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KESIHATAN (PERUBATAN)
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Tarikh : 3 Sept. 2002

Timbalan Ketua Pengarah Kesihatan (Kesihatan Awam)

Pengarah Kesihatan Negeri ....

Pengarah Hospital Kuala Lumpur

Y. Bhg Dato' / Datin / Tuan / Puan,

SURAT PEKELILING KETUA PENGARAH KESIHATAN MALAYSIA BIL 6 / 2002

GARISPANDUAN BAGI UJIAN PENGESANAN PENYALAHGUNAAN DADAH DALAM AIR KENCING

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1. TUJUAN

Surat ini bertujuan untuk memaklumkan mengenai garispanduan bagi ujian pengesanan penyalahgunaan dadah. Ini adalah untuk menyeragamkan dan mengemaskini prosidur-prosidur ujian pengesanan dadah di makmal-makmal Kementerian Kesihatan Malaysia (KKM) serta sebagai panduan bagi agensi-agensi yang terlibat dalam program pengesanan dadah seperti Agensi Dadah Kebangsaan dan Polis. Selain daripada itu garispanduan ini akan memudahkan proses menulis dokumen kerana terdapat penyeragaman prosedur bagi proses mendapatkan pensijilan ISO/IEC 17025 serta dapat menghasilkan keputusan ujian berkualiti dan diakui kerana semua prosidur dijalankan dengan mengambilkira isu keselamatan, kerahsiaan, kawalan kualiti dan berpandu kepada prosidur-prosidur di peringkat antarabangsa.

2. LATARBELAKANG

Garispanduan ini disediakan berlanjutan dari Bengkel Polisi dan Prosidur Ujian Dadah pada tahun 2000 di mana banyak pertanyaan mengenai polisi dan prosidur samada teknikal atau berundangan telah dikemukakan oleh peserta-peserta yang menghadiri bengkel itu.

Berikutan dengan itu, satu Jawatankuasa Teknikal Polisi dan Prosidur telah diwujudkan yang dianggotai oleh Pakar Patologi, Pegawai Sains dan Juruteknologi Perubatan. Di bawah jawatankuasa ini terdapat dua jawatankuasa kerja iaitu, Jawatankuasa Polisi dan Prosidur Ujian Dadah serta Jawatankuasa *Quality Assurance* dan Latihan.

Jawatankuasa Teknikal Polisi dan Prosidur Ujian Dadah telah mengadakan beberapa siri mesyuarat serta perbincangan dengan lain agensi seperti pihak Polis dan pihak Peguam Negara dan telah berjaya mengeluarkan satu garispanduan *Guidelines For Drugs of Abuse Testing* untuk rujukan makmal-makmal pengesanan dadah di Kementerian Kesihatan dan agensi-agensi berkaitan di negara ini.

3. ISU-ISU YANG DIKENALPASTI

Antara isu-isu yang dikenalpasti adalah:

3.1 Cara melaporkan ujian Cannabis. Ini adalah berikutan terdapat kes mahkamah yang dibuang berdasarkan cara melapor sekarang.
3.2 Penyimpanan sampel selepas menjalankan ujian pengesahan dan juga penyimpanan rekod-rekod serta cara melupuskan rekod .
3.3 Analisis dan *Quality Control*. Pendekatan penggunaan sampel kualiti adalah tidak ada keseragaman.
3.4 *Turn Around Time (TAT)* yang terlalu lama terutama bagi kes-kes polis.
3.5 Sistem rujukan (ke mana sampel akan dihantar) jika sesuatu hospital tidak mempunyai anggota dan fasiliti untuk menjalankan ujian.
3.6 Isu keselamatan dan kerahsiaan.
3.7 Prosidur tidak dikemaskini semenjak *Manual For The laboratory Detection of Drugs of Abuse in Urine* dikeluarkan pada tahun 1988.

4. RUMUSAN GARISPANDUAN

Garispanduan ini mengandungi prosidur-prosidur lengkap mengenai ujian pengesanan dadah dalam air kencing dan prosidur-prosidur ini disediakan berdasarkan rujukan di peringkat nasional dan antarabangsa seperti yang dinyatakan dalam sumber rujukan. Jabatan Peguam Negara juga dirujuk bagi prosidur yang melibatkan isu medikolegal. Ia dibahagikan kepada tiga bahagian. Bahagian permulaan menyentuh perkara-perkara seperti pengenalan, pusat-pusat pengesanan dadah KKM serta ciri-cirinya dan prosidur rujukan antara pusat-pusat pengesanan. Bahagian Kedua menerangkan prosidur pengesanan bermula dari pemungutan sampel sehingga penyimpanan sampel dan sistem pengrekodan. Bahagian ini diolah secara terperinci untuk diikuti oleh semua pihak yang terlibat dalam program ini. Bahagian ketiga mengandungi sumber rujukan, definasi terma-terma yang digunakan dalam garispanduan serta lampiran ia itu, Lampiran 1 : Borang Permintaan Ujian Pengesanan Dadah Dalam Air Kencing- UPD 1 Pindaan dan Lampiran 2: Borang Akuan Pemberi.

5. TARIKH BERKUATKUASA

Garispanduan ini adalah berkuatkuasa mulai dari tarikh surat ini dikeluarkan.

6. TINDAKAN DAN PENGAWASAN

Pengarah Kesihatan Negeri adalah bertanggungjawab mengedarkan surat pekeliling dan garispanduan ini ke semua hospital dan klinik di bawah pentadbiran Y. Bhg. Dato'/Datin/Tuan/Puan.

6. PERTANYAAN

Sekiranya terdapat pertanyaan, sila merujuk kepada Kementerian di alamat berikut:

Pengarah Perkembangan Perubatan
Cawangan Perkhidmatan dan Kepakaran
Bahagian Perkembangan Perubatan
Kementerian Kesihatan Malaysia
Jalan Cenderasari
50590 Kuala Lumpur

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

(TAN SRI DATU DR. HAJI MOHAMAD TAHA BIN ARIF)
Ketua Pengarah Kesihatan Malaysia
Kementerian Kesihatan Malaysia

s.k. Ketua Setiausaha Kementerian Kesihatan Malaysia

Timbalan Ketua Pengarah Kesihatan (Perubatan)

Timbalan Ketua Pengarah Kesihatan (Penyelidikan dan Sokongan Teknikal)

Penasihat Undang-Undang, Kementerian Kesihatan Malaysia

Pengarah
Institut Penyelidikan Perubatan

Pengarah
Bahagian Perkhidmatan Farmasi

Pengarah
Jabatan Kimia Malaysia

Pengarah Agensi Dadah Kebangsaan
Kementerian Dalam Negeri

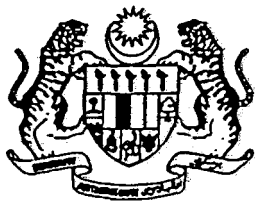
Ketua Bahagian Pendakwaan
Jabatan Peguam Negara

Ketua Pengarah
Bahagian Perkhidmatan Kesihatan
Angkatan Tentera Malaysia

Pengarah
Jabatan Narkotik, Polis DiRaja Malaysia

GARIS PANDUAN
BAGI UJIAN PENGESANAN
PENYALAHGUNAAN DADAH DALAM AIR KENCING

GUIDELINES
FOR TESTING
DRUGS OF ABUSE IN URINE



BAHAGIAN PERKEMBANGAN PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA
2002

GARISPANDUAN BAGI UJIAN PENGESANAN PENYALAHGUNAAN DADAH DALAM AIR KENCING

GUIDELINES FOR TESTING DRUGS OF ABUSE IN URINE

1. Introduction

(a) This guideline is intended to be used by all agencies involved in the National Drug Detection Programme and is not applicable to clinical testing.

(b) It describes procedures that shall fulfill the necessary criteria in order to guarantee optimum validity of drug detection results.

(c) Consideration shall be given to the procedures for collection, transportation, analysis, reporting of results, dispatching of results and storage of samples and records.

