

Urine Ethyl Glucuronide (EtG) Testing Policy

1. Introduction

Ethyl Glucuronide (EtG) is a specific and sensitive biomarker of ethanol consumption. EtG is a metabolite of alcohol that is much more slowly eliminated from the body than alcohol itself. It is the best marker currently available to monitor abstinence from alcohol and has been adopted by the Council for use in circumstances where abstinence is required.

This EtG Testing Policy to inform practitioners of the Council's expectations and to ensure maximum consistency in the day-to-day running of the program.

The participant must bear the cost of participation in the program (both collection and testing). As a medico-legal investigation, it cannot be funded by Medicare.

2. Collection and Testing

The Council's provider of EtG testing services is Concord Hospital. Contact details for can be found in the section titled *Contact Details*.

2.1 Collection

There are three options in arranging supervised collection of urine samples:

- a) Supervised collection at a PaLMS collection facility.
- b) Collection supervised by a supervisor approved by the Council such as a GP or pathology worker, using postage paid collection kits provided by PaLMS **directly to the approved supervisor**. (*Supervised Collection Guidelines* can be found later in the policy). Kits can be obtained by the supervisor by contacting PaLMS on telephone (02) 9887 5666. The participant will be invoiced for the collection kits by PaLMS. Under no circumstances may collection kits be supplied directly to the participant.
- c) Collection supervised by another pathology provider approved by the Council. Other collection centres may be prepared to supervise collection, and forward the samples to Concord Hospital for testing.

2.2 Testing

EtG testing is by way of enzyme immunoassay (EIA) conducted in the Biochemistry Department, Diagnostic Pathology Unit, Concord Hospital. However, a practitioner may submit the name of an alternative pathology provider which meets the testing requirements and the Supervised Collection Guidelines for approval by the Council.

3. Detailed Requirements

Strict compliance with the following general requirements is necessary.

- Within seven days of the introduction of a condition requiring EtG testing, the participant is required to advise the Council of the name, address and telephone number of the nominated supervisor or pathology collection centre.
- The participant is required to meet the cost of testing by paying Concord Hospital

directly. The participant may also incur costs for supervised collection, at the discretion of the supervisor.

- Urine samples are to be collected under **direct** supervision according to the protocol detailed in the section titled *Supervised Collection Guidelines*. Direct supervision means the supervisor must witness the urine passing from the urethra to the container.
- Test results must be forwarded to the Council, the treating medical practitioners and the Council appointed practitioners. The participant may find it helpful to also have the results sent directly to him / her. The participant must include the treating practitioners' name and address on the request form.
- The testing cut-off value is set at 500ng/mL which the Council is advised is high enough to minimize interference from accidental or unavoidable alcohol exposure. Nevertheless, the participant should avoid exposure to alcohol in fermented products such as wine vinegar and soy sauce, communion wine, alcohol-based medications, antibacterial gels etc.
- Should accidental or unavoidable consumption of alcohol occur, the Council should be advised immediately and if possible, provided with supporting evidence.

3.1 *Twice-weekly Testing*

- Testing is conducted on Monday, and Thursday of each week. It is not acceptable to present on other days without prior approval.

If the participant is required to undergo thrice weekly urine drug testing and are also required to undergo twice weekly EtG testing, it may be more practical to have EtG testing thrice weekly. This will be considered by the Council.

- The decision to vary testing from twice-weekly to random can only be made with endorsement from the Council. This decision will be made by considering the recommendations from the Council appointed practitioner and/or the Council.

3.2 *Random Testing*

- Random testing means a minimum of 15 tests in each consecutive period of six months. The timing of the collection will be determined by the Council secretariat.
- The participant is required to telephone the free-call 1800 number each weekday to ascertain whether they are required to attend for testing. The participant must attend on the specified day.
- The following number must be called Monday to Friday between midnight & 5pm.

1800 654 068

- Cessation of EtG testing can only occur with approval of the Council. This decision will be made by considering the recommendations from the Council appointed practitioner and/or the Council.

3.3 *Absence from testing*

- The participant is required to advise the Council, in writing, at least five business days before any anticipated absence - fax or email notifications are acceptable]. Only under extraordinary circumstances will permission be given to abstain from testing on certain

days on a routine basis. In those situations, the participant may be required to undertake testing on the required days when he / she is available.

- The participant is required to provide evidence of absence (eg. copies of boarding passes, hotel receipts).
- If a testing day falls on a public holiday, the participant is required to provide a urine sample on the following day.

3.4 Missed tests

- If the participant is aware that he / she has missed a test, the participant must immediately notify the Council, in writing and provide an explanation. Explanations may be considered by the Council, which may view the matter as a breach of conditions and recommend disciplinary action.

3.5 Positive tests

- If the participant returns a positive test he / she will be required to provide a written explanation. That explanation, together with any additional information obtained from the testing laboratory, may be considered by the Council. The Council may view the matter as a breach of conditions and recommend disciplinary action. If the participant is subject to random testing, he / she may be required to return to twice-weekly testing.

3.6 Dilute samples

- The Council considers a sample to be dilute when the urine creatinine is below 2.0 mmol/l. Dilute urine suggests that the participant has consumed a large volume of water prior to passing the urine, or that there has been adulteration of the sample after collection. This renders the test invalid as EtG may be diluted to concentrations below testing detection levels.
- If dilute samples are received, the participant will be notified and will be expected to take the necessary action to avoid further dilute samples.
- Should further dilute samples be received, the participant will be notified in writing and required to provide a written explanation. That explanation will be placed before the Council which may view the matter as a breach of conditions and recommend disciplinary action.

