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SPECIMEN VALIDITY TESTING

(ADULTERATED AND SUBSTITUTED URINE SPECIMENS)

In late 2004, the Departments of Health and Human Services and Transportation issued final rules revising the procedures for how drug testing laboratories must conduct specimen validity tests on urine specimens for Federal drug testing programs. Specimen validity testing is the analysis of urine specimens to determine if they have been adulterated with an agent or substance or have been substituted with a non-urine fluid. The HHS rule sets the analytic standards for determining the validity of specimens. These procedures apply to Federally-mandated drug testing in DHHS certified laboratories. The drug testing laboratories must:

1. Determine the creatinine concentration of every specimen
2. Determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL
3. Determine the pH on every specimen
4. Perform one or more validity tests for oxidizing adulterants on every specimen; and
5. Perform additional validity tests when necessary because of specimen quality, interference, or other atypical results.

The criteria for reporting specimen validity testing results to the MRO are as follows:

- Adulterated Specimen—The pH is less than 3 or greater than or equal to 11; the nitrite concentration is greater than or equal to 500 mcg/mL; chromium, halogen, glutaraldehyde, pyridine or a surfactant are detected at or above DHHS established cut-offs.
- Substituted specimen—Creatinine less than 2 mg/dL and Specific Gravity less than or equal to 1.0010 or greater than or equal to 1.0200
- Dilute Specimen—Creatinine greater than or equal to 2 mg/dL, but less than 20 mg/dL and Specific Gravity is greater than 1.0010, but less than 1.0030
- Invalid Specimen—Inconsistent creatinine and Specific Gravity results are obtained; pH 3-4.5 or 9-11; nitrite 200-499; possible presence of other adulterants or interferants;

The laboratory must report to the MRO the numerical values for specimens it reports as adulterated or substituted. The MRO must review and interpret every adulterated, substituted and invalid result, including interviewing the specimen donor. If no medical explanation is documented for the laboratory findings, the MRO will verify the results as follows:

Adulterated—Refusal to Test, Specimen Adulterated
Substituted—Refusal to Test—Specimen Substituted
Invalid—Test Cancelled—Recollection of Specimen under direct observation required.

For dilute specimens, the MRO will report the result as Negative-dilute or Positive-dilute. For dilute specimens where the creatinine is 2-5 mg/dL, the DOT requires that the MRO order an immediate collection of another specimen under direct observation. For all other negative-dilute results the employer may conduct another specimen collection, however, direct observation procedures are NOT authorized. The employer must accept a second negative-dilute result as final and cannot require a third collection. A positive-dilute result is a positive test and no recollection of a specimen is authorized.