(d) This guideline shall be read together with the "Manual For The Laboratory Detection of Drugs of Abuse in Urine and Guidelines on Cold Turkey Detoxification and Treatment" 1988. Wherever there is any discrepancy of the fact, the present guidelines shall be referred.

2. Centres For Drugs of Abuse Tests

(a) Centres with facilities such as Hospital Kuala Lumpur (HKL), Institiut of Medical Research (IMR) and some state hospitals (Johor Bharu, Penang, Kuala Terengganu and Kota Kinabalu) shall do screening and confirmation of Morphine, Cannabis and Amphetamine Type Stimulant (ATS).

(b) Secondary centres (state hospitals) shall do screening of Morphine, Cannabis, Amphetamine Type Stimulant and confirmation of Morphine and Cannabis.

(c) Primary centres (district hospitals) with Biochemist shall do screening and confirmation of Morphine and Cannabis.

(d) Primary centres (district hospitals) without Biochemist shall do at least screening of Morphine and Cannabis.

3. Requirement for Setting up of Drugs of Abuse Testing Laboratories

(a) The drug laboratory shall be in a separate room with limited personnel access.

(b) The laboratory shall be secured at all time.

(c) The laboratory shall have sufficient security measures to ensure that no unauthorised personnel handle specimens or gain access to laboratory processes or areas where records are kept.

(d) Visitors shall be accompanied by authorised personnel and their visits documented.

4. Referral Procedure

If a centre does not do any of the confirmation tests, the second sample shall be sent for confirmation to:

(a) Nearest district hospital or

(b) State hospital or

(c) Regional Centre / HKL / IMR

Urine Collection

(a) Collection Personnel

(i) Samples shall be collected by authorised trained personnel of: the-.

- Out-patient Department / Clinic, Accident and Emergency Department (A&E), Psychiatric Clinic and wards of the hospitals.
- Police Department, Rehabilitation Centres and Agensi Dadah Kebangsaan.
- Other centres/agencies that are authorised by the government for collection of samples for the purpose of drug of abuse testing.

(ii) Laboratory personnel shall not be involved in the sample collection.

Refer to the Dangerous Drugs Act, 1952

(b) *Collection Site*

(i) The collection site shall be responsible for collecting, labeling, packaging and transporting of samples, ensuring that the collection and storage procedures have the proper documentation and security methods necessary.

(ii) The collection site shall also provide all staff with sufficient training to understand the collection process and its significance on laboratory results.

(iii) Procedures shall be in place to provide for the designated collection site to be secure. If a facility cannot be dedicated solely to the collection of urine, then the portion of the facility used shall be secured during collection.

(iv) No unauthorised personnel shall be permitted in any part of the

(d) Visitors shall be accompanied by authorised personnel and their visits documented.

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(iii) Procedures shall be in place to provide for the designated collection site to be secure. If a facility cannot be dedicated solely to the collection of urine, then the portion of the facility used shall be secured during collection.

(iv) No unauthorised personnel shall be permitted in any part of the

(v) Chain of custody forms/records shall be properly executed by an authorized collector upon receipt of the laboratory samples. Handling and transportation of urine samples from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Every effort shall be made to minimize the number of persons handling the specimens.

(vi) Criteria for collection site:

- The Collection site shall have all the necessary personnel, materials, equipment, facilities and supervision for the collection, security, temporary storage and shipping or transportation of urine samples to drug testing laboratory.

- The Collection site shall have suitable toilet facilities. Toilet facilities shall be set up without soap dispensers or cleaning agents. The toilet shall be surveyed for any contraband which can be used to invalidate the sample for example:-

  - Placing various chemical substances into the sample.

  - Placing pinhole in the bottom of the container, which results in leaks.

  - Placing table salt, detergents or commonly used household items that can destroy the drugs or affect the assay to generate false negative results.

  - Using fluid-filled bulb under the arm with a tube leading to the genital area. The subject can squeeze the bulb and release water or other substances that could dilute or contaminate the urine.

  - The subject can obtain urine from friends not using drugs.

  - Scooping water from the commode into the collection container to dilute the urine.

(c) ***Collection Procedure***

(i) At least 30 ml urine sample shall be collected in one bottle or duplicate if screening and confirmation are done in two different places. The requesting officer/referring centre shall keep the second urine sample and shall send the urine sample to the confirmation centre if the screening result is positive.

(ii) Both the collection personnel and the donor shall keep the urine samples in view at all times prior to it being sealed or labeled. If the second bottle cannot be provided (sample is 30 ml only), testing shall be done on the first sample. Absence of second sample shall be recorded.

(iii) At the collection site, if the volume is less than 30 ml, the donor may be given a reasonable amount of liquid to drink e.g. 240 ml of water every 30 minutes, but not to exceed a maximum of 720 ml. The second urine sample shall be collected and mixed with the previous sample, by the donor himself/herself or the collection personnel in front of the donor.

(iv) Type of bottle used for sample collection should be disposable in nature.

(v) During collection, if adulteration of urine sample is suspected, the collection personnel shall collect another urine sample and both urine samples shall be sent to the laboratory.

(vi) The collection personnel shall stand close enough to the donor to see that the urine is genuinely passed out from the person and to see that there is no attempt to falsify the specimens.

(vii) After the urine is collected, the bottles shall be securely capped and labeled as follows:

- Name: .....
- I/C No: .....
- Date of Collection: .....

Note: Labeling of bottles shall be made in front of the donor.

(viii) All urine samples shall be sealed in the presence of the donor. Auto seal device or security seal (wax seal with departmental stamp) shall be used.

(ix) The donor shall be asked to read and sign a statement ' Akuan Pemberi' certifying that the urine sample identified as having been collected from him or her is in fact that sample he or she has provided. Refer Appendix 2 [Lampiran 2 – Borang PER (LAB)-SS 301 B].

(x) Personal details of each urine sample donor are filled in a drug request form which accompanies the specimen to the laboratory (Appendix 1).

(xi) Accurate records of individuals involved in urine collection shall be maintained.

(xii) Proper Chain of Custody procedures for urine collection shall be maintained.

6. Request Form for Drug Analysis

(a) All requests for drug analysis shall be accompanied with a drug request form filled in four copies preferably carbonised. Refer Appendix 1 [Lampiran 1 Borang UPD 1-Pindaan- PER (LAB)-SS 301 A].

(b) An authorised officer requesting the drug analysis shall complete all request forms.

(c) Personnel authorised to request for drug analysis are: -

(i) Registered Medical Officer

(ii) Police Officer not below the rank of Sergeant or any other officer in charge of a police station.

(iii) Rehabilitation Officer from the Agency Dadah Kebangsaan.

(iv) Customs Officer

(v) Others (as specified by the collection centre).

Note: Refer to the Dangerous Drug Act, 1952.

(d) Completed forms shall be signed by the requesting officer and stamped with departmental stamp.

(e) Any amendment on the request form shall be crossed and signed.

(f) Name and Identity Card Number of :

(i) Donor

(ii) Collecting Officer

(iii) Requesting Officer

Shall be clearly printed or written as in his/her identity card.

7. Transport of Samples to Drug Detection Laboratory

The dispatch person shall be responsible for transporting urine samples to the laboratory and maintaining appropriate chain of custody records for ensuring that the urine samples are not tampered with during transit.

(a) Packing procedures:

(i) Samples shall be transported in a container, which shall be securely sealed or locked.

(ii) Gel or ice shall be used when necessary

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(v) Others (as specified by the collection centre).

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(a) Packing procedures:

(i) Samples shall be transported in a container, which shall be securely sealed or locked.

(ii) Gel or ice shall be used when necessary

(b) After the request forms have been completed, the samples with the forms shall be given to the dispatch person to be sent to the drug detection laboratory.

Note: Donor shall not be permitted to transport samples to the laboratory.

(c) Dispatch personnel:

(i) Police

(ii) Identified hospital personnel

(iii) Agensi Dadah Kebangsaan

(iv) Other authorised personnel identified by the relevant agencies

(d) Transportation

(i) All transported samples shall be accompanied by authorised personnel.

