has been a resource to treatment court teams throughout the nation and overseas for the past two decades.

Introduction

The fundamental goal of abstinence monitoring in a treatment court environment is to enable the court to evaluate a participant's compliance with program requirements—in other words, the participant's abstinence from prohibited substances. If the court is unable to reliably monitor abstinence, the ability to use rewards/incentives and sanctions as treatment intervention strategies is all but lost. If the court is unable to identify participant relapse or prohibited substance use, it is powerless to intervene therapeutically to change undesired behavior.

When urine is being used as the drug testing specimen, the monitoring of creatinine in each sample obtained is critical in establishing specimen validity. For example, if a urine specimen is determined to be dilute, the drug test may not be able to detect the presence of prohibited substances in the sample, because the concentrations of the drugs have been diluted until they are below the cutoff point of the assay. In this circumstance, test results would produce a false negative finding: prohibited substances were present, participant drug use occurred, but the testing was unable to detect the violation because the sample was more like water than urine. A dilute urine sample, regardless of whether it is intentional or not, prevents the court from evaluating a participant's abstinence.

Unlike testing for drugs, in which the analysis produces either a negative or positive result, the interpretation of urine creatinine concentrations is not always straightforward. Consequently, the therapeutic response to a urine sample that falls outside the acceptable creatinine criteria is often more complicated. This fact sheet addresses many of the issues associated with testing for urine creatinine concentrations in a treatment court context and provides guidance as to appropriate court responses to urine samples that fall outside the acceptable criteria.

Q. Why is specimen validity testing using urine creatinine concentrations necessary with treatment court participants?

A.

The ramifications of a positive drug test (i.e., sanction, incarceration, etc.), combined with the denial component of a substance use disorder, often create circumstances in which participants feel the need to "beat the drug test" by tampering with the sample. Sample tampering represents a significant challenge to the court's mission and can undermine the legitimacy of the court's policies and procedures as well as its decisions.

When a court is using urine as an abstinence monitoring specimen, participants employing tampering techniques generally use one of three approaches: dilution (excessive hydration via copious fluid consumption), adulteration (chemical contamination to mask the presence of drugs), or substitution (providing a drug-free alternative sample). Of these three approaches, sample dilution represents the most common form of urine tampering (Cone et al, 1998; Lafolie et al., 1991; Lin et al., 2018; Robinson & Jones, 2000). The frequency of diluted urine samples within the treatment court population has not been studied. However, in a recent online survey of probation department staff, about 40% of respondents said probation clients were somewhat likely to tamper with drug tests and that overhydrating was the most common form of that tampering (Reichert et al., 2020). In a 2015 study examining inpatient and outpatient populations, the researchers assert, "In conclusion, recovery (R) participants have more dilute specimens, reflected by significantly lower creatinine concentration and may indicate participants' attempts to tamper with their drug test results through dilution means" (Love et al., 2016).

Urine sample dilution can be achieved by either adding a drug-free liquid (such as water) directly to the sample after specimen collection, known as postcollection tampering, or by consuming large volumes of liquid prior to sample donation, known as precollection tampering. Courts that require directly observed collections during urine sample donation generally prevent most postcollection sample dilution. But given that treatment court staff cannot monitor a participant's fluid intake prior to urine sample collection, the measurement of urine creatinine concentrations becomes a critical safeguard to ensuring specimen integrity. Without that precaution, falsely negative drug testing results, due to a diluted specimen, would be incorrectly presumed to represent participant abstinence.

In order for treatment courts to respond appropriately to undesired behavior, it is essential that abstinence monitoring strategies produce accurate and reliable findings. When urine is used for drug and alcohol detection, the integrity and validity of the sample is essential. Testing for creatinine in the urine of treatment court participants provides that assurance.

Q. What is creatinine, and how is it produced in the human body?

A. Creatinine is a breakdown product of creatine phosphate and is produced by muscle and protein metabolism. All movement in the body is controlled by muscles. Creatine phosphate is a molecule that serves as an energy source for muscle tissue. When a muscle starts to contract and needs energy, creatine phosphate transfers its energy, via a chemical reaction, to the muscle fibers (Baker et al., 2010). This chemical reaction produces byproducts that include creatinine. Given that creatinine, as a biological chemical, has no physiological usefulness in the human body, it is eliminated in urine as a waste byproduct.

Creatinine is released at a relatively constant rate by the body depending on the percentage of muscle mass (Patel et al., 2013; Wang et al., 1996). Therefore, generally speaking, males produce and eliminate more creatinine than females, younger people produce and eliminate more creatinine than older adults, etc. In drug-tested populations, urine creatinine can be used as an indicator of urine water content (dilution detection) or as a biomarker capable of determining whether a specimen is actually urine (substitution detection). Most products used by participants in urine substitution attempts (such as water with yellow food coloring, apple juice, Mountain Dew, etc.) do not contain creatinine.

Q. What is a normal urine creatinine concentration?

A. A 2005 study that determined the urine creatinine concentrations of more than 22,000 subjects, with samples taken from persons of various ages, different ethnic groups, and different geographical locations, and at various times throughout the day, determined that the average, normal urine creatinine for an individual living in the United States was 130 milligrams per deciliter (mg/dL) (Barr et al., 2005). That creatinine level establishes a benchmark from which all treatment court urine samples can be judged. Perhaps more importantly, the study found that the incidence of dilute urine samples (with a urine creatinine concentration of less than 20 mg/dL) represented less than 1% of the studied population. In other words, diluted urine is not a common occurrence. It is unusual for a healthy individual to produce a urine sample with a creatinine level of less than 20 mg/dL and could potentially represent a symptom of an illness or disease (as I discuss later) or be related to the individual's lifestyle. The determination that dilute samples are not commonplace in the general population is significant when compared to drug testing samples from recovery populations, where the incidence of dilute samples has been reported to be substantially higher (Love et al., 2016).

NADCP
National Association of Drug Court Professionals

Q. What is the best practice when it comes to urine creatinine testing in treatment court participants?

A. Given that the consumption of large volumes of liquid prior to urine sample collection is the most common form of specimen tampering and that the testing of diluted urine specimens produces results that often do not accurately reflect the drug use history of the person being tested, the best practice is to test for urine creatinine concentrations on every urine sample collected for drug testing (National Association of Drug Court Professionals [NADCP], 2015, Chapter 7). Visual assessment of a urine specimen to determine color intensity (or lack thereof) is not an appropriate method for determining whether the specimen is valid for drug testing. Regardless of the target population being served by the treatment court (adult, juvenile, family, DWI, veterans, mental health, etc.), if urine is being used as the abstinence monitoring specimen, testing for urine creatinine concentrations in every sample is highly encouraged and is a best practice.

