December 7, 1993

MEMORANDUM TO: Department of Health and Human Services (DHHS)
Certified Drug Testing Laboratories
Medical Review Officers (MROs)

FROM: Donna R. Smith, Ph.D.
Acting Director, Drug Enforcement and Program Compliance

SUBJECT: Reporting of Drug Test Results: Abnormal Test Results and Analysis for Presence of Adulterants

Recent publicity about commercial urine specimen adulterants such as UrinAid and Mary Jane SuperClean 13 has led to a variety of responses from the drug testing laboratories. Several laboratories have issued test results that report adulterated specimens, specifically identifying an adulterant product or a specific adulterant chemical or compound such as glutaraldehyde. Other laboratories have issued testing results that report "suspected adulteration" or "unsuitable for testing". Still other laboratories have issued reports concerning abnormal immunoassay results or atypical screening results. The wide variety of laboratory reports providing information about adulteration has created confusion among Medical Review Officers (MROs) and employers interpreting Department of Transportation (DOT) mandated drug tests.

The DOT procedural rule does not specifically address adulteration of specimens in the context of laboratory reports. The rule clearly authorizes, but does not require, laboratory analysis for the "presence of adulterants" (S 40.21(d)). In addition, the rule addresses attempts to substitute or adulterate a specimen as determined at the collection site (S 40.25(e) (2)). There is, however, no guidance for MROs or employers concerning laboratory reports of adulteration findings, except for specific gravity and creatinine values.

In order to facilitate uniform interpretation of laboratory reports of abnormal test results and analysis for the presence of adulterants, the following language will be used on laboratory reports or in the laboratory remarks section of the drug testing custody and control form for DOT mandated drug test specimens:

1) **Specific gravity < 1.003 and creatinine <0.2g/L.**
May apply in conjunction with a negative or positive result or when no immunoassay result is reported. Actual values of specific gravity and creatinine should not be reported.

2) **Specimen not suitable.**
This applies when a valid immunoassay result is not achieved (abnormal high or low readings) or pH is out of normal range, but the presence of adulterants is not substantiated.

3) **Specimen adulterated: Presence of _____ detected.**
This applies when a specific adulterant(s) is identified by the laboratory through procedures that can be forensically validated.

As with all reported laboratory results, the laboratory should be prepared to provide DOT regulated clients with expert witness testimony to defend its finding in arbitration, litigation or other actions pursuant to the employer's actions based on the drug test report.

The following guidance for MROs reviewing and interpreting laboratory reports detailed in the above paragraphs is provided:

1) Specific gravity <1.003 and creatinine <0.2g/L.
MROs shall report the laboratory findings (including negative result or cancelled test) to the employer. The employer may require the next specimen submitted by the donor to be collected under direct observation. A dilute specimen (SG. <1.003 and creatinine <0.2 g/L) is not reasonable suspicion/cause to require the donor to submit to another specimen collection.

2) Specimen not suitable.
In specimen not suitable reports, the MRO should first discuss the laboratory findings with the laboratory forensic toxicologist to obtain more specific information about the specimen. The MRO should then contact the donor and inform him/her that the specimen was not suitable. After explaining the limits of disclosure in accordance with S40.33 (h) (2) the MRO should inquire as to medications (e.g. non-steroidal anti-inflamatory agents) or other medical explanations for the specimen's unsuitability. If no acceptable explanation for the unsuitability is provided, the MRO should inform the donor that another specimen will be collected under direct observation. The MRO should report the result to the employer and inform the employer that another collection under direct observation is required. If

there is an acceptable explanation for the unsuitability the MRO should report the specimen as cancelled.

3) Specimen adulterated.
The MRO should report the result as specimen adulterated to the employer and inform the employer that the laboratory finding constitutes a refusal to test, which under the DOT testing program, requires removal from safety-sensitive function.