(ii) Where courier service is employed, unbroken chain of custody and documents shall be maintained.

(iii) Containers shall be designed to minimize the possibility of damage during shipment, e.g. specimen boxes or padded mailers and those containers shall be securely sealed to eliminate the possibility of undetected tampering.

(e) All samples shall be sent to the laboratory as soon as possible.

(f) Records of individuals involved in transporting the samples shall be maintained by the requesting or referring agencies.

8. Reception of samples

(a) Pathologist / Scientific Officer / Research Officer / Medical Laboratory Technologist (MLT) in the laboratory shall be responsible for sample reception.

(b) Upon receipt, the laboratory personnel shall inspect the containers or packages for any tampering and such observation shall be notified to the requesting agency/referring centre and recorded in the request form.

(c) Laboratory personnel shall check the samples and forms to ensure that all forms are correctly filled and all samples are suitable for analysis.

(d) Accepted samples and request forms shall be acknowledged by the receiving personnel by filling slips found at the bottom of request forms which are then returned to the dispatch personnel immediately or to the requesting officer by post.

(e) The receiving details recorded must be as follows:

(i) Name of the Referring Centre.

(ii) Number of samples received.

(iii) Number of samples rejected / not suitable to process.

(iv) Name and signature of dispatch personnel.

(v) Date and time of samples received.

(vi) Name and signature of receiving personnel.

(vii) Description of samples.

(f) All details are to be recorded in the Laboratory Information System (LIS) or in a designated record book.

9. Rejection Criteria

Any sample that does not meet the criteria for testing should be rejected and signed by officer in-charge of the laboratory.

(a) The rejection criteria are as follows: -

(i) Name / I/C number on the bottle and the form do not tally.

(ii) Bottle is not sealed or seal is broken.

(iii) Leaking bottle.

(iv) Unsealed or unlocked container.

(v) Request form is not signed by requesting officer.

(vi) Insufficient sample.

(vii) Request form without departmental stamp of requesting officer.

(viii) Any other reasons appropriately identified by the receiving personnel.

(b) Records of sample rejection shall be maintained.

(c) The request form shall be returned to the requesting officer through the dispatch personnel or posted with reasons.

(d) Rejected samples unsuitable for testing shall be disposed by the testing laboratory.

J. Analysis

(a) Standard recommended methods shall be used for all drug analysis. Where non- standard methods/laboratory developed methods are used, these methods shall be validated.

(b) All urine samples for general drug screening are to be screened for Opiates and Cannabinoids using Immunoassay method.

(c) Amphetamine Type Stimulant (ATS) or others are screened by Immunoassay method when requested.

(d) All samples positive for Opiates and Cannabinoids are to be confirmed by Thin Layer Chromatography (TLC) / Gas Chromatography Mass Spectrometry (GCMS) / High Performance Liquid Chromatography (HPLC) / Gas Chromatography (GC) method where available.

(e) Accurate and completed records of all personnel involved in sample analysis shall be maintained.

(f) All samples positive for Amphetamine Type Stimulant shall be confirmed by Gas Chromatography Mass Spectrometry or High Performance Liquid Chromatography method.

(g) Cut off values to be used are as follows:

Screening :	Confirmation:
Opiates: 300 µg/L	Morphine by TLC : 200µg/L
Cannabinoids: 100 µg/L	Cannabis by TLC : 25 µg/L
ATS: 1000 µg/L	ATS by GCMS and HPLC :500 µg/L

(h) Quality control and proficiency testing shall be carried out to ensure reliability and quality of the drug testing results.

(i) Drug standards and urine controls (**positive AND negative**) shall be used in every analysis. At least 10% of the analytical samples shall be quality control samples.

(j) If adulteration is suspected upon analysis, collection of a second urine sample shall be suggested.

(k) Problems arising in the laboratory detection shall be referred to :

(i) Nearest hospital Biochemist or

(ii) State Biochemist or

11. Quality Assurance (QA)

(a) Drug testing laboratory shall have a Quality Assurance Programme that covers all aspects of testing process, including but not limited to specimen handling, chain of custody (COC), security, screening test, confirmation test and reporting of results. As part of QA, the laboratories shall ensure that:

(i) Proper documentation of procedures are maintained in accordance with the requirements of ISO/IEC 17025, 1999.

(ii) Chain of custody procedures are maintained for specimen and related records.

(iii) Screening and confirmation test methods with known sensitivity, specificity and precision are used.

(iv) Instruments and test calibration are carried out according to the requirements or recommendations of instrument/reagent manufacturers.

(v) Standard/reference material obtained from drug/chemical companies or hospital pharmacy are used as standards. As these materials are controlled substances, they shall be kept in secure storage and usage shall be recorded.

(b) Supervision

The Chemical Pathologist or Senior Scientific Officer (Biochemist) shall be directly responsible to provide supervision on all testing laboratories within the respective state. In his or her absence, the State Pathologist shall provide the overall supervision.

12. Quality Control (QC)

(a) Every drug testing laboratory shall have an internal Quality Control (QC) Programme and participate in an external QC Programme such as The National Drug Quality Control Programme (NDQCP).

(b) Internal QC Programme

- Screening test and Confirmation test: Every batch of analysis shall include positive and negative QC samples.
- If the number of samples is more than 10, then at least 10 % of the samples analysed shall be QC samples.

Reporting Of Results

(a) Screening results shall be reported by Pathologist/Biochemist/Medical Laboratory Technologist (MLT) directly involved in the drug testing.

(b) Confirmation results shall be reported by Pathologist / Biochemist or by trained senior MLT (in the absence of Biochemist or Pathologist) directly involved in the drug testing.

(c) Any amendment of reports shall be crossed and signed.

(d) Results shall be reported according to the drugs tested.

(i) Positive results shall be reported as:-

ADA MENGANDUNGI 11-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid
(Kaedah Thin Layer Chromatography)

ADA MENGANDUNGI MORPHINE
(Kaedah Thin Layer Chromatography)

ADA MENGANDUNGI AMPHETAMINE

ADA MENGANDUNGI 3,4-METHYLENE DIOXYMETHAMPHETAMINE (MDMA)

ADA MENGANDUNGI METHYLENEDIOXY-AMPHETAMINE (MDA)

ADA MENGANDUNGI METHAMPHETAMINE
(Kaedah Gas Chromatography Mass Spectrometry/
High Performance Liquid Chromatography)

(ii) Negative results shall be reported as: -

TIDAK MENGANDUNGI 11-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid
Kaedah Thin Layer Chromatography / Immunoassay)

TIDAK MENGANDUNGI MORPHINE
(Kaedah Thin Layer Chromatography / Immunoassay)

TIDAK MENGANDUNGI AMPHETAMINE

TIDAK MENGANDUNGI 3,4-METHYLENE DIOXYMETHAMPHETAMINE (MDMA)

TIDAK MENGANDUNGI METHYLENEDIOXY-AMPHETAMINE (MDA)

TIDAK MENGANDUNGI METHAMPHETAMINE

(Kaedah Gas Chromatography Mass Spectrometry (GCMS)/High Performance Liquid Chromatography (HPLC))

(iii) ATS screening centres shall only report negative results as: -

TIADA MENGANDUNGI AMPHETAMINE TYPE STIMULANT (ATS)
(Kaedah Immunoassay)

Note: The term "11-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid" is used to report result for cannabis as stated in the amendment of First Schedule Order 2002 of the Dangerous Drugs Act, 1952 .

(e) Lab Turn Around Time for Drug Of Abuse tests shall be:

Screening: Not more than 3 working days
Morphine and Cannabis Confirmation: Not more than 5 working days
ATS Confirmation: Not more than 7 working days
Other drugs Confirmation: Not more than 7 working days.

(f) Results shall be submitted only to authorised personnel of the referring centre or requesting agency.

(g) The name and signature of reporting personnel shall be recorded in the chain of custody form or in a record book with date of reporting.