Q. What is the appropriate creatinine threshold for designating a urine sample as dilute?

A. A urine creatinine concentration of less than 20 mg/dL is the current standard threshold for establishing a sample as "dilute." In large measure, this benchmark is "settled" science. The use of this standard is widely accepted and is a best practice for treatment courts (the position of NADCP) and for many nontreatment substance use monitoring environments, including the military, the transportation industry, school programs, probation and criminal justice, the World Anti-Doping Agency, and the International Olympic Committee (James-Burdumy et al., 2010; Jones & Robinson, 2000; Mandatory Guidelines, 2017; Procedures for Transportation Workplace, 2021; Riah-Zanjani, 2014; U.S. Department of Defense, 2020; World Anti-Doping Agency, 2021). The use of creatinine concentrations other than 20 mg/dL for establishing a sample as dilute is not recommended.

In cases of dilute samples, with urine creatinine concentrations that are less than 20 mg/dL, corresponding negative or "none detected" drug testing results should never be interpreted as indicating no drug use or participant abstinence. Because the urine sample has yielded a dilute finding, any drugs that were present may have been concealed by the precollection hydration which will have reduced the concentration of the drugs to below the cutoff threshold of the test.

Q. What testing methods are used to determine creatinine concentrations in urine samples?

A. The most common creatinine analysis in the drug testing arena is the Jaffe method (Delanghe & Speeckaert, 2011; Gounden et al., 2021). Creatinine reacts with picric acid in an alkaline solution to form a reddish-colored complex that can be measured by an automated instrument (laboratory-based testing or court-based benchtop analyzer). While this methodology is considered a "screening" test in urine, it has been determined to be accurate (Apple et al., 1986; Küme et al., 2018). There are also enzymatic creatinine tests that are used by some testing facilities.

Creatinine testing can also be performed using on-site, point-of-care testing devices for programs that rely on instant/rapid cup analyses for drugs. These dip-stick or hand-held products generally do not produce numeric creatinine results, but rather provide above or below (20 mg/dL) color-generated indicators. Therefore, if numeric creatinine concentrations are required for case adjudication, alternative laboratory-based testing methods will be needed.

Q. Urine drug testing samples that screen positive for drugs can be submitted for confirmation testing by alternative high-resolution methods (gas chromatography/mass spectrometry [GC/MS] or liquid chromatography with tandem mass spectrometry [LC/MS/MS]). Can urine samples with disputed creatinine concentrations undergo confirmation testing?

A. While there are mass spectrometry methods that could be used as creatinine "confirmation" tests, in reality they are not practical for routine use in court-mandated testing applications due to availability and cost. Creatinine in urine is rather stable, and therefore reanalysis of a portion of the original sample should be considered in situations where the initial results are called into question. Contested results produced by on-site devices should be submitted for instrumented laboratory testing, which is more precise. Repeat laboratory or court-based instrumented testing can be performed by the original testing facility or an alternative laboratory.

Q. The use of urine drug concentrations is not appropriate for evaluating a participant's drug use behavior or history, but can the treatment court use urine creatinine concentrations to assist in result interpretation?

A. If urine samples are being tested by an instrumented methodology, it is recommended that treatment courts receive the actual urine creatinine numeric values. Urine creatinine concentrations can be quite useful in the therapeutic process of intervention and toward recovery. It's not just about whether the urine creatinine level is above or below 20 mg/dL, it is also about the patterns

and profiles associated with a participant's creatinine concentrations over time and from day to day that assist in the interpretation process.

While it is true that urine creatinine concentrations will evolve during an awake person's day (as they routinely consume more fluids while awake than when sleeping), the rapidly changing and significantly high and low urine creatinine levels exhibited by some treatment court clients are generally not commonplace in the general population. Normal urine creatinine levels do not demonstrate extreme intraday fluctuations in an otherwise healthy person without some form of rigorous physical activity followed by necessary fluid replacement. In other words, if a participant is capable of producing "normal" urine creatinine levels at least some of the time, barring some physiological explanation, the production of dilute samples may represent a tampering attempt.

Having the actual urine creatinine values can be useful in establishing a participant's behavioral patterns and potential tampering trends. For example, if a participant's urine creatinine concentrations show a pattern of continuing decreases in levels, the court does not have to wait until the samples reach a dilute status. Rather, the court can begin to explore possible behavioral causes for these declines and develop therapeutic adjustments before the participant produces an actual dilute sample (less than 20 mg/dL).

Additional information on this subject is provided in the section on differentiating between intentional and unintentional dilutes.

Q. How much fluid intake is required to produce a diluted urine sample?

A.

This is a difficult question to answer because of the number of variables associated with attempting to calculate urine creatinine levels after fluid consumption. A participant's "normal" urine creatinine concentrations are dependent upon muscle mass, age, gender, metabolism rate, amount of fluids regularly consumed, dietary habits, occupation, etc.

That said, the rapid (within 60 to 90 minutes) intake of 2 to 4 quarts of water (or other liquid beverage) is routinely sufficient to produce urinary creatinine levels of less than 20 mg/dL and result in a specimen that is sufficiently watered down to the point that the testing is no longer reliable or predictive of drug use behavior (Cary, 2011; Heit & Gourlay, 2004; Mandatory Guidelines, 2017). The important concept is that a urine creatinine concentration of less than 20 mg/dL, associated with a court-mandated drug test is highly predictive of an attempt by the specimen donor to avoid detection of drug use, regardless of how much liquid was consumed (Cary, 2011). This statement, of course, assumes that the participant does not have any physiological issues that would prevent the production of a urine sample with an acceptable urine creatinine concentration.

It is also possible for an individual to unintentionally consume enough liquid to produce a dilute sample, but that circumstance should be considered the exception rather than the rule and should be evaluated based upon known case-specific facts. Individuals working in harsh environmental conditions could consume copious amounts of fluids to avoid dehydration, thus producing urine samples with low creatinine concentrations. In those situations, the court should consider collecting a participant's urine sample before their work shift or early in the morning.

Q. Is it possible for the treatment court to differentiate between the production of an intentional dilute sample to avoid relapse detection and an innocent, unintentional dilute sample?

A.

