Answering the Challenge

In 1987 the American Association for Clinical Chemistry initiated a program to inform the public and the media about the accuracy of clinical laboratory testing. Part of the impetus for this effort was to counter reports of inaccurate testing that permeated the media and even prompted Congress to convene hearings and finally pass the first major rewrite of clinical laboratory legislation in 20 years.

With generous support from E. I. du Pont de Nemours & Company, AACC launched a public issues campaign to increase public awareness about the clinical chemistry profession and to maintain public confidence in the accuracy of testing.

Focusing first on drug testing, we conducted a study of 47 laboratories and their accuracy in testing for five drug categories: opiates, cannabinoids, amphetamines, cocaine, and phencyclidine (PCP). Their overall accuracy rate was an impressive 99.3%. These results clearly demonstrated that laboratories that are regularly monitored by external proficiency testing, that participate in quality-control programs, and whose personnel participate in continuing-education programs can produce very accurate results. A full report on the 1987 study appeared in the September 1987 issue of Clinical Chemistry (33:1683–6).

Some criticized our original study because it was not a blind test of the laboratories. Although that was not the intention of the original study, we did agree that a blind study would add important information to the understanding of laboratory accuracy. Having demonstrated just how accurate drug testing could be, we wanted to demonstrate also that it was indeed being performed accurately under everyday conditions.

Late last year we went back to the 47 laboratories to test their accuracy under blind conditions. In this blind study we used drug levels close to those mandated by the National Institute on Drug Abuse (NIDA) as our low-level thresholds. Except for cannabinoids, these concentrations were lower than those used in the open study.

Once again, laboratories demonstrated their ability to perform very accurately. The 31 laboratories participating achieved 97% accurate results. (Only 31 of the original 47 laboratories still qualified and were able to process the necessary paperwork to participate in the blind study.) The data are significant because these are the only current evaluations of the accuracy of drug testing laboratories. Details of the study appear below.

AACC will continue its efforts to assess and improve the accuracy of clinical laboratory testing and to strive to educate the public and the press about how well testing can be and is being done. This is an essential task. It also gives clinical chemists a chance to say with pride that we are a profession willing to examine itself and to constantly strive for improvement.

Carl A. Burtis
President
American Association for Clinical Chemistry

CLIN. CHEM. 35/5, 891–894 (1989)

Status of Drugs-of-Abuse Testing in Urine under Blind Conditions: an AACC Study
Christopher S. Frings,1 Daniele J. Battaglia,2 and Robert M. White3

We report results of a blind study designed to determine the accuracy of drugs-of-abuse testing in urine as done in 31 laboratories across the United States. The drugs studied were amphetamines, cannabinoids, cocaine, opiates, and phencyclidine. These laboratories confirmed all positive drug results with a different analytical method. Ten urine samples were sent to each laboratory, which resulted in 1486 trials. There were no false-positive results. The overall accuracy rate was 97%. Our study demonstrates that urine drug testing can be accurate when performed by qualified staff, using up-to-date screening and confirmation methods, appropriate quality-assurance measures, and a chain of custody.

In 1987 the American Association for Clinical Chemistry (AACC) conducted an open study to determine the ability of laboratories to perform accurate testing for abused drugs in urine. This study showed an overall accuracy rate of 99.2% for the five drugs or drug classes tested by 47 laboratories across the United States (1). The study was criticized by some because it was not a blind study and because some of the drugs were tested at concentrations higher than might be considered appropriate for such a study.

In November 1988, we repeated the study under blind conditions, using much lower drug concentrations for all drug classes (except cannabinoids) than those used in the open study. The drugs or drug classes studied were those specified by the National Institute on Drug Abuse (NIDA) in their 1988 mandatory guidelines for federal workplace testing programs (2).

We believed that a current study was necessary to assess the accuracy of laboratories, under blind conditions, measuring drug concentrations similar to those used as cutoffs by the NIDA.

1 Address correspondence to this author at: Chris Frings & Associates, 633 Winwood Drive, Birmingham, AL 35226.
2 American Association for Clinical Chemistry, 2029 K Street, N.W., Washington, DC 20006.
3 Diagnostic Services, Inc., 549 Tamiami Trail N., Naples, FL 33940.