3.7 Sample adulteration or substitution

- The Council may, at any time, conduct any test on a urine sample as may be required to determine whether the sample has been adulterated with or substituted. If the participant returns a result indicating adulteration or substitution, he / she will be notified in writing and required to provide a written explanation. That explanation, together with any additional information obtained from the testing laboratory, will be placed before the Council which may view the matter as a breach of conditions and recommend disciplinary action.

3.8 *Participants required to undergo EtG testing as a result of Critical Compliance Conditions imposed on their registration by the Tribunal or Professional Standards Committee (Medical and Nursing and Midwifery)*

- If the participant is subject to a critical compliance condition in relation to EtG testing and is in breach of this protocol, the discretion which the Council may exercise is severely limited. The Council is required by the *Health Practitioner National Law (NSW)* to take the following action:
 - Convene proceedings pursuant to Section 150 of the Health Practitioner

Regulation National Law (NSW). If the delegates of the Council conducting the proceedings are satisfied that the participant has contravened the Critical Compliance Condition imposed on his or her registration, the participant will be suspended until a complaint concerning the matter can be dealt with by the Tribunal.

- Refer a complaint concerning the participant's breach of the critical compliance condition to the Tribunal. If the Tribunal is satisfied that the participant has contravened the critical compliance condition, the Tribunal must order the participant's de-registration.

4. Advice to Supervisors

- Supervisors should be familiar with all aspects of the Council's Testing Policy, as well as the medical and behavioural consequences of the misuse of alcohol.
- Supervisors should have only a professional / doctor-patient relationship with the practitioner undertaking testing.
- Supervisors should generally be available to supervise collection, and ensure that in their absence, an alternative supervisor is available and informed of the Council's requirements. The responsibility of actually securing an alternative supervisor is that of the registrant undergoing testing.
- Payment for supervised collection is to be directly negotiated between the supervisor and the the participant undergoing testing.
- The Council is appreciative of the service supervisors provide, but supervisors should be aware that failure to comply with the supervised collection guidelines may be viewed unfavourably by the Council. Supervisors are strongly advised not to cut any corners.
- Supervisors should contact the Council speak to the Council's Executive Officer if there are any queries or concerns.

5. Supervised Collection Guidelines

Supervisors must maintain a permanent record of specimen collection. The record is to comprise of the collection date, the nature of the specimen, the serial number on the specimen seal and the supervisor's signature. Copies of this record, or part thereof, must be made available to the Council on request. It is also recommended that the participant maintains his / her own diary that is signed by the supervisor on each occasion.

If the collection protocol is adhered to correctly, including the collection procedure and preparation for dispatch set out below, there will be no opportunity for the urine specimen to be adulterated, substituted or diluted by another person. Similarly, the urine container and the request form will be correctly completed if there is adherence to the protocol. The information recorded on the request form must be identical to that recorded on the urine container.

5.1 Collection procedure

The following procedures will ensure that unadulterated specimens are obtained and correctly identified. Every effort should be made to minimise the number of persons handling specimens.

- a) After washing hands, the participant must remain in the presence of the supervisor and not have access to any water fountain, tap, soap dispenser, cleaning agent or any other materials that might be used to adulterate the specimen.

- b) The participant must provide the specimen under direct supervision. Direct supervision means the supervisor must witness the passing of the urine from the urethra to the container. This may include video supervision, where such facilities are available.
- c) Upon receiving the specimen, the supervisor shall determine that there is a sufficient sample to enable all required testing to be performed. A sample of at least 20ml must be collected. In the event that insufficient urine is collected, an additional sample must be provided.
- d) Immediately after the specimen is collected, the supervisor should inspect the urine specimen to determine its colour and look for any indication of adulterants or diluents. Any unusual finding should be noted in the supervisor's record.
- e) If the integrity of the sample cannot be established, or if it is suspected that the specimen may have been adulterated or substituted, then another specimen should be collected as soon as possible and both samples forwarded to the laboratory for testing. These specimens must be labeled and documented appropriately.
- f) Both the participant and the supervisor should keep the specimen in view at all times prior to it being sealed and labeled.
- g) The supervisor should request that the participant observes the transfer of the specimen and the placement of the tamper-proof seals over the bottle cap and down the sides of the bottles. The participant must sign the seals.
- h) After the specimen has been provided and submitted to the supervisor, the participant will be allowed to wash his / her hands.

5.2 Preparation for dispatch by the Supervisor

The participant and the supervisor must be present during the steps (a) to (e) of the following preparation for dispatch procedures.

- a) The supervisor must securely place labels on the bottle. The label should list the date of collection and a minimum of two identifiers for the participant. One of these must be the name, and the second, in the ID field, the participant's 12 digit Identifier provided by AHPRA).
- b) The supervisor must enter the date and time of supervised collection into their record and sign the record.
- c) The participant will be asked to read and counter-sign the record.
- d) The supervisor shall complete the request form. The supervisor must record the participant's name and registration number, as well as the date and time when the sample was collected. **The name and registration number must appear identical to the entries on the urine container.**
- e) The urine bottles and the request form are now ready for dispatch by the supervisor. If the specimens are not immediately prepared for transport, they must be appropriately safeguarded and refrigerated during temporary storage. Postage should occur as soon as possible.
- f) It is essential that the urine specimen(s) and request form are under the control of the supervisor **at all times**. At no stage should the specimen be in the participant's custody.

5.3 Transportation to the Laboratory

- a) The supervisor must place the specimen(s) and request form in the containers provided.
- b) The containers must be securely sealed to eliminate the possibility of tampering.
- c) The supervisor should arrange postage to the laboratory as soon as possible.

Adapted from the Medical Council of New South Wales *Protocol 2010*

Document control

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