Differentiating between an intentional and unintentional dilute sample represents a significant challenge for the treatment court team and can complicate effective therapeutic responses. Treatment strategies such as motivational interviewing and other direct therapeutic approaches may be successful in breaking down the denial component and learned dishonesty that are features of a substance use disorder. A technique that has proven helpful in differentiating between deliberately tampered samples and innocently produced invalid samples is to determine whether the unacceptable samples occur episodically (i.e., once in a while) and the timing of these problematic samples.

It could be argued that if an individual is able to produce urine samples with "normal" creatinine levels on some days, then samples with exceedingly low creatinine levels (less than 20 mg/dL) produced on other days are not due to any type of disease process, medical condition, or medications. In other words, if the dilute samples were associated with a disease-related problem or medications being taken regularly, dilute sample production would be routine rather than episodic. In order to determine whether a dilute sample is intentional or unintentional, the court needs to determine whether the dilute samples occur episodically and potentially suggest sample tampering (precollection hydration) to avoid drug use detection.

Tracking of a participant's urine creatinine concentrations over time is a practical method for identifying episodic incidences and establishing potential tampering patterns. Charting the dilute sample events in a spreadsheet or graphing low creatinine levels over a period of weeks can produce revealing information about episodic dilute samples and may enable the court to discern specific patterns or trends. Do the dilute samples occur only after a weekend or on the participant's payday or on their day off? Do dilute samples occur when known stressors are impacting other client behaviors?

If such patterns are established (evidence of tampering and potential relapse), this data can become a powerful therapeutic tool that enables treatment to focus on factors that are obstructing recovery. Treatment's involvement in dilute sample case adjudication, in which a variety of therapeutic adjustments are considered, is critical. Treatment must address dilute samples (an undesired behavior) with the same level of therapeutic intensity that is given to positive drug test results.

Q. What diseases could cause a treatment court participant to produce dilute urine samples?

A.

When this question arises within the treatment court environment, the court is advised to seek professional medical advice. As previously described, muscle mass is a key determining factor in the production of creatinine and its ultimate concentration in urine. Therefore, diseases that significantly reduce muscle mass would correspondingly reduce urine creatinine concentrations. Sarcopenia (loss of muscle tissue due to the aging process), cachexia (muscle loss from diseases such cancer, end-stage HIV or AIDS, chronic obstructive pulmonary disease, significant kidney disease, or congestive heart failure), and anorexic disorders (protein-energy malnutrition) represent the major causes of muscle-wasting disorders (Bell et al., 2016; Evans, 2010; McLoughlin et al., 1998). Amyotrophic lateral sclerosis (ALS) can also lead to significant muscle reduction (Pansarasa et al., 2014).

Simply having one of these conditions does not necessarily equate to the production of dilute urine samples. The degree to which any of these aforementioned diseases has the potential to reduce a participant's production of creatinine to an unacceptable level should be assessed by a physician specializing in muscle-wasting pathologies. The portion of the treatment court population with muscle mass conditions serious enough to produce dilute urine samples is unreported. However, the number of individuals with diseases that have the potential to result in unacceptable urine samples should be considered relatively small. Additionally, these participants would produce urine samples that were always (or nearly always) dilute, not episodically dilute.

A client who always produces low urine creatinine levels should be referred to a nephrologist for medical surveillance. A nephrologist is a doctor that specializes in treating diseases of the kidney and has expertise on how kidney disease or dysfunction can affect other parts of the body. Such a referral is designed to ensure that the client is capable of producing a "normal" urine or to determine if aberrant urine creatinine levels are related to a kidney dysfunction. If a physician is unable to correlate a particular pathology with the production of dilute samples, the court can eliminate diseases with the potential for causing reduced creatinine production from the list of potential reasons for the dilute samples. This allows the court's intervention strategies to focus on other explanations for this undesired behavior.

Treatment court participants will often claim that a variety of illnesses or diseases are the causal factor for problematic urine creatinine levels. Maladies often cited by participants include diabetes (an endocrine disorder that affects the kidneys), hypertension (high blood pressure, often treated with a diuretic), and hepatitis (inflammation of the liver). The question that arises is whether these ailments are sufficient to produce creatinine level anomalies. Take diabetes, for example. Medical research shows that even the most significant diabetic conditions reduce urine creatinine concentrations by only up to 30 mg/dL (Sinkeler et al., 2013). In most situations, this reduction would not preclude a participant from producing a urine sample with a creatinine concentration that met the acceptance criteria.

None of the diseases mentioned, by themselves, would likely result in a dilute urine specimen (with a creatinine concentration of less than 20 mg/dL). That said, seeking professional medical advice is always the best course of action. If the court, for whatever reason, deems that a participant is unable to produce an acceptable urine specimen, the court should consider alternative monitoring techniques (oral fluids, sweat patch, continuous alcohol monitoring devices, etc.).

Q. What prescription medications could cause a treatment court participant to produce dilute urine samples?

A.

This question also requires input from appropriate medical professionals. That discussion should include the diagnosis associated with the prescription medications and the potential physiological ramifications that might complicate the assessment of urine creatinine concentrations.

One medication that may be particularly problematic is diuretics (sometimes referred to as "water pills"). The most common condition treated with diuretics is high blood pressure (Shah et al., 2004). Diuretics reduce the amount of fluid in the blood vessels and helps lower blood pressure. They act by increasing the renal excretion of sodium via the urine. When the kidneys excrete sodium, they excrete water from the blood as well; therefore, diuretics elevate the rate of urination and thus provide a means of forced diuresis (Wile, 2012).

One of the side effects of taking diuretics can be increased thirst. Participants compensating for thirst may consume more liquids, which could result in a urine sample with a reduced creatinine concentration. But in most cases, this increase in thirst should not cause an individual to consume so much liquid that they produce a sample with a urine creatinine level of less than 20 mg/dL. Thus, diuretics, in and of themselves, should not routinely produce low creatinine (dilute samples) in urine. But again, discussions with the treating physician and the gathering of case-specific information should assist the court in determining whether this or other medications present a challenge to obtaining a valid urine sample. Finally, tracking of a participant's urine creatinine concentrations over time while taking their medication as prescribed can produce information on the effect of the medication on creatinine values. Baseline creatinine values can be established over the course of treatment.

Q. What over-the-counter (OTC) products could affect the urine creatinine concentrations of treatment court participants?

A.

Given the sheer number of OTC products available to treatment court participants, it is impossible to create a definitive list of commercially available merchandise with the potential to affect creatinine production and elimination. Many OTC products are unregulated and contain unstudied substances or may even contain substances that are not listed on the product label. Despite the overwhelming array of products, the court cannot abandon its mandate to monitor for abstinence from prohibited substances using appropriately valid samples.

