



OFFICE OF THE DEPARTMENT OF DEFENSE COORDINATOR  
FOR DRUG ENFORCEMENT POLICY AND SUPPORT

1510 DEFENSE PENTAGON  
WASHINGTON DC 20301-1510



19 JUN 1995

MEMORANDUM FOR UNDER SECRETARY OF THE NAVY (ATTN: CAPT WEISBERG)  
ASSISTANT SECRETARY OF THE ARMY (IL&E)  
DEPUTY ASSISTANT SECRETARY OF THE AIR FORCE (RA&CDP)

SUBJECT: DoD Laboratory Certification for Reporting Drug  
Screening by Immunochemistry Analysis on Olympus AU800  
Analyzers

Instrumentation has been installed in the military drug screening laboratories which will improve operational efficiency and cost effectiveness of the urinalysis drug testing program by a transition from radioimmunoassay (RIA) to non-isotopic immunochemistry screening procedures.

Department of Defense (DoD) Directives 1010.1 and 1010.16, require the DoD Coordinator for Drug Enforcement Policy and Support to maintain a certification program for the drug testing laboratories and to ensure the quality and accuracy in the drug analyses performed by each drug testing laboratory. In accordance with the above Directives, the drug assays currently certified by RIA must be certified for non-isotopic immunochemistry testing on the Olympus AU800 prior to any reporting of test results.

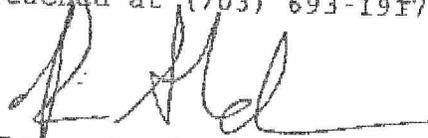
The drug screening laboratories must validate the analytical screening methods for each drug to be tested on the Olympus AU800. Validation will require the submission of data printouts from the Olympus AU800 using the attached validation protocol. The data printouts shall accompany a request for blind proficiency certification specimens forwarded to:

Armed Forces Institute of Pathology  
Division of Forensic Toxicology  
Washington, D.C. 20306  
ATTN: LTC Kuhlman, USAF, BSC

Upon completion of blind proficiency immunochemistry screening analyses, the results are returned to the AFIP. Based upon the DoD calibration cutoff level, at least 85 percent of the immunoassay results for blind positive specimens of a drug must be correct. Successful submission of analytical validation data and blind proficiency testing will result in certification of the Laboratory by the Department of Defense Coordinator, Drug Enforcement Policy and Support. Upon receipt of DoD certification, the Drug Testing Laboratory may begin data reporting using immunochemistry procedures on the Olympus AU800.



My point of contact for this matter is Captain John F. Jemioneck, MSC, USN who may be reached at (703) 693-1917.



Brian E. Sheridan  
Deputy Assistant Secretary for  
Drug Enforcement Policy and Support

Attachment:  
Validation data requirements

cf:

FTDTL Fort Meade	ATTN: COL Armitage
FTDTL Tripler AMC	ATTN: COL Jacobs
NDSL S.D.	ATTN: CAPT Christopher
NDSL JAX	ATTN: CDR Fast
NDSL Glakes	ATTN: CDR Thomas
AL/AOT Brooks AFB	ATTN: LTC Mehm
AFIP, WRAMC	ATTN: COL Smith
OTSG, ARMY	ATTN: COL O'Brien
BUMED, MED-244	ATTN: CAPT Hughes
USADAO	ATTN: Mr. Cunningham
NEHC, Norfolk	ATTN: CDR Trocha

IMMUNOCHEMISTRY VALIDATION DATA REQUIREMENTS:  
FOR EACH DRUG ANALYTE AND FOR EACH OLYMPUS AU800  
IMMUNOCHEMISTRY ANALYZER INTENDED TO BE USED  
IN THE REPORTING OF DRUG TESTING DATA

1. Four batch runs containing:

10 sequential specimens each of negative control samples, 20% of screening calibration drug cutoff, 50% screening calibration drug cutoff, 75% calibration drug cutoff, calibration drug cutoff, 125% calibration drug cutoff, 200% calibration drug cutoff.

To be acceptable the following conditions must be met:

(1.a.) Within individual batch runs, the coefficient of variation of the mean concentration values of samples for the cutoff calibrator, negative control, 75% calibrator cutoff, and 125% calibrator cutoff, and 200% calibrator cutoff must be less than 7.5%.

(1.b.) The batch to batch coefficient of variation of the mean concentration values of samples for the cutoff calibrator, negative control, 75% calibrator cutoff, and 125% calibrator cutoff, and 200% calibrator cutoff must be less than 10%.

(1.c.) The mean value of the negative control must be less than the mean value of the 20% calibration cutoff control for each batch.

(1.d.) 90% of the 75% calibration cutoff control samples within each batch must screen negative.

(1.e.) 90% of the 125% calibration cutoff control samples within each batch must be identified as positive.

2. Carryover Check:

a) four batch run containing specimens in the following sequence:

- two negative urine samples:
- four 200% of calibrator cutoff samples
- four 75% of calibrator cutoff samples

The carryover check is to monitor the degree of carryover, if any, under the conditions of a high positive directly ahead of a below calibration cutoff specimen.

Note: Please identify by property number or serial number the instrument for which data is being submitted.