(h) Confidentiality and security of records and reports shall be maintained at all time.

(i) Where results are issued on a separate form, it shall have the following: -

(i) A title
(ii) Name and address of the laboratory and location where the test were carried out
(iii) Lab identification number
(iv) Name, IC No of the donor
(v) The name and address of the requesting officer
(vi) Condition of sample
(vii) Date of sample collected, received and test performed
(viii) Name of the method used
(ix) The name, designation and signature of person authorising the results.
(x) Where relevant a statement to the effect that the results relate only to the sample tested.

An example of the format is as shown in Appendix 3 (Lampiran 3).

Dispatching Of Results

(a) Dispatch personnel shall be identified authorised personnel.

(b) Means of dispatching results:

(i) Reports shall be sealed (wax seal with departmental stamp)
(ii) Report shall be dispatched by hand or by post (double sealed envelope).

(c) The name and signature of personnel collecting the results shall be recorded in the chain of custody form or in a record book with the date the results were taken.

Storage of Samples and Records

(a) The laboratory shall maintain records of sample storage at all time.

(i) If analysis is delayed, urine samples should be stored at 4°C or frozen if storage is more than 3 days and shall be kept in a secured area.

(ii) Negative samples for screening shall only be disposed after the screening results have been released.

(iii) Positive confirmation samples are to be stored for at least 2 months after the confirmation test.

(iv) Reports and records including TLC plates, GCMS and HPLC reports shall be kept for at least seven year. Where applicable these records shall be kept in electronic form.

(v) Samples and TLC plates shall be properly discarded after the storage period.

References:

1. Dangerous Drugs Act 1952 (Act 234) & Drug Dependents (Treatment And Rehabilitation) Act 1983 (Act 283) & Regulation & Rules.

2. Dangerous Drugs Act 1952, Amendment of First Schedule Order 2002.

3. Manual For The Laboratory Detection Of Drugs Of Abuse In Urine and Guidelines On `Cold Turkey' Detoxification and Treatment, 1988. Ministry Of Health and Anti 'Dadah' Task Force, National Security Council, Prime Minister's Department, Malaysia.

4. Substances Abuse and Mental Health Services Administration (SAMHSA) Guidelines, Department of Health and Human Services, United States.

5. Section 3: Specimen Collection and Storage Procedures; Australian And New Zealand Standards (AS/NZS), 4308: 2001

DEFINITIONS:

1. **Chain Of Custody (COC)**

   Procedures to account for the integrity of each urine sample by tracking its handling and storage from point of samples received to final disposition of the sample.

2. **Chain Of Custody Form / Record**

   The form (s) / records used by the testing laboratory to document the security of the sample and all aliquots of the sample during collection, transportation, testing and storage by the laboratory. The form, which may account for an entire laboratory test batch, shall include the names and signatures of all individuals who accessed the sample and its aliquots with the date and purpose of the access.

3. **Collection Site**

   A designated area where samples are collected.

4. **Confirmation Test**

   A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique, chemical and principle from that of the initial test in order to ensure reliability and accuracy.

5. **Cut Off**

   Value serving as an administrative breakpoint for labeling result as positive or negative.

6. **Donor**

   The individual from whom urine sample is collected.

7. **Drug standards**

   Reference materials of known purity or a solution containing a reference material of known concentration.

8. **False Negative**

   A test result reported as NEGATIVE when an individual has indeed used the drug tested for.

9. **False Positive**

   A test result reported as POSITIVE when an individual has NOT used a drug tested for.

10. Negative Control

Biological sample with no detectable drugs added, routinely analysed to ensure that no false positive results are obtained.

11. Positive Control

Biological sample with detectable and known concentration of drug added.

12. Quality Control

Those techniques used to monitor errors, which can cause deterioration in the quality of laboratory results. Control material most often refers to a sample (the expected results of which are known to the analyst) that is routinely analysed to ensure that the expected results are obtained.

13. Regional Centres

The Regional Centres, currently refer to the State hospitals in Johor Bahru, Penang, Kuala Terengganu and Kota Kinabalu.

14. Screening Test

A series of initial tests designed to separate samples with drugs at a particular minimum concentration from those below minimum concentration.

15. Sensitivity

The minimal or threshold concentration of a drug or its metabolites that can be detected.

16. Specificity

Quality of an analytical technique that tends to exclude all substances but the analyte from affecting the results. The degree to which a test can discriminate between closely related drugs, metabolites or naturally occurring substances.

17. True Negative

A test result reported as NEGATIVE when an individual has not used the drug tested for.

18. True Positive

A test result reported as POSITIVE when a person had indeed used the drug tested for.

19. Turn Around Time (TAT)

The time taken to complete the analysis of a sample from the moment it is received to the time when result is available.

Appendix 1/Lampiran1 UPD 1 (PINDAAN) PER (LAB)-SS 301A

BORANG PERMINTAAN UJIAN PENGESANAN DADAH DALAM AIR KENCING

NEGERI: _____ SEKSYEN: _____

HOSPITAL: _____ NO.RUJUKAN MAKMAL: _____

NAMA:

ALAMAT:

NO. K/P:

TARIKH LAHIR:

NO. PENDAFTARAN / NP / DD:

NO. LAPORAN POLIS:

TARIKH SPESIMEN DIPUNGUT:

PEGAWAI YANG MEMUNGUT:

NO. K/P:

PEG. YANG MEMBUAT PERMINTAAN:

NO. K/P:

.....

(T/TANGAN & COP JABATAN)

BANGSA: ☐ Melayu ☐ Cina ☐ India ☐ Lain-lain

JANTINA: ☐ Lelaki ☐ Perempuan

RUJUKAN ☐ Polis ☐ Tentera ☐ Pemulihan ☐ Lain-lain

TARAF PERKAHWINAN: ☐ Berkahwin ☐ Janda/Duda ☐ Bujang

JENIS UJIAN DADAH YANG DIMINTA:

☐ Morphine
☐ Cannabis
☐ Amphetamine Type Stimulants
☐ Lain-lain

Nyatakan:.....

Tandakan [/] di ruangan yang berkenaan

PEMBAWA SPESIMEN: NAMA:

TANDATANGAN: .....

KEPUTUSAN MAKMAL:

.....

(T/TANGAN & COP JABATAN)

KEADAAN AIR KENCING:

☐ Normal ☐ Keruh ☐ Jernih

☐ Berubah Warna ☐ Mengandungi Bendasing ☐ Lain-lain .....

TARIKH:

PENGESAHAN PENERIMAAN CONTOH AIR KENCING:(Keratan dikembalikan)

NO. RUJUKAN MAKMAL:

NAMA:

NO. K/P:

NO LAPORAN POLIS

AKUAN PEMBERI

Saya yang bernama .....

dan

No. Kad Pengenalan:.....

dengan ini mengesahkan telah memberi contoh air kencing saya untuk dijalankan ujian dan berpuas hati dengan prosidur pemungutan contoh yang dijalankan.

Tarikh: ..... Tandatangan: .....

Appendix 3 / Lampiran 3

Makmal Dadah & Penyelidikan,
Jabatan Patologi,
Hospital Kuala Lumpur.
Tel: 03-26155612 / 26155607

No. Repot Polis:
No. Laporan Makmal :
Tarikh laporan :

Kepada:

Nama Pegawai Yang Membuat Permintaan

Alamat Pegawai Yang Membuat Permintaan

Laporan Ujian Pengesanan Dadah Dalam Air Kencing

Butir- butir contoh adalah seperti berikut:

Nama :

No. Kad Pengenalan :

Tarikh Spesimen Dipungut:

Tarikh Spesimen Diterima:

Tarikh Spesimen Dianalisa:

Keadaan Spesimen:

Keputusan Ujian:

Rujuk Garispanduan bahagian Bagi Ujian Pengesanan Penyalahgunaan Dadah Dalam Air Kencing, Bahagian 13 'Reporting Of Results'.

.....
(Tandatangan)

Nama dan Jawatan Pegawai
yang mengesahkan keputusan.

