



### **K23 Is Your Urine Really Dilute? An Analysis of Normal Urine Creatinine Measured by HPLC-UV Below the Cutoff Limit of 20 Mg/Dl**

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After attending this presentation, attendees will understand a simple method for the detection of creatinine in urine samples, how creatinine concentrations is used in clinical medicine to determine adulteration of samples, factors effecting creatinine concentration in urine, and hear a proposal to change the cutoff limit of adulterated urine samples.

This presentation will impact the forensic science community by addressing concerns of the Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for urine adulteration by reviewing the creatinine concentration of a population of unknown advanced toxicology urine samples.

In clinical and forensic toxicology laboratories there is a need to establish criteria for identifying a random urine sample submitted for drug testing as being adulterated by using creatinine analysis. According to SAMHSA, the cutoff value mandated for workplace drug testing is 20mg/dL; however, there are many factors that independently influence the concentration of creatinine in a urine sample. These factors include but are not limited to: gender, muscle mass, diet, fluid consumption, and several clinical conditions such as polyuria. With so many factors influencing the concentration of creatinine in the urine it is possible that many samples may be determined to be dilute or substituted when, in fact, a value of less than 20mg/dL is normal for that donor. This presentation will discuss the use of creatinine concentration data from the aforementioned population of samples to address the issue of the 20mg/dL SAMHSA cutoff being too high as well as predispose the samples to falsely high level of positive diluted urine samples.

A simple method for the detection of creatinine in urine samples was used in this study to determine the creatinine concentration in 4,600 advanced toxicology urine samples. This method uses cation-pairing high pressure liquid chromatography with a ultra-violet detector (HPLC-UV). This HPLC-UV method allows for simple sample preparation and the automation of sample analysis. Using this method also allows for a large linear range of quantitation in the physiologically relevant range of 0.1-500 mg/dL and a limit of detection as low as 0.05mg/dL. For this study, 4,595 samples were tested for creatinine using the method described above. Out of these samples, 160 (3.48%) tested for a creatinine concentration of less than 20mg/dL. From these samples determined to be dilute or substituted, 140 (87.5%) samples were confirmed positive for one or more drugs. Altogether, 70% of the dilute samples were from women and 30% were from men. The average value for the dilute samples was 12.3 and the median value was 14. Twenty-one of these low creatinine samples were tested for pH, specific gravity and creatinine using urine drug adulteration test strips. Out of these 21 samples, 20 of them were suspected of adulteration based off the results of creatinine or specific gravity.

In conclusion, this presentation addresses the concerns of the SAMHSA guidelines for urine adulteration by reviewing the creatinine concentration of a population of unknown advanced toxicology urine samples and noting potential issues with the current cutoff limit. As many factors can influence the creatinine concentration this newly proposed value will help reflect this and help to reduce the number of samples reported to be falsely diluted.

**Creatinine, Adulteration, Toxicology**