In its supervisory role, the court often prohibits the use of products that have the potential to interfere with the evaluation of drug testing results. Courts routinely ban the use of alcohol and the consumption of poppy seeds and creatine supplements. Inasmuch as it is not possible to list all of the commercially available products a participant must avoid, treatment courts should consider a blanket prohibition of problematic OTC merchandise, including OTC chemicals, ingestibles, OTC drugs, nonmedicinal products, non-FDA-approved supplements, herbal products, kombucha, energy drinks, dietary supplements, sports medicine powders, etc.), that have the potential to interfere with the court's ability to accurately and

reliably evaluate the results of abstinence monitoring tests—unless a product has been legally prescribed by a licensed physician or approved by the court prior to use. In other words, courts should ban any OTC product that has the potential to interfere with their evaluation of abstinence monitoring strategies.

Clearly, a primary goal of treatment court is building participant self-responsibility. In so doing, the court develops ways to sanction client behaviors that fail to meet mandated standards. Participants' uninformed use of the commercially available products is a behavior that necessitates therapeutic attention. While not all OTC products carry a definitive ingredient list, participants should be counseled to read product labels and gather product information carefully. All treatment court participants should routinely be instructed that when in doubt, don't use, consume, or apply.

Q. What recommendations are available for sanctioning participants for dilute samples?

A.

A question often posed regarding dilute samples goes something like this: "We sanction for dilute samples in the same way we sanction for positive samples. Is that okay?" The most appropriate reply is a question. "How does your court sanction for positives?"

The *Adult Drug Court Best Practice Standards*, Volume I, details the importance of progressivity when the court employs incentives, sanctions, and therapeutic adjustments for noncompliant behavior. This guidance instructs the court that consequences for participants' behavior should be "predictable, fair, consistent, and administered in accordance with evidence-based principles of effective behavior modification" (NADCP, 2013, p. 26).

There are no national standards for the sanctioning of participants who continue to produce dilute samples with unacceptable urine creatinine concentrations. That said, if this behavior is identified as specimen tampering, the court should use the same sanctioning regime that it uses to correct any other undesired behavior that needs modification. From this perspective a tampered sample is no different from any other untoward behavior that the court wishes to change. Progressive sanctions and therapeutic adjustments should be designed to remediate unacceptable conduct.

Some suggested sanctions and therapeutic adjustments for repeated dilute samples include:

- Receiving a verbal warning from the judge
- Requiring community service
- Keeping a weekly fluid consumption log
- Researching and writing a report on how the kidney works
- Expanding the frequency of urine drug testing with early morning collections
- Accelerating therapeutic measures (increased treatment sessions or group meetings)
- Increasing contacts with supervisory staff (probation, case managers)
- Loss of valued privileges
- Limited incarceration

Strategically designed and progressively employed responses to repeated dilute sample production must be initiated in order to produce long-term changes in the tampering behavioral mindset of participants.

To avoid using sanctions designed to address participant relapse events, the court should consider rethinking how dilute samples are categorized. As the initial question that began this section suggests, some courts classify dilute samples as "positives." This classification is insufficiently nuanced—dilute samples are not positive. Some courts find it helpful to modify the test result language in an effort to guide the consequences of continued dilute samples away from the relapse-centric terminology of "positive." In federal drug testing programs, a result showing that a urine sample has failed to meet established acceptance criteria, indicating that the sample may be dilute, adulterated, substituted, or otherwise invalid, is referred to as "nonnegative" (Center for Substance Abuse Prevention, 2018, p. 2-7). Nonnegative results indicate that the urine sample lacks sufficient integrity for drug testing purposes and is suspected of being tampered with. It is recommended that dilute urine samples not be labeled as "positive."

Q. Are there proactive steps that the court can take to reduce the frequency of dilute samples?

A. The court should initiate the conversation about specimen integrity on day one. This discussion fits nicely into a general discussion of the importance of honesty. Honesty is a touchstone concept within the treatment court environment and represents a proximal goal. It is not unreasonable to view sample tampering as an act of dishonesty and an undesired behavior that necessitates modification. Honesty is a behavior that participants can and should control. In most cases, specimen tampering that produces a dilute result is an act of dishonesty and an attempt to defraud the court's policies and procedures. If honesty is a proximal goal and producing intentionally diluted samples is an act of dishonesty, the elimination of intentionally diluted samples should also be a proximal goal.

Proximal goals represent behaviors that a treatment court participant is already capable of engaging in and achieving. Proximal goals are short-term accomplishments that are often linked to phase advancement (Marlowe, 2011). The continued production of intentionally diluted samples should be taken into consideration in the decision process associated with moving a participant to the next phase. If a participant has not mastered the critical concept of honesty and is still producing intentionally diluted samples, phase advancement may not be appropriate until that behavioral issue is resolved.

The court can begin disseminating guidance regarding dilute samples via the client contract, court handbook, or other documents designed to provide participants with a clear and comprehensive explanation of their rights and responsibilities. The following verbiage is designed to educate participants regarding their obligations to provide a valid sample while at the same time adding specificity to the compliance benchmarks:

> I understand that I will be tested for the presence of drugs and alcohol in my system on a random basis according to procedures established by the treatment court team and/or my treatment provider.
>
> I understand that I will be given a location and time to report for my drug test.
>
> I understand that it is my responsibility to report to the assigned location at the time given for the test.

I understand that if I am late for a test, or miss a test, it will be considered to be an invalid test for drugs or alcohol or a "no show" and I may be sanctioned.

I understand that if I am unable to produce a urine specimen, or if the sample provided is not of sufficient quantity, it will be considered to be an invalid test for drugs or alcohol and I may be sanctioned.

I have been informed that the ingestion of excessive amounts of fluids can result in a diluted urine sample, and I understand that my urine sample will be tested to ensure that the sample is not dilute.

I understand that if I produce a dilute urine sample with a creatinine concentration of less than 20 mg/dL it will be considered to be an invalid test for drugs or alcohol and I may be sanctioned.

Peer education is another technique that can promote participant knowledge about specimen integrity and tampering. A presentation targeting new participants, made by a graduate of the treatment court, discussing the realities and ramifications of specimen tampering may enhance the value of the discussions associated with dilute samples. A graduate's disclosure of personal tampering experiences and the presentation of fact-based information aimed at dispelling tampering myths early in the program can reduce new participants' learning curve regarding dilute sample production.