Tarikh:

PEJABAT KETUA PENGARAH KESIHATAN MALAYSIA
(OFFICE OF THE DIRECTOR GENERAL OF HEALTH MALAYSIA)
KEMENTERIAN KESIHATAN MALAYSIA
(MINISTRY OF HEALTH MALAYSIA)
JALAN CENDERASARI
50590 KUALA LUMPUR

Telefon: 26925196
Fax: 26911436

Ruj. Kami: (3) dlm. KKM-87(P20/506) Bhg. 6

Tarikh: 3 Sept. 2002

Timbalan Ketua Pengarah Kesihatan (Kesihatan Awam)

Pengarah Kesihatan Negeri .....

Pengarah Hospital Kuala Lumpur

Y. Bhg Dato' / Datin / Tuan / Puan,

SURAT PEKELILING KETUA PENGARAH KESIHATAN MALAYSIA BIL 6 / 2002

GARISPANDUAN BAGI UJIAN PENGESANAN PENYALAHGUNAAN DADAH DALAM AIR KENCING

1. TUJUAN

Surat ini bertujuan untuk memaklumkan mengenai garispanduan bagi ujian pengesanan penyalahgunaan dadah. Ini adalah untuk menyeragamkan dan mengemaskini prosidur-prosidur ujian pengesanan dadah di makmal-makmal Kementerian Kesihatan Malaysia (KKM) serta sebagai panduan bagi agensi-agensi yang terlibat dalam program pengesanan dadah seperti Agensi Dadah Kebangsaan dan Polis. Selain daripada itu garispanduan ini akan memudahkan proses menulis dokumen kerana terdapat penyeragaman prosedur bagi proses mendapatkan pensijilan ISO/IEC 17025 serta dapat menghasilkan keputusan ujian berkualiti dan diakui kerana semua prosidur dijalankan dengan mengambilkira isu keselamatan, kerahsiaan, kawalan kualiti dan berpandu kepada prosidur-prosidur di peringkat antarabangsa.

2. LATARBELAKANG

Garispanduan ini disediakan berlanjutan dari Bengkel Polisi dan Prosidur Ujian Dadah pada tahun 2000 di mana banyak pertanyaan mengenai polisi dan prosidur samada teknikal atau berundangan telah dikemukakan oleh peserta-peserta yang menghadiri bengkel itu.

Berikutan dengan itu, satu Jawatankuasa Teknikal Polisi dan Prosidur telah diwujudkan yang dianggotai oleh Pakar Patologi, Pegawai Sains dan Juruteknologi Perubatan. Di bawah jawatankuasa ini terdapat dua jawatankuasa kerja iaitu, Jawatankuasa Polisi dan Prosidur Ujian Dadah serta Jawatankuasa *Quality Assurance* dan Latihan.

Jawatankuasa Teknikal Polisi dan Prosidur Ujian Dadah telah mengadakan beberapa siri mesyuarat serta perbincangan dengan lain agensi seperti pihak Polis dan pihak Peguam Negara dan telah berjaya mengeluarkan satu garispanduan *Guidelines For Drugs of Abuse Testing* untuk rujukan makmal-makmal pengesanan dadah di Kementerian Kesihatan dan agensi-agensi berkaitan di negara ini.

3. ISU-ISU YANG DIKENALPASTI

Antara isu-isu yang dikenalpasti adalah:

3.1 Cara melaporkan ujian Cannabis. Ini adalah berikutan terdapat kes mahkamah yang dibuang berdasarkan cara melapor sekarang.
3.2 Penyimpanan sampel selepas menjalankan ujian pengesahan dan juga penyimpanan rekod-rekod serta cara melupuskan rekod .
3.3 Analisis dan *Quality Control*. Pendekatan penggunaan sampel kualiti adalah tidak ada keseragaman.
3.4 *Turn Around Time (TAT)* yang terlalu lama terutama bagi kes-kes polis.
3.5 Sistem rujukan (ke mana sampel akan dihantar) jika sesuatu hospital tidak mempunyai anggota dan fasiliti untuk menjalankan ujian.
3.6 Isu keselamatan dan kerahsiaan.
3.7 Prosidur tidak dikemaskini semenjak *Manual For The laboratory Detection of Drugs of Abuse in Urine* dikeluarkan pada tahun 1988.

4. RUMUSAN GARISPANDUAN

Garispanduan ini mengandungi prosidur-prosidur lengkap mengenai ujian pengesanan dadah dalam air kencing dan prosidur-prosidur ini disediakan berdasarkan rujukan di peringkat nasional dan antarabangsa seperti yang dinyatakan dalam sumber rujukan. Jabatan Peguam Negara juga dirujuk bagi prosidur yang melibatkan isu medikolegal. Ia dibahagikan kepada tiga bahagian. Bahagian permulaan menyentuh perkara-perkara seperti pengenalan, pusat-pusat pengesanan dadah KKM serta ciri-cirinya dan prosidur rujukan antara pusat-pusat pengesanan. Bahagian Kedua menerangkan prosidur pengesanan bermula dari pemungutan sampel sehingga penyimpanan sampel dan sistem pengrekodan. Bahagian ini diolah secara terperinci untuk diikuti oleh semua pihak yang terlibat dalam program ini. Bahagian ketiga mengandungi sumber rujukan, definasi terma-terma yang digunakan dalam garispanduan serta lampiran ia itu, Lampiran 1: Borang Permintaan Ujian Pengesanan Dadah Dalam Air Kencing- UPD 1 Pindaan dan Lampiran 2: Borang Akuan Pemberi.

5. TARIKH BERKUATKUASA

Garispanduan ini adalah berkuatkuasa mulai dari tarikh surat ini dikeluarkan.

6. TINDAKAN DAN PENGAWASAN

Pengarah Kesihatan Negeri adalah bertanggungjawab mengedarkan surat pekeliling dan garispanduan ini ke semua hospital dan klinik di bawah pentadbiran Y. Bhg. Dato'/Datin/Tuan/Puan.

6. PERTANYAAN

Sekiranya terdapat pertanyaan, sila merujuk kepada Kementerian di alamat berikut:

Pengarah Perkembangan Perubatan
Cawangan Perkhidmatan dan Kepakaran
Bahagian Perkembangan Perubatan
Kementerian Kesihatan Malaysia
Jalan Cenderasari
50590 Kuala Lumpur

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

(TAN SRI DATU DR. HAJI MOHAMAD TAHA BIN ARIF)
Ketua Pengarah Kesihatan Malaysia
Kementerian Kesihatan Malaysia

s.k. Ketua Setiausaha Kementerian Kesihatan Malaysia

Timbalan Ketua Pengarah Kesihatan (Perubatan)

Timbalan Ketua Pengarah Kesihatan (Penyelidikan dan Sokongan Teknikal)

Penasihat Undang-Undang, Kementerian Kesihatan Malaysia

Pengarah
Institut Penyelidikan Perubatan

Pengarah
Bahagian Perkhidmatan Farmasi

Pengarah
Jabatan Kimia Malaysia

Pengarah Agensi Dadah Kebangsaan
Kementerian Dalam Negeri

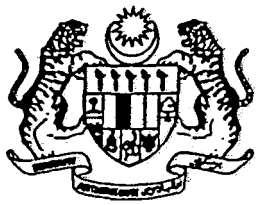
Ketua Bahagian Pendakwaan
Jabatan Peguam Negara

Ketua Pengarah
Bahagian Perkhidmatan Kesihatan
Angkatan Tentera Malaysia

Pengarah
Jabatan Narkotik, Polis DiRaja Malaysia

GARIS PANDUAN
BAGI UJIAN PENGESANAN
PENYALAHGUNAAN DADAH DALAM AIR KENCING

GUIDELINES
FOR TESTING
DRUGS OF ABUSE IN URINE



BAHAGIAN PERKEMBANGAN PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA
2002

GARISPANDUAN BAGI UJIAN PENGESANAN PENYALAHGUNAAN DADAH DALAM AIR KENCING

GUIDELINES FOR TESTING DRUGS OF ABUSE IN URINE

1. Introduction

(a) This guideline is intended to be used by all agencies involved in the National Drug Detection Programme and is not applicable to clinical testing.

