

Regulations Governing Drug Abuse Urine Testing Operations

Promulgated by the Department of Health, Executive Yuan, on December 24, 2003.

Amendment to Article 15,18,and 36,Promulgated by the Department of Health, Executive Yuan, on September 10, 2004.

Amendment to Article 18 and 36,Promulgated by the Department of Health, Executive Yuan, on October 14, 2005.

Amendment to Article 18,Promulgated by the Department of Health, Executive Yuan, on January 8, 2008.

Chapter 1 General Principles

Article 1

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

Article 2

These Regulations are applicable to all kinds of drug abuse urine testing institutions (hereinafter "testing institutions" for short) set forth in Paragraph One, Article 33-1 of the Statute.

Article 3

The terms used in these Regulations are defined as follows:

1. Drug abuse: means the use of the narcotics referred to in the Statute for any purpose other than medical treatment and without prescription or instruction of physicians.
2. Urine specimen: means the urine used for testing. Urine specimen (A) is used for routine test, and specimen (B) for retest.
3. Test consignor: means the institution that consigns the urine test.
4. Custody and control form: means the log sheet recording the operations conducted during the process from the collection of the urine specimen until test in the testing institution.
5. Batch: a batch means a group of test specimens being pretreated and tested at the same time.
6. Initial test: means the test of using immunoassay or gas chromatography method to eliminate negative specimens.
7. Confirmatory test: means the test conducted to confirm the suspected specific drug or drug metabolite in the urine specimen.

8. Retest: means the confirmatory test conducted over specimen (B) to confirm again the existence of the drug or drug metabolite in the urine specimen.
9. Quality control urine: means the urine specimen used to confirm whether the urine test is conducted accurately, including quality control specimen prepared by tester and blind quality control specimen prepared by quality personnel.
10. Standard: means the substance or solution used to prepare quality control urine.
11. Calibrator: means the urine specimen with known concentration of drug used for quantitative comparison.
12. Blind performance specimen: means the specimen prepared by the test consignor to perform blind performance test.
13. Cutoff value: means the concentration of drug or drug metabolite used to judge whether the specimen is negative or positive.
14. Limit of quantification: means the lowest concentration enabling the instrument to confirm and quantify the drug tested.

Chapter 2 Specimen Collection and Management

Article 4

The testing institutions shall prescribe the chain of custody procedures for specimen collection and management, from the collection of urine specimen, test, reply of test report, to the storage of urine specimen and disposal of residual specimen, and record the handler, date and purpose of each operation.

Article 5

Matters records in the custody and control form shall include, at least, the serial number of urine specimen, the name and ID No. of donor, the name and address of test consignor, the name and address of urine collecting institution, the name of collector, the time of urine collection, important and special evidences, as well as the time, purpose and operator of the collection, disposal, storage and withdrawal of specimen. Both the copy for testing institution of the custody and control form and test specimen sent to testing institution shall not include the name and ID No. of donor, or any other personal data sufficient for identification.

Article 6

Upon receipt of a urine specimen, the testing institution shall first confirm whether the specimen conforms to the description in the custody and control form. If any abnormality is found, the testing institution shall immediately notify the consignor and

record it in the custody and control form.

Article 7

The testing institution shall take the following safety measures for the disposal of specimens and in the storage place of test data:

1. Any unauthorized person may not dispose the urine specimen or participate in the disposal conducted by the testing institution;
2. Any person may not enter the storage place of urine or data without being accompanied by authorized personnel; and
3. When an authorized person needs to dispose the urine specimen, participate in the disposal conducted by the testing institution or enter the storage place of data, the name, date and time shall be recorded.

Article 8

Upon receipt of a urine specimen, the testing institution shall store the specimen in a refrigerator below 6°C before proceeding drug test.

Article 9

The testing institution shall dispose the residual specimens in accordance with the relevant provisions or the agreement reached with the test consignor. Except for juridical cases, a negative urine specimen shall be destroyed fourteen days after the test report is delivered, and a positive urine specimen shall be stored in a freezer below -20°C.

Article 10

The testing institution shall store the urine specimen (B) in freezer below -20°C, and all access operations shall be recorded in the custody and control form.

Chapter 3 Test Operations and Cutoff Values

Article 11

Urine test is classified into initial test and confirmatory test.

Article 12

The testing institution shall access the urine specimens into several lots and test them lot by lot, and the quantity of each lot shall be determined in respect of the testing method. Every lot of specimens for initial or confirmatory test shall include proper

quantity of quality control urine and blind quality control urine, and shall be tested as common urine specimens.

Article 13

The sources of the standard and quality control urine used by the testing institution shall be recorded and the content, date of production and validity period shall be marked.

Article 14

The testing institution shall prepare a quality manual to prescribe all the standard operation procedures for laboratory operations, and the contents shall at least include the following items:

1. Chain of custody procedures;
2. Storage and withdrawal for use of specimens;
3. Analytical methods and procedures:
 - (1) Principle of each drug test
 - (2) Methods to prepare reagent, standard and quality control urine.
 - (3) Testing methods and calibration procedures.
 - (4) Principle for judgment of testing result.
 - (5) Sensitivity, linear range, limit of detection, and limit of quantification, of the testing method.
4. Quality management and quality assurance.
5. Measures for correction and prevention of system abnormality.
6. List of testing equipments and maintenance plan.
7. Employee training.
8. Procedures of producing test report and format of report.
9. Computer, software and laboratory information management system.

Article 15

Initial test shall use immunoassay method. Where the concentration of drug or drug metabolite in the urine specimen are not lower than the following cutoff values, the specimen shall be judged as positive:

1. Amphetamines: 500 ng/mL.
2. Opiate metabolites: 300 ng/mL.
3. Marijuana metabolites: 50 ng/mL.
4. Cocaine metabolites: 30 ng/mL.

5. Ketamine metabolites: 100 ng/mL.

The initial test results of abused drugs or their metabolites other than listed in the preceding paragraph shall be determined according to the cutoff values in respect of the immunoassay method. In absence of suitable immunoassay method, other suitable analytical method may be adopted to conduct test with the support of proper detector, and the cutoff values may be determined appropriately according to the limit of quantification.

Article 16

Where the initial test results are lower than the cutoff values set forth in the preceding Article, the urine specimen shall be judged as negative; and the residual specimen shall be disposed in accordance with the provision of Article 9.

Article 17

The testing institution may use two or more initial test methods to test a same kind of abused drug, and shall observe the provisions set forth in these Regulations.

Article 18

Where the initial test results are not lower than the cutoff values or any doubt arises about the test result of the urine specimen, gas chromatography/mass spectrometry method shall be used to perform confirmatory test. In absence of suitable gas chromatography/mass spectrometry method, other suitable liquid chromatography/mass spectrometry method may be adopted to perform confirmatory test. If the test results are not lower than the following cutoff values, the specimen shall be judged as positive:

1. Amphetamines:

- (1) Amphetamine: 500 ng/mL.
- (2) Methamphetamine: Methamphetamine 500 ng/mL, and its metabolite amphetamine not less than 100 ng/mL.
- (3) 3,4-Methylenedioxymethamphetamine (MDMA): 500 ng/mL. If both MDMA and MDA are found and the concentration of each is lower than 500ng/mL, but the total concentration is not lower than 500 ng/mL, the specimen shall also be judged as MDMA positive.
- (4) 3,4-Methylenedioxyamphetamine (MDA): 500 ng/mL.
- (5) 3,4-Methylenedioxyethylamphetamine (MDEA): 500 ng/mL.

2. Opiates:

- (1) Morphine: 300 ng/mL.
- (2) Codeine: 300 ng/mL.
3. Marijuana metabolite (Delta-9-tetrahydrocannabinol-9-carboxylic acid): 15 ng/mL.
4. Cocaine metabolite (Benzoylecgonine): 150 ng/mL.
5. Ketamine metabolites:
 - (1) Ketamine: 100 ng/mL. If both Ketamine and Norketamine are found and the concentration of each is lower than 100 ng/mL, but the total concentration is not lower than 100 ng/mL, the specimen shall also be judged as Ketamine positive.
 - (2) Norketamine: 100 ng/mL.

For the abused drugs other than listed in the preceding paragraph or other metabolites, proper cutoff values may be set forth according to the limit of quantification in respect of the gas chromatography/mass spectrometry method. In absence of suitable gas chromatography/mass spectrometry method, other suitable liquid chromatography/mass spectrometry method may be adopted to perform confirmatory test, and the proper cutoff values may be set forth according to the limit of quantification in respect of the liquid chromatography/mass spectrometry method.

Article 19

Where the confirmatory test results are lower than the limit of quantification set forth in the preceding Article, the urine specimen shall be judged as negative; and the residual specimen shall be disposed in accordance with the provision of Article 9.

Article 20

For the drug abuse urine used for juridical cases, the limits of quantification may be used as cutoff values where necessary, without being limited by the provisions of Articles 15 and 18.

Article 21

The test report shall be produced by the testing institution in writing.

Article 22

Where necessary, the test consignor may request the testing institution to provide original test records or test results.

Article 23

If the test consignor doesn't agree with the result of urine test, it may explain the reasons to request retest within fourteen days following receipt of test report.

Article 24

The limit of quantification of abused drugs or their metabolites tested by the testing institution shall be used as the basis of the cutoff values for retest of urine specimens. Where the retest result are lower than the limit of quantification, the specimen shall be judged as negative; where not lower than the limit of quantification, positive.

Chapter 4 Quality Control and Quality Assurance

Article 25

Each batch of initial test specimens shall include the following quality control urines:

1. At least one urine specimen without the drugs to be tested or their metabolites.
2. At least one specimen of quality control urine with a concentration of the drugs to be tested or their metabolites about 25% above the cutoff value.
3. At least one specimen of quality control urine with a concentration of the drugs to be tested or their metabolites about 25% below the cutoff value.

Article 26

Each batch of initial test specimens shall include at least 10% of quality control urines, among which 1% (at least one) shall be the blind quality control urines prepared by the testing institution itself.

Article 27

Each batch of confirmatory test specimens shall include the following quality control urines:

1. Single-point calibration specimen at the cutoff value.
2. At least a urine specimen without the drugs to be tested or their metabolites.
3. At least one specimen of positive quality control urine with a concentration of the drugs to be tested or their metabolites about 25% above the cutoff value .
4. At least one specimen of negative quality control urine with a concentration of the drugs to be tested or their metabolites about 25% below the cutoff value .
5. At least one specimen of blind quality control urine prepared inside the testing institution.

Article 28

Each batch of confirmatory test specimens shall include at least 10% of quality control urines.

Article 29

Each batch of retest specimens shall include at least one specimen of quality control urines with a concentration of the drugs or their metabolites 40% below the cutoff value.

Article 30

The linearity, precision and accuracy of the confirmatory test methods of the testing institutions shall be validated at least once every half year.

Article 31

The testing institutions shall prescribe a quality assurance plan of the testing procedures, including the procedures of specimen management, initial and confirmatory test methods, and test reports, and designate full-time personnel to carry through the plan.

Article 32

The testing institutions shall work out procurement procedure and acceptance standards conforming to the quality requirements for the material and technical services regarding urine test, and keep the related recording documents.

Article 33

The testing institutions shall prescribe the principles for settling the disputes raised by the test consignor.

Article 34

The testing institutions shall prescribe the procedures for internal periodical audit and management review.

Chapter 5 Supplementary Provisions

Article 35

The health institutions designated by the Department of Health, Executive Yuan to conduct drug abuse urine test and the laboratories established by government departments before these Regulations take effect shall, within three years

commencing from the date when these Regulations come into force, modify the original test items and methods in accordance with the provisions of these Regulations.

Article 36

These Regulations shall come into force on 9 January 2004.

The amended articles hereof shall come into effect as of the day of promulgation.