Q. What about samples with high urine creatinine concentrations? How are these different from dilute samples?

A. Unlike the dilute sample threshold of 20 mg/dL, which is widely recognized as a reliable indicator of a watered-down urine sample, there is no universally recognized creatinine concentration standard for designating high urine creatinine levels as potential tampering. Regrettably, the data on "high" levels of urine creatinine is not as clear and straightforward as the material on low levels (dilutes) because there is much less research. The number one cause of high urine creatinine concentrations in the general population is dehydration (a condition that occurs when the loss of body fluids, mostly water, exceeds the amount that is taken in, as in profuse sweating). Research indicates that urine creatinine concentrations associated with dehydration, as measured following prolonged exercise, can increase five-fold from baseline levels (Bongers et al., 2018). As a result, dehydration should be eliminated as a causal source of high creatinine levels prior to case adjudication involving sanction.

Referring back to the 2005 study referenced earlier, less than 3% of the subjects had urine creatinine levels greater than 300 mg/dL, and less than 1% had over 400 mg/dL, which demonstrates that exceptionally high urine creatinine concentrations should be considered uncommon (Barr et al., 2005).

High creatinine levels generally indicate that the kidneys are not functioning as well as they should. A variety of kidney dysfunctions could result in elevated urine creatinine concentrations (Shahbaz & Gupta, 2020). Here again, the court is advised to seek professional medical advice. As with the investigation of dilute samples, if participants routinely produce urine samples with high creatinine concentrations, the court should require these individuals see a nephrologist (kidney doctor) to ensure that the client is capable of producing a "normal" urine sample or to determine whether the participant has a kidney dysfunction of some kind. In other words, let a trained professional sort out these issues.

Similar to the patterns evaluated for dilute samples, if high urine creatinine levels are due to a kidney ailment, the participant would produce these high levels on an ongoing, routine basis, not just once in a while. Establishing the episodic occurrence of samples with high urine creatinine concentrations helps the court determine if the high levels are intentional (due to tampering) or unintentional. Best practices in cases of high creatinine levels judged to be intentional would be to follow progressive sanctioning and refine therapeutic adjustments in order to modify this conduct.

Urine creatinine levels are affected naturally during the day by the amount of fluid intake. However, creatinine concentrations can also be affected unnaturally by the consumption of creatine. As previously discussed, creatine is a biological chemical that is converted to creatinine by muscle metabolism. Supplements containing creatine are legally sold over the counter and are readily available at GNC and other health-related stores. Creatine is often classified as a dietary supplement and is commonly used by athletes and body builders to add muscle mass. Broken down in the body into creatinine, creatine can also be used by treatment court clients to mask dilution efforts. Studies indicate that ingested creatine can result in artificially evaluated blood and urine creatinine levels (Feigenbaum et al., 2017; Jackson et al., 2010; Schedel et al., 2000; Williamson & New, 2014).

Participants attempting to hide sample dilution would ingest creatine in amounts above the recommended doses. The creatine would be metabolized in the body to creatinine, which would be eliminated from the body via the urine, causing the urine concentration of creatinine to exceed the level that would have occurred naturally. The participant would then hydrate with large volumes of fluid. The goal would be to produce a sample in which concentrations of prohibited substances are diluted to below their detection threshold, while also having a creatinine concentration that meets acceptance criteria.

Oftentimes clients consuming creatine supplements (to tamper with a urine sample) cannot predict the urine creatinine level that will result from this scheme. It's difficult for participants to titrate the various components—amount of creatine ingested, amount of liquid consumed, time of urine collection, etc. This tampering strategy frequently results in excessively elevated urine creatinine concentrations, considerably higher than those of individuals not engaging in creatine supplementation.

Differentiating between the covert consumption of creatine resulting in high urine creatinine concentrations and a medical explanation resulting in the same high creatinine outcome involves examining a participant's urine creatinine levels over time. This approach was discussed in detail previously as a strategy for differentiating between the production of intentionally diluted samples versus unintentionally dilute samples. If a client produces "normal" urine creatinine levels for some collections and high urine creatinine levels on other occasions (episodic), sample tampering via creatine ingestion should be considered. Episodically occurring high creatinine samples may suggest sample tampering—a relapse flag. Charting high creatinine samples over time can be helpful in seeing patterns, and if a pattern is present (evidence of tampering), this data can be used to establish appropriate sanctions and/or therapeutic adjustment responses.

Because dehydration is a potential cause for high urine creatinine concentrations, one question that arises for the court is whether a client who works in harsh environmental conditions (excessive heat) and consumes insufficient fluids (becomes severely dehydrated) can have elevated urine creatinine levels. The answer, of course, is yes and highlights the importance of obtaining case-specific facts prior to case adjudication for high creatinine samples. However, here are two points to keep in mind: (1) the data seems to indicate that this occurrence is rather rare in the general workplace (because

laborers routinely consume fluids to prevent dehydration under OSHA regulations) and (2) anecdotal information suggests that the incidence of high urine creatinine levels is greater in court-mandated drug testing programs than in the general population (Brake & Bates, 2003). If high urine creatinine levels become problematic in participants who work in severe environmental conditions, the court should consider testing these individuals before they report to the job site or on their days off. Alternatively, abstinence monitoring may necessitate the testing of specimens other than urine.

A urine creatinine concentration of over 400 mg/dL in an untampered sample would indicate a catastrophic kidney condition that would be evident in a participant's physical presentation. For tampered samples, treatment courts have developed appropriate intervention strategies, including sanctions, to respond to high creatinine occurrences. If the court is monitoring urine creatinine concentrations over time and scrutinizing data for trends, it is advisable to initiate a treatment discussion before the participant reaches the consensus 400 mg/dL threshold. More intense participant supervision should begin when urine creatinine concentrations exceed 300 mg/dL. At this concentration, while sanctions are not warranted, participant engagement presents an opportunity to interrupt the ever-increasing likelihood of successful urine tampering.

Q. Should the treatment court also test for specific gravity to establish whether a participant's sample is dilute?

A.