(b) It describes procedures that shall fulfill the necessary criteria in order to guarantee optimum validity of drug detection results.

(c) Consideration shall be given to the procedures for collection, transportation, analysis, reporting of results, dispatching of results and storage of samples and records.

(d) This guideline shall be read together with the "Manual For The Laboratory Detection of Drugs of Abuse in Urine and Guidelines on Cold Turkey Detoxification and Treatment" 1988. Wherever there is any discrepancy of the fact, the present guidelines shall be referred.

2. Centres For Drugs of Abuse Tests

(a) Centres with facilities such as Hospital Kuala Lumpur (HKL), Institiut of Medical Research (IMR) and some state hospitals (Johor Bharu, Penang, Kuala Terengganu and Kota Kinabalu) shall do screening and confirmation of Morphine, Cannabis and Amphetamine Type Stimulant (ATS).

(b) Secondary centres (state hospitals) shall do screening of Morphine, Cannabis, Amphetamine Type Stimulant and confirmation of Morphine and Cannabis.

(c) Primary centres (district hospitals) with Biochemist shall do screening and confirmation of Morphine and Cannabis.

(d) Primary centres (district hospitals) without Biochemist shall do at least screening of Morphine and Cannabis.

3. Requirement for Setting up of Drugs of Abuse Testing Laboratories

(a) The drug laboratory shall be in a separate room with limited personnel access.

(b) The laboratory shall be secured at all time.

(c) The laboratory shall have sufficient security measures to ensure that no unauthorised personnel handle specimens or gain access to laboratory processes or areas where records are kept.

(d) Visitors shall be accompanied by authorised personnel and their visits documented.

4. Referral Procedure

If a centre does not do any of the confirmation tests, the second sample shall be sent for confirmation to:

(a) Nearest district hospital or

(b) State hospital or

(c) Regional Centre / HKL / IMR

5. Urine Collection

(a) Collection Personnel

(i) Samples shall be collected by authorised trained personnel of: the-.

- Out-patient Department / Clinic, Accident and Emergency Department (A&E), Psychiatric Clinic and wards of the hospitals.
- Police Department, Rehabilitation Centres and Agensi Dadah Kebangsaan.
- Other centres/agencies that are authorised by the government for collection of samples for the purpose of drug of abuse testing.

(ii) Laboratory personnel shall not be involved in the sample collection.

Refer to the Dangerous Drugs Act, 1952

(b) *Collection Site*

(i) The collection site shall be responsible for collecting, labeling, packaging and transporting of samples, ensuring that the collection and storage procedures have the proper documentation and security methods necessary.

(ii) The collection site shall also provide all staff with sufficient training to understand the collection process and its significance on laboratory results.

(iii) Procedures shall be in place to provide for the designated collection site to be secure. If a facility cannot be dedicated solely to the collection of urine, then the portion of the facility used shall be secured during collection.

(v) Chain of custody forms/records shall be properly executed by an authorized collector upon receipt of the laboratory samples. Handling and transportation of urine samples from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Every effort shall be made to minimize the number of persons handling the specimens.

(vi) Criteria for collection site:

- The Collection site shall have all the necessary personnel, materials, equipment, facilities and supervision for the collection, security, temporary storage and shipping or transportation of urine samples to drug testing laboratory.

- The Collection site shall have suitable toilet facilities. Toilet facilities shall be set up without soap dispensers or cleaning agents. The toilet shall be surveyed for any contraband which can be used to invalidate the sample for example:-

  - Placing various chemical substances into the sample.

  - Placing pinhole in the bottom of the container, which results in leaks.

  - Placing table salt, detergents or commonly used household items that can destroy the drugs or affect the assay to generate false negative results.

  - Using fluid-filled bulb under the arm with a tube leading to the genital area. The subject can squeeze the bulb and release water or other substances that could dilute or contaminate the urine.

  - The subject can obtain urine from friends not using drugs.

  - Scooping water from the commode into the collection container to dilute the urine.

(c) ***Collection Procedure***

(i) At least 30 ml urine sample shall be collected in one bottle or duplicate if screening and confirmation are done in two different places. The requesting officer/referring centre shall keep the second urine sample and shall send the urine sample to the confirmation centre if the screening result is positive.

(ii) Both the collection personnel and the donor shall keep the urine samples in view at all times prior to it being sealed or labeled. If the second bottle cannot be provided (sample is 30 ml only), testing shall be done on the first sample. Absence of second sample shall be recorded.

(iii) At the collection site, if the volume is less than 30 ml, the donor may be given a reasonable amount of liquid to drink e.g. 240 ml of water every 30 minutes, but not to exceed a maximum of 720 ml. The second urine sample shall be collected and mixed with the previous sample, by the donor himself/herself or the collection personnel in front of the donor.

(iv) Type of bottle used for sample collection should be disposable in nature.

(v) During collection, if adulteration of urine sample is suspected, the collection personnel shall collect another urine sample and both urine samples shall be sent to the laboratory.

(vi) The collection personnel shall stand close enough to the donor to see that the urine is genuinely passed out from the person and to see that there is no attempt to falsify the specimens.

(vii) After the urine is collected, the bottles shall be securely capped and labeled as follows:

- Name: .....
- I/C No: .....
- Date of Collection: .....

Note: Labeling of bottles shall be made in front of the donor.

(viii) All urine samples shall be sealed in the presence of the donor. Auto seal device or security seal (wax seal with departmental stamp) shall be used.

(ix) The donor shall be asked to read and sign a statement ' Akuan Pemberi' certifying that the urine sample identified as having been collected from him or her is in fact that sample he or she has provided. Refer Appendix 2 [Lampiran 2 – Borang PER (LAB)-SS 301 B].

(x) Personal details of each urine sample donor are filled in a drug request form which accompanies the specimen to the laboratory (Appendix 1).

(xi) Accurate records of individuals involved in urine collection shall be maintained.

(xii) Proper Chain of Custody procedures for urine collection shall be maintained.

6. Request Form for Drug Analysis

(a) All requests for drug analysis shall be accompanied with a drug request form filled in four copies preferably carbonised. Refer Appendix 1 [Lampiran 1 Borang UPD 1-Pindaan- PER (LAB)-SS 301 A].

(b) An authorised officer requesting the drug analysis shall complete all request forms.

(c) Personnel authorised to request for drug analysis are: -

(i) Registered Medical Officer

(ii) Police Officer not below the rank of Sergeant or any other officer in charge of a police station.

(iii) Rehabilitation Officer from the Agency Dadah Kebangsaan.

(iv) Customs Officer

(v) Others (as specified by the collection centre).

Note: Refer to the Dangerous Drug Act, 1952.

(d) Completed forms shall be signed by the requesting officer and stamped with departmental stamp.

(e) Any amendment on the request form shall be crossed and signed.

(f) Name and Identity Card Number of :

(i) Donor

(ii) Collecting Officer

(iii) Requesting Officer

Shall be clearly printed or written as in his/her identity card.

7. Transport of Samples to Drug Detection Laboratory

The dispatch person shall be responsible for transporting urine samples to the laboratory and maintaining appropriate chain of custody records for ensuring that the urine samples are not tampered with during transit.

(a) Packing procedures:

(i) Samples shall be transported in a container, which shall be securely sealed or locked.

(ii) Gel or ice shall be used when necessary

(b) After the request forms have been completed, the samples with the forms shall be given to the dispatch person to be sent to the drug detection laboratory.

Note: Donor shall not be permitted to transport samples to the laboratory.

(c) Dispatch personnel:

(i) Police

(ii) Identified hospital personnel

(iii) Agensi Dadah Kebangsaan

(iv) Other authorised personnel identified by the relevant agencies

(d) Transportation

(i) All transported samples shall be accompanied by authorised personnel.

