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DILUTION CONCERNS IN RECOVERY MONITORING

Urine Specimen Validity Testing

Are participants attempting to mask or hide drug or alcohol use by intentional acts of specimen dilution, substitution or adulteration?

Recovery Management programs are justifiably concerned about the ability to accurately interpret the results of urine drug tests that are found to be either "dilute" or of lower than average concentration. Are participants attempting to mask drug/alcohol use and to compromise the integrity of the monitoring program by intentional acts of specimen dilution? Or is this dilution caused by normal physiological processes that vary from participant to participant?

To begin to answer these questions, it is necessary to understand just what it means when a result is reported as dilute. The concentration of urine specimens is measured using two values: creatinine and specific gravity.

- Creatinine is a protein found in all human urine caused by the normal metabolism of muscle tissue.
- Specific gravity is a measure of the density of the specimen as it compares to water.

The average creatinine concentration of laboratory specimens tested is 130 mg/dL (range 100 mg/dL-150 mg/dL). The lowest acceptable creatinine concentration is 20 mg/dL. Specific gravity is not measured in specimens until the creatinine value drops below this number, and the lowest acceptable specific gravity value is 1.0030. When both the creatinine and the specific gravity levels are below acceptable range, the specimen is labeled as 'dilute'. These values have been chosen after much research relative to the accuracy of the testing process in specimens of varying concentrations. Please notice that there is a considerable range of possible concentration values that are less than average but still higher than dilute. As specimen concentration varies in any way, so does the concentration of drug and alcohol in that specimen. The lower the concentration of the specimen, the lower the concentration of drug and alcohol that is in that specimen, and the lower the likelihood of the laboratory finding that drug or alcohol. Studies have been conducted in specimens of lower, but not dilute, level creatinines where those creatinines were mathematically corrected to a value of 100 mg/dL. These studies have shown an increase in the percentage of positive results by as much as 150% for some drugs when the specimen concentration is corrected to more closely resemble the average specimen concentration.

It is fair to say that testing of any specimen with a creatinine concentration of less than the average concentration of 130 mg/dL has a lower chance of finding drug or alcohol in that specimen than if the specimen had been within average range. Strategies to monitor participants should be developed that take this into account. These strategies include the appropriate establishment of cutoff levels, the direct observation of specimen collection, the appropriate random mixing of alternative specimens into the testing program, and the follow-up evaluation of low creatinine and dilute specimens (please see FSSolutions Dilute Urine Specimen Follow-up Protocol Report). Participants in Monitoring Programs are intelligent and knowledgeable about the drug testing process and are able to devise means to compromise that process. However, some people do physiologically produce specimens of lower concentration than others. It is not correct to assume that all low concentration specimens are the results of attempts to compromise the testing program. Dietary practices, including intake of water or other fluids as part of a healthy lifestyle, can produce dilute urine specimens. It is difficult to distinguish "intentional water-loading" several hours prior to a specimen collection from a regular regime of significant fluid intake, but one important thing to look for is any significant change in creatinine and specific gravity from one specimen to another. Ongoing regular hydration may be expected to produce ongoing regular creatinine and specific gravity values however these values do fluctuate during the day to some degree. Significant changes between specimens are not always signs of "intentional water-loading", but they still warrant evaluation because the testing is less accurate in specimens of lower concentrations. Programs need to take that into account.

Here are general guidelines that FSSolutions recommends for programs in reference to creatinine and specific gravity values:

1) Specimens reported as negative with creatinine 5-20 mg/mL AND specific gravity >1.0010 and <1.0030—should be considered negative dilute. If the program wants to require a re-collection of the specimen, it should be done as soon as practical and with no prior notice to the participant. FSSolutions also recommends consideration be given to including the FSSolutions dilute specimen follow-up protocol into the testing program.
2) Specimens reported as negative with creatinine between 2 and ≤5 mg/dL AND specific gravity >1.0010 and <1.0030, may be interpreted by an MRO. If the collection of this specimen was not observed, an immediate re-collection under direct observation should be performed. The program might also consider requiring an alternative specimen test. Data shows that it is highly unlikely that dietary practices, fluid intake or physiological conditions will produce urine specimens with creatinine in the 2-≤5 mg/dL range.
3) Specimens with creatinine <2 mg/dL AND specific gravity ≤1.0010 or ≥1.0200 are considered substituted – these values are not physiologically possible. These specimen results should be considered a Refusal to Test and a program violation. It is recommended that the participant is offered an MRO interview/ review if they disagree with the laboratory findings.

4) Specimens with creatinine <2 mg/dL AND specific gravity >1.0010 and <1.0200 or creatinine ≥2 AND specific gravity ≤ 1.0010 are considered to be creatinine/specific gravity mismatches and are reported as invalid. These specimens are highly suspect, and some manipulation by the participant is considered likely but is not able to be forensically proven, MRO review is not recommended because it takes time and there is no medical explanation for this result. If the collection was not observed, an immediate recollection under direct observation should be performed and alternative specimen testing should be considered.

Based on all the information FSSolutions has available, we strongly advise RMS programs against taking disciplinary actions based SOLEY ON CREATININE LEVELS. The creatinine measurement should be interpreted in conjunction with the specific gravity and all of the possible reasons a specimen may have a lower than average concentration before action is taken.

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