Specific gravity is the measurement of the total amount of dissolved solids in a liquid, such as urine, and includes creatinine in addition to other excreted compounds. It represents an alternative method for determining whether a urine sample is diluted. The use of specific gravity for the purpose of defining dilute urine samples dates back to the first federal workplace mandatory guidelines for the drug testing of federally regulated employees (Bush, 2008). The federal workplace drug testing guidelines have little in common with abstinence monitoring in a treatment court environment, particularly when it comes to specimen validity testing (creatinine, pH, nitrites, specific gravity, etc.). The federal guidelines were established as a "beyond a reasonable doubt" standard and incorporate both urine creatinine and specific gravity into the dilute urine sample calculation. This "beyond a reasonable doubt" safeguard was instituted to protect prospective employees—people not involved in the criminal justice system. In a treatment court context, the burden of proof standard is generally not "beyond a reasonable doubt." Instead, the proof threshold is usually a "preponderance of the evidence" admissibility standard. Adopting the federal dilute standard raises the evidential bar to a point that it can create a barrier to addressing the undesired behavior commonly seen in substance use disorders.

While specific gravity is mandated for some types of employment-related drug testing, it is optional for criminal justice testing. This is most likely true for two reasons: first, specific gravity testing can be a more difficult analytical procedure (more time consuming) than creatinine testing; second, result interpretation is much more complex. Added to these concerns are the evolving federal rules regarding the measurement of specific gravity and the consequences associated with unacceptable results. Finally, some laboratories report specific gravity results using a three-decimal-place reading (i.e., 1.003) while others use a four-place reading (i.e., 1.0029), further complicating result interpretation.

Like creatinine, an individual's specific gravity level will fluctuate during the day and is influenced by the amount of fluids consumed. In that regard, the relationship between urine creatinine and the

specific gravity of urine is generally proportional—as the urine creatinine decreases, so does the specific gravity, and vice versa. While there is nothing that prohibits treatment courts and their testing facilities from monitoring specific gravity and attempting to use a combination of specific gravity and creatinine levels to determine urine specimen acceptability, treatment courts routinely use only creatinine measurements to determine whether a urine specimen is dilute, an approach that is legally defensible based upon a "preponderance" standard (Meyer, 2011).

An example of how specific gravity can complicate dilution interpretation follows. In this scenario a participant's urine sample produces a specific gravity of 1.003 and a creatinine measurement of 18.0 mg/dL. Does this sample meet the criteria for a diluted specimen? The creatinine is less than 20 mg/dL; however, under federal workplace guidelines the specific gravity may be acceptable based on a four-place specific gravity reading. A court using only creatinine concentrations to determine specimen validity would assess this sample as dilute. But if the court is receiving both creatinine and specific gravity readings, additional evaluation procedures and policies are required to make the dilute determination. Further, if made based on both creatinine and specific gravity, the court's final determination (dilute or not dilute) may appear arbitrary because the creatinine level may be below the cutoff while the specific gravity is deemed to meet acceptance criteria. Confusion for all involved.

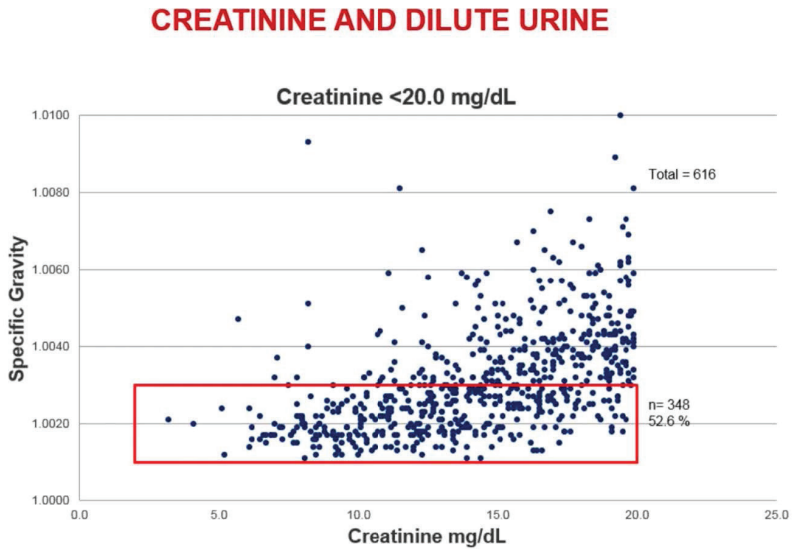

FIGURE 1. Results of tests of 616 urine samples for both creatinine concentration and specific gravity. Courtesy of Bert Toivola, Ph.D.

Figure 1 reflects the results of a study that tested 616 urine samples for both creatinine concentration and specific gravity. All of the samples plotted on this graph represent samples with creatinine values of less than 20 mg/dL, but with specific gravity measured between 1.0000 and 1.0100. The red box indicates 348 samples that produced results indicating both a low urine creatinine concentration (less than 20 mg/dL) and a specific gravity measurement of less than 1.003—the federal workplace criteria. The remaining samples (outside the box; n = 268) represent urine samples that have only a low urine creatinine concentration.

Using the more stringent federal standards that require dual unacceptable criteria to establish a dilute sample (both low creatinine and low specific gravity), just over half of the urine samples would have been classified as meeting these dilute benchmarks. Put another way, a court using the federal guidelines would have missed nearly half of the potentially "dilute" samples. Thus, the unidentified dilute samples ultimately would go unaddressed by the court as potential sample tampering. That represents an unacceptable practice in the assessment of client behavior and a significant loss of opportunities to intervene therapeutically to modify behavior and promote recovery.

Using urine creatinine measurements only as a single dilute assessment decision standard is both a scientifically valid and legally defensible approach to evaluating potential tampering. It is important to note that the treatment court environment can be a confusing setting for participants with a substance use disorder. Setting aside the overarching scientific issues, using a cutoff for dilution that is equivalent to 20 mg/dL (creatinine only) makes it easier for clients to understand the threshold used to classify a sample as dilute, is a less complex interpretational process for the court, and is easier to place into a policy statement or participant contract.

Final Thoughts

Urine sample dilution is the number one form of specimen tampering. Performing urine creatinine measurements is a scientifically valid approach to detecting sample tampering. Treatment court best practice standards specify that every urine sample collected for drug and alcohol testing is also analyzed for the presence and concentration of creatinine. A false negative drug detection result occurring as a result of intentional urine sample dilution precludes the court from deploying its many therapeutic tools to promote and achieve recovery from substance use disorders. Simply put, you cannot intervene to change behavior if relapse goes undetected. Measuring creatinine in order to verify urine specimen integrity and to reduce the frequency of false negative results demonstrates the court's commitment to accurate and reliable abstinence monitoring.

