

Standards Governing the Drug Abuse Urine Testing Laboratories Established by Government Agencies

(Promulgated by the Department of Health, Executive Yuan, 24 December 2003)

Chapter 1 General Principles

Article 1

These Standards are enacted pursuant to Paragraph Two, Article 33-1 of Statute for Narcotics Hazard Control (hereinafter referred to as "the Statute").

Article 2

The testing laboratories for drug abuse urine test (hereinafter "testing laboratories" for short) established by the government agencies prescribed in Subparagraphs 2 and 3, Paragraph One, Article 33 of the Statute (hereinafter "government agencies" for short) shall meet the provisions of these Standards and the Regulations Governing Drug Abuse Urine Testing Operations.

Article 3

Government agencies shall conduct periodical examination to supervise the testing laboratories subordinate to them meet these Regulations.

Chapter 2 Staffing

Article 4

The testing laboratories shall designate responsible person to take charge of the following drug abuse urine testing activities:

1. To handle on-job training, auditing of workload and technical confirmation of internal personnel;
2. To ensure there is a complete standard operating procedure for urine test, audit the revision of the procedure and record the date of revision;
3. To establish and implement quality assurance plan;
4. To supervise the implementation of quality management and quality control urine test;
5. To ensure the accuracy of the testing system and the test of each batch of test samples, and take relevant records;
6. To subscribe or sign the test report; and
7. To take necessary correction and prevention measures and take relevant records if

any incompliance with the quality management system occurs.

Article 5

The testing laboratories shall set certifying scientist to confirm all the data and quality control results.

Article 6

The personnel of a testing laboratory shall have accepted enough training and master the technologies required for accomplishing the work.

Article 7

The responsible person, certifying scientist, testers and other personnel of a testing laboratory all shall have a positional representative, and records in written form shall be taken about the representation.

Article 8

The testing laboratories shall periodically carry out on-job training plans.

Article 9

The testing laboratories shall work out and actually implement performance test plans.

Article 10

The testing laboratories shall set up personnel data file, and the contents of the files shall include at least educational background, working experiences, training records, performance evaluation records, and description of the current job.

Chapter 3 Facilities and Maintenance

Article 11

The facilities of a testing laboratory shall meet the relevant legal provisions. Electrical equipment shall be earthed appropriately, and fume hood, fire extinguisher, emergency shower, eye wash device, and other facilities ensuring the safety of the testing personnel shall be provided, and their functions shall be periodically evaluated.

Article 12

The water, electricity, emergency light, temperature, humidity, spatial layout, equipment, safety and other environmental conditions of the testing laboratories shall meet the testing requirements, and the environmental factors that will influence the test results shall be monitored and relevant records shall be taken.

Article 13

The testing laboratories shall have separated and controlled specimen storage area, testing area and records storage area.

Article 14

The testing laboratories shall set forth the standard operating procedures for operating, maintenance and calibration of the instruments, as well as relevant implementation records.

Article 15

The testing laboratories shall set forth the calibration procedures for balances, thermometers, pipettes, measuring flask, and other measuring equipments, so as to explicitly define the calibration methods, calibration frequency, range of qualification, and restrictions on use and correction measures of unqualified equipments.

Chapter 4 File and Archive Management

Article 16

Upon receipt of specimen, the laboratory shall conduct tests in accordance with the items designated by the test consignor as soon as possible, and produce a test report. The results of initial test or confirmatory test shall first be confirmed by the certifying scientist, and the test report shall be subscribed or signed by the responsible person. A test report shall at least include the serial number of urine specimen, the cutoff values of drugs and the drugs detected or not detected, and shall remark the test method employed, the limit of quantification, and other data.

Article 17

The testing laboratories shall work out file control procedures to normalize the formulation, amendment, periodical examination, distribution, control, archiving and storage of the related files. The files and records relating to test shall be stored for at least two years or disposed in accordance with the Archives Act, and the storage period may be prolonged according to the request of the test consignor.

Article 18

The testing laboratories shall establish relevant archives, at least including personnel data, log sheet for specimen management, quality manual, quality management and quality assurance records, all original test data, test report, inspection and performance test reports, and data printed by computer, and store them appropriately.

Article 19

Every month the testing laboratories shall, before the tenth day of the next month, summarize the results of urine tests in specified format and submit to the National Bureau of Controlled Drugs, Department of Health, Executive Yuan for reference.

Chapter 5 Supplementary Provisions

Article 20

The government agencies designated by the Department of Health, Executive Yuan to conduct drug abuse urine test before these Standards take effect shall meet the provisions of these Standards within three years following the day when these Standards come into force.

Article 21

These Standards shall come into force on 9 January 2004.