(ii) Where courier service is employed, unbroken chain of custody and documents shall be maintained.

(iii) Containers shall be designed to minimize the possibility of damage during shipment, e.g. specimen boxes or padded mailers and those containers shall be securely sealed to eliminate the possibility of undetected tampering.

(e) All samples shall be sent to the laboratory as soon as possible.

(f) Records of individuals involved in transporting the samples shall be maintained by the requesting or referring agencies.

8. Reception of samples

(a) Pathologist / Scientific Officer / Research Officer / Medical Laboratory Technologist (MLT) in the laboratory shall be responsible for sample reception.

(b) Upon receipt, the laboratory personnel shall inspect the containers or packages for any tampering and such observation shall be notified to the requesting agency/referring centre and recorded in the request form.

(c) Laboratory personnel shall check the samples and forms to ensure that all forms are correctly filled and all samples are suitable for analysis.

(d) Accepted samples and request forms shall be acknowledged by the receiving personnel by filling slips found at the bottom of request forms which are then returned to the dispatch personnel immediately or to the requesting officer by post.

(e) The receiving details recorded must be as follows:

(i) Name of the Referring Centre.

(ii) Number of samples received.

(iii) Number of samples rejected / not suitable to process.

(iv) Name and signature of dispatch personnel.

(v) Date and time of samples received.

(vi) Name and signature of receiving personnel.

(vii) Description of samples.

(f) All details are to be recorded in the Laboratory Information System (LIS) or in a designated record book.

9. Rejection Criteria

Any sample that does not meet the criteria for testing should be rejected and signed by officer in-charge of the laboratory.

(a) The rejection criteria are as follows: -

(i) Name / I/C number on the bottle and the form do not tally.

(ii) Bottle is not sealed or seal is broken.

(iii) Leaking bottle.

(iv) Unsealed or unlocked container.

(v) Request form is not signed by requesting officer.

(vi) Insufficient sample.

(vii) Request form without departmental stamp of requesting officer.

(viii) Any other reasons appropriately identified by the receiving personnel.

(b) Records of sample rejection shall be maintained.

(c) The request form shall be returned to the requesting officer through the dispatch personnel or posted with reasons.

(d) Rejected samples unsuitable for testing shall be disposed by the testing laboratory.

J. Analysis

(a) Standard recommended methods shall be used for all drug analysis. Where non- standard methods/laboratory developed methods are used, these methods shall be validated.

(b) All urine samples for general drug screening are to be screened for Opiates and Cannabinoids using Immunoassay method.

(c) Amphetamine Type Stimulant (ATS) or others are screened by Immunoassay method when requested.

(d) All samples positive for Opiates and Cannabinoids are to be confirmed by Thin Layer Chromatography (TLC) / Gas Chromatography Mass Spectrometry (GCMS) / High Performance Liquid Chromatography (HPLC) / Gas Chromatography (GC) method where available.

(e) Accurate and completed records of all personnel involved in sample analysis shall be maintained.

(f) All samples positive for Amphetamine Type Stimulant shall be confirmed by Gas Chromatography Mass Spectrometry or High Performance Liquid Chromatography method.

(g) Cut off values to be used are as follows:

Screening :	Confirmation:
Opiates: 300 µg/L	Morphine by TLC : 200µg/L
Cannabinoids: 100 µg/L	Cannabis by TLC : 25 µg/L
ATS: 1000 µg/L	ATS by GCMS and HPLC :500 µg/L

(h) Quality control and proficiency testing shall be carried out to ensure reliability and quality of the drug testing results.

(i) Drug standards and urine controls (**positive AND negative**) shall be used in every analysis. At least 10% of the analytical samples shall be quality control samples.

(j) If adulteration is suspected upon analysis, collection of a second urine sample shall be suggested.

(k) Problems arising in the laboratory detection shall be referred to :

(i) Nearest hospital Biochemist or

(ii) State Biochemist or

11. Quality Assurance (QA)

(a) Drug testing laboratory shall have a Quality Assurance Programme that covers all aspects of testing process, including but not limited to specimen handling, chain of custody (COC), security, screening test, confirmation test and reporting of results. As part of QA, the laboratories shall ensure that:

(i) Proper documentation of procedures are maintained in accordance with the requirements of ISO/IEC 17025, 1999.

(ii) Chain of custody procedures are maintained for specimen and related records.

(iii) Screening and confirmation test methods with known sensitivity, specificity and precision are used.

(iv) Instruments and test calibration are carried out according to the requirements or recommendations of instrument/reagent manufacturers.

(v) Standard/reference material obtained from drug/chemical companies or hospital pharmacy are used as standards. As these materials are controlled substances, they shall be kept in secure storage and usage shall be recorded.

(b) Supervision

The Chemical Pathologist or Senior Scientific Officer (Biochemist) shall be directly responsible to provide supervision on all testing laboratories within the respective state. In his or her absence, the State Pathologist shall provide the overall supervision.

12. Quality Control (QC)

(a) Every drug testing laboratory shall have an internal Quality Control (QC) Programme and participate in an external QC Programme such as The National Drug Quality Control Programme (NDQCP).

(b) Internal QC Programme

- Screening test and Confirmation test: Every batch of analysis shall include positive and negative QC samples.
- If the number of samples is more than 10, then at least 10 % of the samples analysed shall be QC samples.

Reporting Of Results

(a) Screening results shall be reported by Pathologist/Biochemist/Medical Laboratory Technologist (MLT) directly involved in the drug testing.

(b) Confirmation results shall be reported by Pathologist / Biochemist or by trained senior MLT (in the absence of Biochemist or Pathologist) directly involved in the drug testing.

(c) Any amendment of reports shall be crossed and signed.

(d) Results shall be reported according to the drugs tested.

(i) Positive results shall be reported as:-

ADA MENGANDUNGI 11-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid
(Kaedah Thin Layer Chromatography)

ADA MENGANDUNGI MORPHINE
(Kaedah Thin Layer Chromatography)

ADA MENGANDUNGI AMPHETAMINE

ADA MENGANDUNGI 3,4-METHYLENE DIOXYMETHAMPHETAMINE (MDMA)

ADA MENGANDUNGI METHYLENEDIOXY-AMPHETAMINE (MDA)

ADA MENGANDUNGI METHAMPHETAMINE
(Kaedah Gas Chromatography Mass Spectrometry/
High Performance Liquid Chromatography)

(ii) Negative results shall be reported as: -

TIDAK MENGANDUNGI 11-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid
Kaedah Thin Layer Chromatography / Immunoassay)

TIDAK MENGANDUNGI MORPHINE
(Kaedah Thin Layer Chromatography / Immunoassay)

TIDAK MENGANDUNGI AMPHETAMINE

TIDAK MENGANDUNGI 3,4-METHYLENE DIOXYMETHAMPHETAMINE (MDMA)

TIDAK MENGANDUNGI METHYLENEDIOXY-AMPHETAMINE (MDA)

TIDAK MENGANDUNGI METHAMPHETAMINE

(Kaedah Gas Chromatography Mass Spectrometry (GCMS)/High Performance Liquid Chromatography (HPLC))

(iii) ATS screening centres shall only report negative results as: -

TIADA MENGANDUNGI AMPHETAMINE TYPE STIMULANT (ATS)
(Kaedah Immunoassay)

Note: The term "11-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid" is used to report result for cannabis as stated in the amendment of First Schedule Order 2002 of the Dangerous Drugs Act, 1952 .

(e) Lab Turn Around Time for Drug Of Abuse tests shall be:

Screening: Not more than 3 working days
Morphine and Cannabis Confirmation: Not more than 5 working days
ATS Confirmation: Not more than 7 working days
Other drugs Confirmation: Not more than 7 working days.

(f) Results shall be submitted only to authorised personnel of the referring centre or requesting agency.

(g) The name and signature of reporting personnel shall be recorded in the chain of custody form or in a record book with date of reporting.

(h) Confidentiality and security of records and reports shall be maintained at all time.