Treatment court participants often refute and attempt to explain away dilute urine sample results with the same level of intensity that they use to deny positive drug test results. The court is obligated to establish sample acceptance criteria and compliance procedures that ensure that only urine samples with documented integrity are tested for abstinence monitoring. Specific guidance should be disseminated about these policies and procedures to the participant population, informing them of the court's mission and responsibilities. Paint a roadmap for participant success. Progressive sanctions and measured therapeutic adjustments should be designed to remediate unacceptable behavior associated with intentionally diluted urine samples.

Accurate and reliable drug testing, the results of which provide a dependable record of either participant substance use or ongoing abstinence, is essential to the overall success of the treatment court program. Creatinine testing plays a vital role in ensuring the accuracy and reliability of the court's abstinence monitoring efforts.

References

Apple, F., Bandt, C., Prosch, A., Erlandson, G., Holmstrom, V., Scholen, J., & Googins, M. (1986). Creatinine clearance: Enzymatic vs Jaffé determinations of creatinine in plasma and urine. *Clinical Chemistry, 32*(2), 388–390. https://doi.org/10.1093/clinchem/32.2.388

Baker, J. S., McCormick, M. C., & Robergs, R. A. (2010). Interaction among skeletal muscle metabolic energy systems during intense exercise. *Journal of Nutrition and Metabolism, 2010,* Article 905612. https://doi.org/10.1155/2010/905612

Barr, D. B., Wilder, L. C., Caudill, S. P., Gonzalez, A. J., Needham, L. L., & Pirkle, J. L. (2005). Urinary creatinine concentrations in the U.S. population: Implications for urinary biologic monitoring measurements. *Environmental Health Perspectives, 113*(2), 192–200. https://doi.org/10.1289/ehp.7337

Bell, K. E., Von Allmen, M. T., Devries, M. C., & Phillips, S. M. (2016). Muscle disuse as a pivotal problem in sarcopenia-related muscle loss and dysfunction. *The Journal of Frailty & Aging, 5*(1), 33–41. https://doi.org/10.14283/jfa.2016.78

Bongers, C. C. W. G., Alsady, M., Nijenhuis, T., Tulp, A. D. M., Eijsvogels, T. M. H., Deen, P. M. T., & Hopman, M. T. E. (2018). Impact of acute versus prolonged exercise and dehydration on kidney function and injury. *Physiological Reports, 6*(11), e13734. https://doi.org/10.14814/phy2.13734

Brake, D. J., & Bates, G. P. (2003). Fluid losses and hydration status of industrial workers under thermal stress working extended shifts. *Occupational & Environmental Medicine, 60*(2), 90–96. http://dx.doi.org/10.1136/oem.60.2.90

Bush, D. M. (2008). The U.S. Mandatory Guidelines for Federal Workplace Drug Testing Programs: Current status and future considerations. *Forensic Science International, 174*(2-3), 111-119. https://doi.org/10.1016/j.forsciint.2007.03.008

Cary, P. L. (2011). The fundamentals of drug testing. In D. B. Marlowe & W. G. Meyer (Eds.), *The drug court judicial benchbook*, pp. 113–138. National Association of Drug Court Professionals. https://www.ndci.org/resource/publications/

Center for Substance Abuse Prevention. (2018). *Medical review officer guidance manual for federal workplace drug testing programs.* U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/sites/default/files/workplace/mro_guidance_manual_508_final_march_2018.pdf

Cone, E. J., Lange, R., & Darwin, W. D. (1998). In vivo adulteration: Excess fluid ingestion causes false-negative marijuana and cocaine urine test results. *Journal of Analytical Toxicology, 22*(6), 460. https://doi.org/10.1093/jat/22.6.460

Delanghe, J. R., & Speeckaert, M. M. (2011). Creatinine determination according to Jaffe—what does it stand for? *NDT Plus, 4*(2), 83–86. https://doi.org/10.1093/ndtplus/sfq211

Evans, W. J. (2010). Skeletal muscle loss: Cachexia, sarcopenia, and inactivity. *The American Journal of Clinical Nutrition, 91*(4), 1123S–1127S. https://doi.org/10.3945/ajcn.2010.28608A

Feigenbaum, J., Hunt, K., & Hoffman, R. (2017). Dietary creatine supplements raise serum creatinine mimicking acute kidney injury. Starting Strength. https://startingstrength.com/article/science-medicine/dietary-creatine-supplements-raise-serum-creatinine-mimicking-acute-kidney-injury

Gounden, V., Bhatt, H., & Jialal, I. (2018, updated 2020). Renal function tests. In *StatPearls*. StatPearls Publishing. https://europepmc.org/article/NBK/nbk507821

Heit, H. A., & Gourlay, D. L. (2004). Urine drug testing in pain medicine. *Journal of Pain and Symptom Management, 27*(3), 260–267. https://doi.org/10.1016/j.jpainsymman.2003.07.008

Jackson, K. A., O'Rourke, K. M., Kark, A., & Kennedy, G. A. (2010), Artefactual elevation of creatinine due to creatine water supplements. *Medical Journal of Australia, 193*(10), 616–617. https://doi.org/10.5694/j.1326-5377.2010.tb04075.x

James-Burdumy, S., Goesling, B., Deke, J., Einspruch, E., & Silverberg, M. (2010). *The effectiveness of mandatory-random student drug testing.* (NCEE 2010-4025). U.S. Department of Education. https://files.eric.ed.gov/fulltext/ED511054.pdf

Küme, T., Sağlam, B., Ergon, C., & Sisman, A. R. (2018). Evaluation and comparison of Abbott Jaffe and enzymatic creatinine methods: Could the old method meet the new requirements? *Journal of Clinical Laboratory Analysis, 32*. Article e22168. https://doi.org/10.1002/jcla.22168

Lafolie, P., Beck, O., Blennow, G., Boréus, L., Borg, S., Elwin, C. E., Karlsson, L., Odelius, G., & Hjemdahl, P. (1991) Importance of creatinine analyses of urine when screening for abused drugs. *Clinical Chemistry, 37*(11), 1927–1931. https://doi.org/10.1093/clinchem/37.11.1927

Lin, S.-Y., Lee, H.-H., Lee, J.-F., & Chen, B.-H. (2018). Urine specimen validity test for drug abuse testing in workplace and court settings. *Journal of Food and Drug Analysis, 26*(1), 380–384. https://doi.org/10.1016/j.jfda.2017.01.001

Love, S. A., Seegmiller, J. C., Kloss, J., & Apple, F. S. (2016). Urine creatinine concentrations in drug monitoring participants and hospitalized patients. *Journal of Analytical Toxicology, 40*(8), 659–662. https://doi.org/10.1093/jat/bkw092

Mandatory Guidelines for Federal Workplace Drug Testing Program. 82 FR 7920. (2017). https://www.hhs.gov/guidance/document/mandatory-guidelines-urine-testing

Marlowe, D. B. (2011). Applying incentives and sanctions. In D. B. Marlowe & W. G. Meyer (Eds.), *The drug court judicial benchbook,* pp. 141–159. National Association of Drug Court Professionals. https://www.ndci.org/resource/publications/

McLoughlin, D. M., Spargo, E., Wassif, W. S., Newham, D. J., Peters, T. J., Lantos, P. L., & Russell, G. F. M. (1998). Structural and functional changes in skeletal muscle in anorexia nervosa. *Acta Neuropathologica, 95*, 632–540. https://doi.org/10.1007/s004010050850

Meyer, W. G. (2011). *Constitutional and other legal issues in drug court.* National Drug Court Institute. https://www.ndci.org/law/

National Association of Drug Court Professionals. (2013). *Adult drug court best practice standards* (Vol. I). https://www.nadcp.org/standards/adult-drug-court-best-practice-standards/

National Association of Drug Court Professionals. (2015). *Adult drug court best practice standards* (Vol. II). https://www.nadcp.org/standards/adult-drug-court-best-practice-standards/

Pansarasa, O., Rossi, D., Berardinelli, A., & Cereda, C. (2014). Amyotrophic lateral sclerosis and skeletal muscle: An update. *Molecular Neurobiology, 49*, 984–990. https://doi.org/10.1007/s12035-013-8578-4

Patel, S. S., Molnar, M. Z., Tayek, J. A., Ix, J. H., Noori, N., Benner, D., Heymsfield, S., Kopple, J. D., Kovesdy, C. P., & Kalantar-Zadeh, K. (2013). Serum creatinine as a marker of muscle mass in chronic kidney disease: Results of a cross-sectional study and review of literature. *Journal of Cachexia, Sarcopenia and Muscle, 4(*1), 19–29. https://doi.org/10.1007/s13539-012-0079-1

Procedures for Transportation Workplace Drug and Alcohol Testing Programs, 49 C.F.R. § 40 (2021). https://www.ecfr.gov/cgi-bin/text-idx?SID=44edbc0e557a4cc5ff03365810ee5b1c&mc=true&node=pt49.1.40&rgn=div5#se49.1.40_193

Reichert, J., Weisner, L., & Otto, H. D. (2020). *A study of drug testing practices in probation.* Illinois Criminal Justice Information Authority, Center for Justice Research and Evaluation. https://icjia.illinois.gov/researchhub/files/Drug%20Testing%20Survey%20Results-200130T22230265.pdf

Riahi-Zanjani, B. (2014) False positive and false negative results in urine drug screening tests: Tampering methods and specimen integrity tests. *Pharmacology OnLine Archives, 1*(1), 102–108. https://pharmacologyonline.silae.it/files/archives/2014/vol1/PhOL_2014_1_A15_Riahi.pdf

Robinson, J. J., & Jones, J. W. (2000). *Drug testing in a drug court environment: Common issues to address.* (Drug Courts Resources Series). U.S. Department of Justice, Office of Justice Programs, Drug Courts Program Office. https://www.ojp.gov/ncjrs/virtual-library/abstracts/drug-testing-drug-court-environment-common-issues-address

Schedel, J. M., Tanaka, M., Tanaka, H., Kiyonaga, A., Shindo, M., Terrier, P., & Schutz, Y. (2000). Consequences of one-week creatine supplementation on creatine and creatinine levels in athletes' serum and urine. *Schweizerische Zeitschrift fur Sportmedizin und Sporttraumatologie, 48*(3), 111–116. https://ssms.ch/fileadmin/user_upload/Zeitschrift/48-2000-3/5-2000-3_Schedel.pdf

Shah, S. U., Anjum, S., & Littler, W. A. (2004). Use of diuretics in cardiovascular disease: (2) hypertension. *Postgraduate Medical Journal, 80*, 271–276. http://dx.doi.org/10.1136/pgmj.2003.010843

Shahbaz, H., & Gupta, M. (2020). Creatinine clearance. In: *StatPearls.* StatPearls Publishing. https://europepmc.org/article/MED/31334948

Sinkeler, S. J., Kwakernaak, A. J., Bakker, S. J. L., Shahinfar, S., Esmatjes, E., de Zeeuw, D., Navis, G., & Lambers Heerspink, H. J. (2013). Creatinine excretion rate and mortality in type 2 diabetes and nephropathy. *Diabetes Care, 36(*6), 1489–1494. https://doi.org/10.2337/dc12-1545

U.S. Department of Defense. (2020). *Technical procedures for the Military Personnel Drug Abuse Testing Program.* DoD Instruction 1010.16. https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/101016p.pdf?ver=yNtAyTrYnY-8wMCQDa9vpw%3D%3D

Wang, Z. M., Gallagher, D., Nelson, M. E., Matthews, D. E., & Heymsfield, S. B. (1996). Total-body skeletal muscle mass: Evaluation of 24-h urinary creatinine excretion by computerized axial tomography. *The American Journal of Clinical Nutrition, 63*(6), 863–869. https://doi.org/10.1093/ajcn/63.6.863

Wile, D. (2012). Diuretics: A review. *Annals of Clinical Biochemistry, 49*(5), 419–431. https://doi.org/10.1258%2Facb.2011.011281

Williamson. L., & New, D. (2014). How the use of creatine supplements can elevate serum creatinine in the absence of underlying kidney pathology. *BMJ Case Reports*, 2014, bcr2014204754. http://dx.doi.org/10.1136/bcr-2014-204754

World Anti-Doping Agency. (2021). *World Anti-Doping Code: International Standard for Testing and Investigations.* https://www.wada-ama.org/sites/default/files/resources/files/international_standard_isti_-_2021.pdf

This project was supported by Grant No. 2019-DC-BX-K012, awarded by the Bureau of Justice Assistance. The Bureau of Justice Assistance is a component of the Department of Justice's Office of Justice Programs, which also includes the Bureau of Justice Statistics, the National Institute of Justice, the Office of Juvenile Justice and Delinquency Prevention, the Office for Victims of Crime, and the SMART Office. Points of view or opinions in this document are those of the author and do not necessarily represent the official position or policies of the U.S. Department of Justice.