



Article Content

Title : Regulations Governing Drug Abuse Urine Testing Operations CH

Amended Date : 2021-06-30

Category : Ministry of Health and Welfare (衛生福利部)

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 that uses methods with different theoretical basis from the confirmatory test so as to eliminate negative specimens.
7. Confirmatory test: means the test conducted to confirm the suspected existence of specific drug or drug metabolite in the initial test results by using the analysis methods of gas or liquid chromatography mass spectrometry.
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.
The 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.

Article 10-1 Medical or research institutions that obtain the remaining urine specimens for research according to Paragraph 2, Article 33-1 of the Statute, shall comply with the provisions in the Human Subjects Research Act, the Personal Data Protection Act, and other relevant laws and regulations.
The specimens in the preceding paragraph shall not be applied in performing DNA tests or other tests sufficient to detect individual identities.

Article 10-2 For the obtaining as in the first paragraph of the preceding Article, the medical or research institution shall submit an application to the test consignor.
The test consignor, if approving the application mentioned in the preceding paragraph, shall provide the remaining urine specimens in a de-identification method, and in case the specimen is stored in the testing institution, shall notify the testing institution of the approval in writing so the specimen is obtainable.
The medical or research institutions shall not transfer the specimens obtained according to the first paragraph.

Article 10-3 The testing institution, when providing the specimen to the recipient in accordance with the second paragraph of the preceding Article, shall record the following items:

1. The serial number of specimen.
2. The amount of the specimen provided.
3. Appearance and characterization of the specimen.
4. The date and time of specimen provided.
5. The name of the obtaining institution.
6. The name of the person releasing the specimen and the person

obtaining the specimen.

7. The approval document number of the test consignor.

The record in the preceding paragraph shall bear the signatures and/or the stamps of the person releasing the specimen and the person obtaining the specimen. The record shall be retained on file by the testing institution for at least two years.

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.
10. Using quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review to improve the effectiveness of management system continually.

- Article 15 The specimen shall be judged as positive if the initial test results indicate the concentration of drug or drug metabolite in the urine specimen not lower than the following cutoff values:
1. Amphetamines: 500 ng/mL.
 2. Opiate metabolites: 300 ng/mL.
 3. Marijuana metabolites: 50 ng/mL.
 4. Cocaine metabolites: 300 ng/mL.
 5. Ketamine metabolites: 100 ng/mL.
- For the initial test results of abused drugs or their metabolites other than listed in the preceding paragraph, the cutoff values shall be determined according to the concentration as announced by the Taiwan Food and Drug Administration, Ministry of Health and Welfare. In absence of the announced concentration, the cutoff values may be determined by the testing institution based on the limit of quantification using its methods of analysis.
- 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, the confirmatory test shall be performed. 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, the cutoff values shall be determined according to the concentration as announced by the Taiwan Food and Drug Administration, Ministry of Health and Welfare. In absence of the announced concentration, the cutoff values may be determined by the testing institution based on the limit of quantification using its methods of analysis.

- 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 or electronic format with anti-counterfeiting design.
- 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 metabolite 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.

4. At least one specimen of blind quality control urine prepared by the testing institution itself.

If a single method of the initial test can be applied on ten or more drugs or their metabolites, the testing institution shall select at least ten drugs or their metabolites as quality control items. The selected items shall be reviewed annually. For the selection of the quality control items as in the preceding paragraph, priority shall be given to those drugs or their metabolites frequently detected.

Article 26 Each batch of initial test specimens shall include at least 10% of quality control urines, and at least among 1% of 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 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 Ministry of Health and Welfare 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 force as of the day of promulgation except Article 1 and Article 10-1 to Article 10-3 amended on 25 December 2020 shall come into force on July 1, 2021.