(i) Where results are issued on a separate form, it shall have the following: -

(i) A title
(ii) Name and address of the laboratory and location where the test were carried out
(iii) Lab identification number
(iv) Name, IC No of the donor
(v) The name and address of the requesting officer
(vi) Condition of sample
(vii) Date of sample collected, received and test performed
(viii) Name of the method used
(ix) The name, designation and signature of person authorising the results.
(x) Where relevant a statement to the effect that the results relate only to the sample tested.

An example of the format is as shown in Appendix 3 (Lampiran 3).

Dispatching Of Results

(a) Dispatch personnel shall be identified authorised personnel.

(b) Means of dispatching results:

(i) Reports shall be sealed (wax seal with departmental stamp)
(ii) Report shall be dispatched by hand or by post (double sealed envelope).

(c) The name and signature of personnel collecting the results shall be recorded in the chain of custody form or in a record book with the date the results were taken.

Storage of Samples and Records

(a) The laboratory shall maintain records of sample storage at all time.

(i) If analysis is delayed, urine samples should be stored at 4°C or frozen if storage is more than 3 days and shall be kept in a secured area.

(ii) Negative samples for screening shall only be disposed after the screening results have been released.

(iii) Positive confirmation samples are to be stored for at least 2 months after the confirmation test.

(iv) Reports and records including TLC plates, GCMS and HPLC reports shall be kept for at least seven year. Where applicable these records shall be kept in electronic form.

(v) Samples and TLC plates shall be properly discarded after the storage period.

References:

1. Dangerous Drugs Act 1952 (Act 234) & Drug Dependents (Treatment And Rehabilitation) Act 1983 (Act 283) & Regulation & Rules.

2. Dangerous Drugs Act 1952, Amendment of First Schedule Order 2002.

3. Manual For The Laboratory Detection Of Drugs Of Abuse In Urine and Guidelines On `Cold Turkey' Detoxification and Treatment, 1988. Ministry Of Health and Anti 'Dadah' Task Force, National Security Council, Prime Minister's Department, Malaysia.

4. Substances Abuse and Mental Health Services Administration (SAMHSA) Guidelines, Department of Health and Human Services, United States.

5. Section 3: Specimen Collection and Storage Procedures; Australian And New Zealand Standards (AS/NZS), 4308: 2001

DEFINITIONS:

1. **Chain Of Custody (COC)**

   Procedures to account for the integrity of each urine sample by tracking its handling and storage from point of samples received to final disposition of the sample.

2. **Chain Of Custody Form / Record**

   The form (s) / records used by the testing laboratory to document the security of the sample and all aliquots of the sample during collection, transportation, testing and storage by the laboratory. The form, which may account for an entire laboratory test batch, shall include the names and signatures of all individuals who accessed the sample and its aliquots with the date and purpose of the access.

3. **Collection Site**

   A designated area where samples are collected.

4. **Confirmation Test**

   A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique, chemical and principle from that of the initial test in order to ensure reliability and accuracy.

5. **Cut Off**

   Value serving as an administrative breakpoint for labeling result as positive or negative.

6. **Donor**

   The individual from whom urine sample is collected.

7. **Drug standards**

   Reference materials of known purity or a solution containing a reference material of known concentration.

8. **False Negative**

   A test result reported as NEGATIVE when an individual has indeed used the drug tested for.

9. **False Positive**

   A test result reported as POSITIVE when an individual has NOT used a drug tested for.

10. Negative Control

Biological sample with no detectable drugs added, routinely analysed to ensure that no false positive results are obtained.

11. Positive Control

Biological sample with detectable and known concentration of drug added.

12. Quality Control

Those techniques used to monitor errors, which can cause deterioration in the quality of laboratory results. Control material most often refers to a sample (the expected results of which are known to the analyst) that is routinely analysed to ensure that the expected results are obtained.

13. Regional Centres

The Regional Centres, currently refer to the State hospitals in Johor Bahru, Penang, Kuala Terengganu and Kota Kinabalu.

14. Screening Test

A series of initial tests designed to separate samples with drugs at a particular minimum concentration from those below minimum concentration.

15. Sensitivity

The minimal or threshold concentration of a drug or its metabolites that can be detected.

16. Specificity

Quality of an analytical technique that tends to exclude all substances but the analyte from affecting the results. The degree to which a test can discriminate between closely related drugs, metabolites or naturally occurring substances.

17. True Negative

A test result reported as NEGATIVE when an individual has not used the drug tested for.

18. True Positive

A test result reported as POSITIVE when a person had indeed used the drug tested for.

19. Turn Around Time (TAT)

The time taken to complete the analysis of a sample from the moment it is received to the time when result is available.

Appendix 1/Lampiran1 UPD 1 (PINDAAN) PER (LAB)-SS 301A

BORANG PERMINTAAN UJIAN PENGESANAN DADAH DALAM AIR KENCING

NEGERI: _____ SEKSYEN: _____

HOSPITAL: _____ NO.RUJUKAN MAKMAL: _____

NAMA:

ALAMAT:

NO. K/P:

TARIKH LAHIR:

NO. PENDAFTARAN / NP / DD:

NO. LAPORAN POLIS:

TARIKH SPESIMEN DIPUNGUT:

PEGAWAI YANG MEMUNGUT:

NO. K/P:

PEG. YANG MEMBUAT PERMINTAAN:

NO. K/P:

.....

(T/TANGAN & COP JABATAN)

BANGSA: ☐ Melayu ☐ Cina ☐ India ☐ Lain-lain

JANTINA: ☐ Lelaki ☐ Perempuan

RUJUKAN ☐ Polis ☐ Tentera ☐ Pemulihan ☐ Lain-lain

TARAF PERKAHWINAN: ☐ Berkahwin ☐ Janda/Duda ☐ Bujang

JENIS UJIAN DADAH YANG DIMINTA:

☐ Morphine
☐ Cannabis
☐ Amphetamine Type Stimulants
☐ Lain-lain

Nyatakan:.....

Tandakan [/] di ruangan yang berkenaan

PEMBAWA SPESIMEN: NAMA:

TANDATANGAN: .....

KEPUTUSAN MAKMAL:

.....

(T/TANGAN & COP JABATAN)

KEADAAN AIR KENCING:

☐ Normal ☐ Keruh ☐ Jernih

☐ Berubah Warna ☐ Mengandungi Bendasing ☐ Lain-lain .....

TARIKH:

PENGESAHAN PENERIMAAN CONTOH AIR KENCING:(Keratan dikembalikan)

NO. RUJUKAN MAKMAL:

NAMA:

NO. K/P:

NO LAPORAN POLIS

AKUAN PEMBERI

Saya yang bernama .....

dan

No. Kad Pengenalan:.....

dengan ini mengesahkan telah memberi contoh air kencing saya untuk dijalankan ujian dan berpuas hati dengan prosidur pemungutan contoh yang dijalankan.

Tarikh: ..... Tandatangan: .....

Appendix 3 / Lampiran 3

Makmal Dadah & Penyelidikan,
Jabatan Patologi,
Hospital Kuala Lumpur.
Tel: 03-26155612 / 26155607

No. Repot Polis:
No. Laporan Makmal :
Tarikh laporan :

Kepada:

Nama Pegawai Yang Membuat Permintaan

Alamat Pegawai Yang Membuat Permintaan

Laporan Ujian Pengesanan Dadah Dalam Air Kencing

Butir- butir contoh adalah seperti berikut:

Nama :

No. Kad Pengenalan :

Tarikh Spesimen Dipungut:

Tarikh Spesimen Diterima:

Tarikh Spesimen Dianalisa:

Keadaan Spesimen:

Keputusan Ujian:

Rujuk Garispanduan bahagian Bagi Ujian Pengesanan Penyalahgunaan Dadah Dalam Air Kencing, Bahagian 13 'Reporting Of Results'.

.....
(Tandatangan)

Nama dan Jawatan Pegawai
yang mengesahkan keputusan.

Tarikh: